GLOBAL MEDICAL DEVICE VALIDATION MASTER LIST

Design Verification & Validation • Equipment DQ/IQ/OQ/PQ • Manufacturing Process Validation • Sterilization • Packaging • Software & Cybersecurity • IVD Performance

2,881 micro-level checkpoints | **38** controlled sections | **India + Ireland** contact details

Prepared for global medical device manufacturing, validation planning and audit preparation.

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01 APPLICATION INSTRUCTIONS

Scope and applicability

Screen each of the 2,881 candidate checkpoints against actual devices, risk class, intended use, materials, supplier/subcontractor activities, device software, sterilization/packaging claims, lifecycle and destination market. Mark non-applicable entries with documented justification; add plant-specific assets.

Differentiate activities

Equipment qualification, special-process validation, design verification, design validation, method validation, calibration, routine monitoring and training competence are distinct. Use all stages only when scientifically justified by intended use and process risk.

Device-specific regulations

FDA QMSR took effect 2 February 2026 and incorporates ISO 13485:2016. EU MDR 2017/745 applies to medical devices; EU IVDR 2017/746 applies to IVDs. India Medical Devices Rules 2017 including Fifth Schedule (with amendments) govern Indian medical-device QMS; pharmaceutical Schedule M or Schedule Y do not substitute for device rules.

Sterile vs nonsterile

Sterilization by EO, radiation, moist heat, VHP and aseptic manufacture require method-specific validation. Choose applicable standard, intended sterility assurance level and valid packaging system. An aseptic process simulation is relevant only for true aseptic operations; not every sterilized device requires a pharmaceutical-style media fill.

Statistical validity

Select sample sizes, cavities, shifts, operators, product variants and worst cases based on risk and process capability. A fixed 3-batch PQ rule or routine annual revalidation is not universal. Avoid generic limits; protocol acceptance criteria must be scientifically preapproved.

Maintain a validated state

Link each record to site asset IDs, change control, approved protocol and report, deviations, status, responsible owner and due date. Perform ongoing review and revalidation when changes or emerging evidence warrant.

Evidence and ownership

Support risk controls with device-specific methods, complete data, traceable test equipment and competent signatories. Clinical/performance evidence, sterility assurance and biological evaluation need qualified personnel and product-specific approval.

Reference caution

Standards may be amended and their recognition differs across jurisdictions. A current standard title does not establish automatic legal applicability. Confirm the authority-recognized edition and related manufacturer obligations before protocol approval.

02 COVERAGE INDEX

NO.	CONTROLLED SECTION	CHECKPOINTS	PRIMARY OWNER GROUP
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04	04 | Warehouse, traceability & distribution	96	Warehouse / Engineering / QA
05	05 | Civil, cleanrooms, facility & environmental control	96	Engineering / QA / Microbiology
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10	10 | Metals, machining, heat treatment & finishing	132	Production / Engineering / QA
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12	12 | Syringes, needles, IV sets, infusion and blood bags	108	Production / QA / Engineering
13	13 | Wound care, textile, sutures & soft goods	96	Production / QA / Engineering
14	14 | Orthopedic, spinal, dental & implantable devices	96	Production / R&D / QA
15	15 | Active electromechanical & electrical devices	120	Production / Engineering / QA / R&D
16	16 | IVD assays, reagents, kits & diagnostics	147	IVD Production / QC / ADL / QA
17	17 | Ophthalmic and specialized precision devices	72	Production / QA / Engineering
18	18 | Sterilization - ethylene oxide (EO)	70	Sterility Assurance / QA / Engineering
19	19 | Sterilization - radiation (gamma, e-beam, X-ray)	56	Sterility Assurance / Engineering / QC
20	20 | Sterilization - moist heat, dry heat & VHP	68	Sterility Assurance / Engineering / QA
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22	22 | Sterile barrier packaging - forming, sealing & assembly	101	Packaging / Engineering / QA
23	23 | Labeling, UDI, vision & final packaging	78	Packaging / QA / IT
24	24 | Cleaning, disinfection, residue & contamination control	95	QA / Production / QC / Engineering
25	25 | Microbiology, sterility, endotoxin & lab methods	85	QC Microbiology / QA / ADL
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27	27 | Biocompatibility, chemical characterization & material risk	18	R&D / Toxicology / QA / QC
28	28 | Software, SaMD, cybersecurity & electronic systems	38	R&D Software / IT / QA / Regulatory
29	29 | Stability, aging, transport, shelf-life & durability	94	QA / QC / R&D / Warehouse
30	30 | Production inspection, release & performance verification	103	QC / QA / Production
31	31 | HR, personnel qualification & gowning	18	HR / QA / Production / Microbiology
32	32 | EHS, containment, waste & emergency controls	114	EHS / Engineering / QA
33	33 | R&D, ADL, process development & transfer	19	R&D / ADL / QA / Engineering
34	34 | Field installation, servicing & reuse validation	15	Service / Engineering / QA / R&D
35	35 | Postmarket, complaints, CAPA & lifecycle review	15	QA / Regulatory / Engineering
36	36 | Specialty, combination and advanced manufacturing	108	R&D / QA / Engineering / Production
37	37 | Product family specific verification matrix	30	R&D / QC / Regulatory

NO.	CONTROLLED SECTION	CHECKPOINTS	PRIMARY OWNER GROUP
38	38 | Cross-functional worst-case and revalidation matrix	35	QA / Engineering / R&D / QC
	TOTAL	2881	Cross-functional QA / Engineering / QC / Production / RA

03 REGULATORY REFERENCE CROSSWALK

M01 | **FDA** - QMSR: 21 CFR Part 820, effective Feb 2 2026; incorporates ISO 13485:2016

https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices

M02 | **ISO** - ISO 13485:2016 Medical device quality management systems

https://www.iso.org/standard/59752.html

M03 | **EU** - Regulation (EU) 2017/745 Medical Devices (MDR)

https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

M04 | **EU** - Regulation (EU) 2017/746 In Vitro Diagnostic Devices (IVDR)

https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng

M05 | **India** - CDSCO Medical Devices Rules 2017, Fifth Schedule + amendments

https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules

M06 | **TGA** - Australian medical device conformity assessment and Essential Principles

https://www.tga.gov.au/resources/guidance/applying-conformity-assessment-certificate-medical-devices

M07 | **ISO** - ISO 14971:2019 Medical devices - Risk management

https://www.iso.org/standard/72704.html

M08 | **ISO** - ISO 11607-1/-2:2019 incl 2023 amendments; sterile barrier packaging

https://www.iso.org/standard/70799.html

M09 | **ISO** - ISO 11135 Ethylene oxide sterilization

https://www.iso.org/search.html?q=ISO%2011135

M10 | **ISO** - ISO 11137 series Radiation sterilization (gamma, electron beam, X-ray)

https://www.iso.org/search.html?q=ISO%2011137

M11 | **ISO** - ISO 17665:2024 Moist heat sterilization

https://www.iso.org/standard/80271.html

M12 | **ISO** - ISO 22441:2022 Vaporized hydrogen peroxide sterilization

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=44295

M13 | **ISO** - ISO 11737-1/-2 Bioburden and sterility tests in process validation

https://www.iso.org/search.html?q=ISO%2011737

M14 | **ISO** - ISO 10993 series Biological evaluation of medical devices

https://www.iso.org/search.html?q=ISO%2010993

M15 | **ISO** - ISO 14644 series Cleanroom classification, testing and monitoring

https://www.iso.org/search.html?q=ISO%2014644

M16 | **IEC** - IEC 62304:2006 + A1:2015 Medical device software lifecycle

https://webstore.iec.ch/en/publication/22794

M17 | **IEC** - IEC 62366-1 Usability engineering for medical devices

https://webstore.iec.ch/en/search?query=62366-1

M18 | **IEC** - IEC 60601 family Medical electrical equipment safety/EMC

https://webstore.iec.ch/en/search?query=60601

M19 | **IEC** - IEC 81001-5-1 Health software product security activities

https://webstore.iec.ch/en/search?query=81001-5-1

M20 | **ISO** - ISO 15223-1 Medical device labels and symbols

https://www.iso.org/search.html?q=ISO%2015223-1

M21 | **ISO** - ISO 20417 Information supplied by medical device manufacturer

https://www.iso.org/search.html?q=ISO%2020417

M22 | **ISO** - ISO 23640 IVD reagent stability evaluation

https://www.iso.org/search.html?q=ISO%2023640

M23 | **ISO** - ISO 17511 IVD metrological traceability

https://www.iso.org/search.html?q=ISO%2017511

M24 | **ISO** - ISO 20916 IVD clinical performance studies

https://www.iso.org/search.html?q=ISO%2020916

M25 | **FDA** - FDA Device Sterilization resources / recognized consensus standards

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

M26 | **ISO** - ISO 13408 series Aseptic processing for healthcare products (where relevant)

https://www.iso.org/search.html?q=ISO%2013408

M27 | **ISO** - ISO 10993-7 Ethylene oxide sterilization residuals

https://www.iso.org/search.html?q=ISO%2010993-7

M28 | **ASTM** - ASTM F88 seal strength, F1929 dye, F2096 bubble, F1980 aging, D4169 distribution (as applicable)

https://www.astm.org/

M29 | **IMDRF** - IMDRF Essential Principles and software / cybersecurity recommendations

https://www.imdrf.org/documents

M30 | **UK** - MHRA medical devices regulatory guidance and UK MDR

https://www.gov.uk/government/collections/medical-devices-guidance-and-regulations

M31 | **ISO** - ISO 14155 clinical investigation of medical devices (when applicable)

https://www.iso.org/search.html?q=ISO%2014155

M32 | **ISO** - ISO 19227 cleanliness of orthopedic implants (when applicable)

https://www.iso.org/search.html?q=ISO%2019227

M33 | **IEC** - IEC 61010-1 / 61010-2-101 test equipment and IVD instrument safety (as applicable)

https://webstore.iec.ch/en/search?query=61010-2-101

M34 | **ISO** - ISO 18562 respiratory gas pathway biocompatibility (when applicable)

https://www.iso.org/search.html?q=ISO%2018562

M35 | **ISO** - ISO 80369 small-bore connector requirements (where applicable)

https://www.iso.org/search.html?q=ISO%2080369

04 LIFECYCLE STAGES & EVIDENCE CONTROL

STAGE	EXPECTED EVIDENCE PRINCIPLE
Design verification	Objective tests show design outputs meet documented design inputs; mechanical, functional, analytical and safety specifications
Design validation	Production-equivalent devices meet user needs and intended uses including usability, performance and clinical evidence where relevant
URS/DQ	Defined needs and engineering design confirmation, design risk controls and technical specifications
IQ	Installation and configuration: manuals, drawings, utilities, sensors, software, critical materials and calibration
OQ	Process operating window including limits, alarms, fail-safes, startup/shutdown, and worst-case conditions
PQ	Representative reproducible performance for device, material, equipment, cavity, personnel, load and process family
Process validation	Validated special processes whose output cannot be fully verified with later inspection, with control and continued verification
Packaging validation	ISO 11607 sterile-barrier forming/sealing/assembly and aged/distributed package integrity for applicable sterile systems
Sterilization validation	Modality-specific biological/physical PQ and routine control, load configuration and product compatibility
Aseptic process simulation	Process-representative contamination challenge for aseptically manufactured devices/filled systems when justified
IVD analytical and clinical performance	Sensitivity, specificity, LoD, precision, bias, interference, traceability and performance in intended use population
Software lifecycle & validation	IEC 62304 lifecycle plus device-intended-use software validation, cybersecurity and usability
Method validation	Measurement uncertainty, sensitivity, selectivity, precision, reproducibility, sampling and GR&R appropriate to risk
Cleaning validation	Worst-case geometries, particulate and residues, microbial/endotoxin risk and cleaning process effectiveness
Continuing lifecycle	Process monitoring, trend review, CAPA and risk-triggered requalification/revalidation

01 GOVERNANCE, VALIDATION PLANNING & QA

29 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-01-0001	Validation Master Plan	Define device-family and risk-classification boundaries	Approved VMP identifies intended markets, sterilization type, outsourced steps and direct/indirect systems	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0002	Validation Master Plan	Maintain validated asset/process inventory	Reconciled equipment/PLC/software/supplier register with unique asset ID and owner	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0003	Validation Master Plan	Classify processes with output not fully verifiable	Special-process justification, post-process inspection limitations and validation requirement	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0004	Validation Master Plan	Determine validation vs verification vs calibration	Approved decision tree distinguishes each activity and evidence record	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0005	Validation Master Plan	Set risk ranking and prioritization	Documented patient-harm linkage, probability severity and process detectability	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0006	Validation Master Plan	Map URS-DQ-IQ-OQ-PQ and design V&V lifecycle	Risk-based sequence and traceability, including justified supplier evidence leverage	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0007	Validation Master Plan	Set family grouping and worst-case bracketing	Representative materials, geometry, size, line, shift and tool-cavity rationale	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0008	Validation Master Plan	Approve protocols before execution	Objective, preconditions, statistical design, acceptance criteria and signatories	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0009	Validation Master Plan	Validate sampling plan for process characterization	Confidence, sample independence, cavities, shifts and operator effects	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0010	Validation Master Plan	Define nonconformance, deviation and invalid-run rules	Contemporaneous investigations; preapproved repeat-test principles	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0011	Validation Master Plan	Require objective raw data and electronic integrity	Attributable, legible, contemporaneous, original, accurate records	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0012	Validation Master Plan	Establish master schedule linked to device launch	Gate approvals, dependencies, risk and resource capacity	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0013	Validation Master Plan	Maintain protocol-to-report traceability	Protocol version, execution references, report disposition and deviations	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0014	Validation Master Plan	Define equipment/process revalidation logic	Changes, PM, relocations, software updates, OOT, complaint trends	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0015	Validation Master Plan	Evaluate supplier and sterilizer responsibilities	Quality agreements, validation data access and audit rights	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0016	Validation Master Plan	Control design and manufacturing site transfer	Comparability, process equivalence and interface qualification	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0017	Validation Master Plan	Approve installation / service validation interface	Site acceptance and final functional verification plan	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0018	Validation Master Plan	Manage validation training and independent QA approvals	Role-based competency and QA approval matrix	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0019	Validation Master Plan	Establish ongoing process monitoring plans	Critical parameter trend, defect rates, SPC and alerts	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0020	Validation Master Plan	Review prior validation lifecycle on periodic basis	Change history, process capability and recurrence assessment	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0021	Regulatory applicability matrix	Map device class and markets US/EU/UK/India/Australia	Product-specific current legal requirements and recognized standards	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0022	Regulatory applicability matrix	Document EU MDR versus IVDR route	Intended purpose/IVD classification and conformity assessment distinctions	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-01-0023	Regulatory applicability matrix	Assess FDA QMSR 2026 impact	Updated QMS procedures, ISO 13485 mappings, records accessible for inspection	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0024	Risk management file	Link risk controls to test requirements	ISO 14971 trace matrix for each manufacturing risk-control verification	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0025	Risk management file	Evaluate benefit-risk and residual manufacturing hazards	Approved risk file with production/post-production feedback	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0026	Process definition	Map outsourced critical processes in production flow	Supplier capability evidence and final manufacturer oversight	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0027	Process definition	Assign software, data and cybersecurity validation boundaries	GxP and device software purpose, versions, interfaces, access	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0028	Quality metrics	Define acceptance for capability indicators	Statistically grounded yield/critical defect trends and trigger rules	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High
MDV-01-0029	Technical documentation	Link validation evidence to technical documentation	Cross-references in device technical file/design history file	Lifecycle	All medical devices	M01 M02 M03 M05 M06 M07	High

02 DESIGN CONTROLS, FEASIBILITY, RISK & TRANSFER

26 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-02-0001	Intended use	Confirm use environment, user profile and intended patient group	Controlled intended purpose and user needs review	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0002	Design inputs	Translate user needs into measurable engineering acceptance criteria	Approved design input matrix and risk controls	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0003	Design outputs	Trace BOM, drawings and specifications to inputs	Released drawings, critical-to-quality tolerances, traceability	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0004	Design reviews	Include cross-functional gates before prototype freeze	Independent reviewers, minutes, issue closure	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0005	Design verification	Verify detailed specifications and tolerance stack-up	Bench tests/dimensional data showing outputs meet inputs	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0006	Design validation	Confirm final device meets user needs/intended uses	Representative production-equivalent devices and user context evidence	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0007	Human factors	Validate critical tasks and use-related risk controls	Summative usability assessment with representative users as relevant	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0008	Design transfer	Verify manufacturing documents faithfully reproduce design	Approved DMR/medical device file, work instructions, QC tests	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0009	Product risk analysis	Link hazardous situations, production failures and controls	ISO 14971 risk assessment, verification of protective measures	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0010	Biological safety	Plan contact category, duration and endpoint evaluation	ISO 10993 biological evaluation plan and toxicological risk review	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0011	Electrical safety	Define essential performance and patient-applied part controls	IEC 60601 test plan for applicable equipment	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0012	EMC	Test immunity/emissions and essential performance	IEC 60601-1-2 test report and risk file linkage	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0013	Cybersecurity	Threat model data integrity and software interface hazards	Approved threat model, security requirements and tests	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0014	Software architecture	Assign software item classification and traceability	IEC 62304 plans and safety classification where applicable	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0015	Design changes	Risk assess component, software and process change	V&V regression selection and equivalence rationale	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0016	Clinical evidence	Define performance evidence needed for intended purpose	Clinical evaluation/performance evaluation plan where applicable	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0017	Shelf life	Identify aging-related performance and materials risk	Real-time/accelerated aging and aged-package test plan	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0018	Distribution profile	Include worst-case handling, pressure and vibration	Representative distribution testing plan	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0019	Label/IFU validation	Verify critical symbols, instructions and user comprehension	ISO 15223-1/20417 plus applicable human-factors evidence	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0020	Product family	Validate family selection, geometry extremes and bridges	Worst-case matrix approved before testing	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0021	Risk management review	Feed post-production complaints into design control	Periodic feedback and risk file updates	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0022	Verification equipment	Qualify custom test fixtures and software used for DV	Test method fitness-for-purpose, GR&R and calibration	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-02-0023	Prototype transfer	Assess raw material changes from prototype to production	Comparability, process scale effects and new hazards	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0024	Device master records	Check manufacturing drawings, BOM, ERP release and QC plan	Controlled released records consistent with design outputs	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0025	Traceability	Trace key lot, UDI, implant serial numbers to inputs	Mock trace and recall verification	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High
MDV-02-0026	Change control	Capture subcontractor manufacturing process changes	Prior notice, impact assessment and revalidation decisions	Lifecycle	All devices; active, implantable, IVD	M01 M02 M03 M04 M07 M17 M29	High

03 SUPPLIER, PURCHASING & CONTRACT PROCESSES

18 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-03-0001	Supplier risk classification	Rank raw material, component, software and critical service suppliers	Risk matrix includes sterility, function and patient contact	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0002	Supplier evaluation	Verify ISO 13485/QMS capability and product-specific operations	Audit report, QMS review, approval evidence	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0003	Polymer suppliers	Qualify resin grade, additives, lot variation and change notifications	Material specifications, COA and comparative test program	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0004	Metal suppliers	Qualify implant metal composition, provenance and cleanliness	MTR chemistry, inclusions, traceability and incoming verification	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0005	Biological raw material suppliers	Qualify source traceability and biosafety assurance	Source risk controls and supplier qualification	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0006	Packaging converters	Qualify roll-stock film, Tyvek/porous webs and barrier properties	Specification, sterile barrier data, incoming test agreement	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0007	Sterilization subcontractor	Approve sterilization validation responsibility matrix	Quality agreement defines cycle ownership, load configuration and release	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0008	Calibration service provider	Qualify standards traceability and uncertainty	Accreditation/scope review and certificates	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0009	Contract test lab	Verify competence for sterile, biological and analytical tests	Method scope, proficiency, method validation and data integrity review	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0010	Contract electronics assembler	Approve PCB solder, traceability, ESD and test capability	Process audits and first article evidence	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0011	Contract software developer	Qualify lifecycle and cybersecurity development controls	SQA agreement, code/test artifacts and deviation disclosure	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0012	Supplier process change	Verify prior-change notification and acceptability limits	Change assessment and bridging validation plan	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0013	Incoming inspection method	Validate automated optical/functional receiving inspection	Reference samples, defect challenges, GR&R	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0014	Supplier statistical sampling	Demonstrate AQL/risk basis for receiving plan	Acceptance sampling rationale for severity of defects	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0015	Critical material storage	Qualify supplier transport conditions where stability is critical	Data loggers, temperature excursion limits and shipping study	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0016	Service vendor	Qualify critical repair intervention and verification	Preventive maintenance qualification and service sign-off	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0017	Supplier deviations	Verify segregation and recovery of supplier nonconformances	CAPA records and effectiveness checks	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High
MDV-03-0018	Supplier re-evaluation	Define risk-based periodic review of quality performance	Trend scorecard and triggers for audit/qualification	Lifecycle	All devices / outsourced operations	M01 M02 M03 M05 M07	High

04 WAREHOUSE, TRACEABILITY & DISTRIBUTION

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0001	Receiving dock environmental controls	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; humidity; time outside controlled area; required outputs: incoming integrity and sensitive material excursion control	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0002	Receiving dock environmental controls	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Receiving dock environmental controls	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0003	Receiving dock environmental controls	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; humidity; time outside controlled area; evaluate incoming integrity and sensitive material excursion control	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0004	Receiving dock environmental controls	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0005	Receiving dock environmental controls	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering incoming integrity and sensitive material excursion control	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0006	Receiving dock environmental controls	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; humidity; time outside controlled area; define risk-based requalification triggers affecting incoming integrity and sensitive material excursion control	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0007	Ambient storage warehouse	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature mapping; seasonal loads; door-opening patterns; required outputs: distribution of mapped ambient conditions	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0008	Ambient storage warehouse	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ambient storage warehouse	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0009	Ambient storage warehouse	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature mapping; seasonal loads; door-opening patterns; evaluate distribution of mapped ambient conditions	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0010	Ambient storage warehouse	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0011	Ambient storage warehouse	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering distribution of mapped ambient conditions	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0012	Ambient storage warehouse	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature mapping; seasonal loads; door-opening patterns; define risk-based requalification triggers affecting distribution of mapped ambient conditions	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0013	Temperature controlled material warehouse	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses 2-8 C or specified qualified band; loaded and empty conditions; required outputs: material integrity and sensor coverage	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0014	Temperature controlled material warehouse	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Temperature controlled material warehouse	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0015	Temperature controlled material warehouse	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for 2-8 C or specified qualified band; loaded and empty conditions; evaluate material integrity and sensor coverage	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0016	Temperature controlled material warehouse	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0017	Temperature controlled material warehouse	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering material integrity and sensor coverage	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0018	Temperature controlled material warehouse	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend 2-8 C or specified qualified band; loaded and empty conditions; define risk-based requalification triggers affecting material integrity and sensor coverage	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0019	Deep freeze storage unit	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses specified subzero band; frost recovery; power interruption; required outputs: IVD/reagent stability and alarms	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0020	Deep freeze storage unit	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Deep freeze storage unit	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0021	Deep freeze storage unit	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for specified subzero band; frost recovery; power interruption; evaluate IVD/reagent stability and alarms	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0022	Deep freeze storage unit	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0023	Deep freeze storage unit	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering IVD/reagent stability and alarms	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0024	Deep freeze storage unit	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend specified subzero band; frost recovery; power interruption; define risk-based requalification triggers affecting IVD/reagent stability and alarms	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0025	Freezer -80 C as applicable	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses storage temperature uniformity; defrost and door cycling; required outputs: biological reagent/critical analyte integrity	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0026	Freezer -80 C as applicable	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Freezer -80 C as applicable	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0027	Freezer -80 C as applicable	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for storage temperature uniformity; defrost and door cycling; evaluate biological reagent/critical analyte integrity	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0028	Freezer -80 C as applicable	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0029	Freezer -80 C as applicable	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biological reagent/critical analyte integrity	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0030	Freezer -80 C as applicable	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend storage temperature uniformity; defrost and door cycling; define risk-based requalification triggers affecting biological reagent/critical analyte integrity	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0031	Sterile barrier film and pouch store	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses relative humidity; stacking compression; cleanliness; required outputs: packaging integrity before conversion	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0032	Sterile barrier film and pouch store	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile barrier film and pouch store	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0033	Sterile barrier film and pouch store	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for relative humidity; stacking compression; cleanliness; evaluate packaging integrity before conversion	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0034	Sterile barrier film and pouch store	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0035	Sterile barrier film and pouch store	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering packaging integrity before conversion	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0036	Sterile barrier film and pouch store	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend relative humidity; stacking compression; cleanliness; define risk-based requalification triggers affecting packaging integrity before conversion	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0037	Quarantine and segregation cages	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses segregation; location scan; label integrity; required outputs: mix-up prevention and status control	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0038	Quarantine and segregation cages	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Quarantine and segregation cages	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0039	Quarantine and segregation cages	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for segregation; location scan; label integrity; evaluate mix-up prevention and status control	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0040	Quarantine and segregation cages	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0041	Quarantine and segregation cages	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering mix-up prevention and status control	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0042	Quarantine and segregation cages	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend segregation; location scan; label integrity; define risk-based requalification triggers affecting mix-up prevention and status control	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0043	RFID/barcode warehouse scanners	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses scan success; duplicate and missing code challenge; required outputs: lot/serial traceability and pick accuracy	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0044	RFID/barcode warehouse scanners	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for RFID/barcode warehouse scanners	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0045	RFID/barcode warehouse scanners	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for scan success; duplicate and missing code challenge; evaluate lot/serial traceability and pick accuracy	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0046	RFID/barcode warehouse scanners	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0047	RFID/barcode warehouse scanners	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering lot/serial traceability and pick accuracy	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0048	RFID/barcode warehouse scanners	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend scan success; duplicate and missing code challenge; define risk-based requalification triggers affecting lot/serial traceability and pick accuracy	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0049	Material handling conveyor	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses speed; vibration; product restraint; required outputs: no component or sterile pack damage	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0050	Material handling conveyor	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Material handling conveyor	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0051	Material handling conveyor	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for speed; vibration; product restraint; evaluate no component or sterile pack damage	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0052	Material handling conveyor	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0053	Material handling conveyor	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no component or sterile pack damage	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0054	Material handling conveyor	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend speed; vibration; product restraint; define risk-based requalification triggers affecting no component or sterile pack damage	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0055	Forklift and pallet transfer process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses shocks; pallet security; contamination barriers; required outputs: product protection during internal logistics	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0056	Forklift and pallet transfer process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Forklift and pallet transfer process	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0057	Forklift and pallet transfer process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for shocks; pallet security; contamination barriers; evaluate product protection during internal logistics	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0058	Forklift and pallet transfer process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0059	Forklift and pallet transfer process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering product protection during internal logistics	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0060	Forklift and pallet transfer process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend shocks; pallet security; contamination barriers; define risk-based requalification triggers affecting product protection during internal logistics	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0061	Cold chain shipping box	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coolant conditioning; pack-out orientation; duration; required outputs: in-spec temperature throughout transit	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0062	Cold chain shipping box	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cold chain shipping box	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0063	Cold chain shipping box	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coolant conditioning; pack-out orientation; duration; evaluate in-spec temperature throughout transit	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0064	Cold chain shipping box	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0065	Cold chain shipping box	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering in-spec temperature throughout transit	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0066	Cold chain shipping box	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coolant conditioning; pack-out orientation; duration; define risk-based requalification triggers affecting in-spec temperature throughout transit	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0067	Validated dry ice shipper	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses thermal distribution; pack quantity; CO2 ventilation; required outputs: target temperature across worst-case route	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0068	Validated dry ice shipper	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Validated dry ice shipper	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0069	Validated dry ice shipper	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for thermal distribution; pack quantity; CO2 ventilation; evaluate target temperature across worst-case route	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0070	Validated dry ice shipper	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0071	Validated dry ice shipper	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering target temperature across worst-case route	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0072	Validated dry ice shipper	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend thermal distribution; pack quantity; CO2 ventilation; define risk-based requalification triggers affecting target temperature across worst-case route	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0073	Finished goods dispatch staging	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses queue time; temperature excursion; segregation; required outputs: traceability and finished goods integrity	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0074	Finished goods dispatch staging	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Finished goods dispatch staging	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0075	Finished goods dispatch staging	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for queue time; temperature excursion; segregation; evaluate traceability and finished goods integrity	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0076	Finished goods dispatch staging	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0077	Finished goods dispatch staging	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering traceability and finished goods integrity	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0078	Finished goods dispatch staging	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend queue time; temperature excursion; segregation; define risk-based requalification triggers affecting traceability and finished goods integrity	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0079	Refrigerated shipping vehicle	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fully loaded/partial loaded mapping; alarms; required outputs: stability and chain-of-custody	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0080	Refrigerated shipping vehicle	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Refrigerated shipping vehicle	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0081	Refrigerated shipping vehicle	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fully loaded/partial loaded mapping; alarms; evaluate stability and chain-of-custody	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0082	Refrigerated shipping vehicle	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0083	Refrigerated shipping vehicle	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering stability and chain-of-custody	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0084	Refrigerated shipping vehicle	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fully loaded/partial loaded mapping; alarms; define risk-based requalification triggers affecting stability and chain-of-custody	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0085	Return material quarantine process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses segregation; disposition; chain-of-custody; required outputs: prevention of inadvertent resale	URS / DQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0086	Return material quarantine process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Return material quarantine process	IQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0087	Return material quarantine process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for segregation; disposition; chain-of-custody; evaluate prevention of inadvertent resale	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0088	Return material quarantine process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-04-0089	Return material quarantine process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering prevention of inadvertent resale	PQ	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0090	Return material quarantine process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend segregation; disposition; chain-of-custody; define risk-based requalification triggers affecting prevention of inadvertent resale	Routine / Change	Incoming components; implants; sterile packs; IVD reagents	M01 M02 M03 M05 M07	Medium
MDV-04-0091	Distribution profile	Set transport temperature, humidity, drop and shock hazards	Approved route/material distribution risk analysis	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High
MDV-04-0092	Ship validation	Test vibration and drop on actual packaged product	Transport simulation with post-stress functional testing	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High
MDV-04-0093	UDI trace	Mock forward/back trace lot/serial and UDI	System reconciliation within site-defined time	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High
MDV-04-0094	Traceability recall	Challenge mixed lots, partial dispatch and returned stock	Mock recall with accuracy, timeliness and disposition	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High
MDV-04-0095	Packaging post-distribution	Recheck seal strength and sterile barrier integrity	Released integrity results after simulated transport	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High
MDV-04-0096	Warehouse alarms	Verify delayed response escalation and backup logging	Challenge alarms, access and escalation records	Lifecycle	All devices	M01 M02 M03 M05 M08 M28	High

05 CIVIL, CLEANROOMS, FACILITY & ENVIRONMENTAL CONTROL

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0001	Cleanroom construction and partition joints	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wall panel leakage; coving; sealant compatibility; required outputs: cleanability, shedding and room integrity	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0002	Cleanroom construction and partition joints	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom construction and partition joints	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0003	Cleanroom construction and partition joints	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wall panel leakage; coving; sealant compatibility; evaluate cleanability, shedding and room integrity	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0004	Cleanroom construction and partition joints	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0005	Cleanroom construction and partition joints	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cleanability, shedding and room integrity	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0006	Cleanroom construction and partition joints	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wall panel leakage; coving; sealant compatibility; define risk-based requalification triggers affecting cleanability, shedding and room integrity	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0007	Personnel airlock	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses door interlocks; recovery; differential pressure; required outputs: controlled personnel transfer	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0008	Personnel airlock	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Personnel airlock	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0009	Personnel airlock	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for door interlocks; recovery; differential pressure; evaluate controlled personnel transfer	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0010	Personnel airlock	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0011	Personnel airlock	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled personnel transfer	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0012	Personnel airlock	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend door interlocks; recovery; differential pressure; define risk-based requalification triggers affecting controlled personnel transfer	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0013	Material airlock	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses transfer sequence; interlocking; recovery; required outputs: contamination transfer prevention	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0014	Material airlock	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Material airlock	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0015	Material airlock	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for transfer sequence; interlocking; recovery; evaluate contamination transfer prevention	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0016	Material airlock	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0017	Material airlock	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering contamination transfer prevention	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0018	Material airlock	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend transfer sequence; interlocking; recovery; define risk-based requalification triggers affecting contamination transfer prevention	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0019	Clean assembly room	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses airborne particle classification; occupancy; flows; required outputs: specified ISO class at rest/operational states	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0020	Clean assembly room	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Clean assembly room	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0021	Clean assembly room	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for airborne particle classification; occupancy; flows; evaluate specified ISO class at rest/operational states	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0022	Clean assembly room	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0023	Clean assembly room	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specified ISO class at rest/operational states	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0024	Clean assembly room	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend airborne particle classification; occupancy; flows; define risk-based requalification triggers affecting specified ISO class at rest/operational states	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0025	Sterile manufacturing clean zone	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses classification; airflow visualization; differential pressure; required outputs: aseptic/clean manufacturing protection	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0026	Sterile manufacturing clean zone	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile manufacturing clean zone	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0027	Sterile manufacturing clean zone	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for classification; airflow visualization; differential pressure; evaluate aseptic/clean manufacturing protection	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0028	Sterile manufacturing clean zone	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0029	Sterile manufacturing clean zone	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering aseptic/clean manufacturing protection	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0030	Sterile manufacturing clean zone	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend classification; airflow visualization; differential pressure; define risk-based requalification triggers affecting aseptic/clean manufacturing protection	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0031	QC microbiology clean zone	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses particle; microbiological contamination control; required outputs: lab test environment suitability	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0032	QC microbiology clean zone	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for QC microbiology clean zone	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0033	QC microbiology clean zone	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for particle; microbiological contamination control; evaluate lab test environment suitability	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0034	QC microbiology clean zone	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0035	QC microbiology clean zone	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering lab test environment suitability	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0036	QC microbiology clean zone	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend particle; microbiological contamination control; define risk-based requalification triggers affecting lab test environment suitability	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0037	High-containment assembly booth	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses directional airflow; enclosure leakage; filter integrity; required outputs: hazard containment and clean-to-dirty flow	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0038	High-containment assembly booth	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for High-containment assembly booth	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0039	High-containment assembly booth	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for directional airflow; enclosure leakage; filter integrity; evaluate hazard containment and clean-to-dirty flow	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0040	High-containment assembly booth	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0041	High-containment assembly booth	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering hazard containment and clean-to-dirty flow	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0042	High-containment assembly booth	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend directional airflow; enclosure leakage; filter integrity; define risk-based requalification triggers affecting hazard containment and clean-to-dirty flow	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0043	Pass-through hatch	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cycle parameters; interlock; cleaning; required outputs: material transfer integrity	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0044	Pass-through hatch	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pass-through hatch	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0045	Pass-through hatch	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cycle parameters; interlock; cleaning; evaluate material transfer integrity	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0046	Pass-through hatch	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0047	Pass-through hatch	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering material transfer integrity	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0048	Pass-through hatch	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cycle parameters; interlock; cleaning; define risk-based requalification triggers affecting material transfer integrity	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0049	Cleanroom door / vestibule assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pressure loss; door opening frequency; auto-close; required outputs: recovery and separation integrity	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0050	Cleanroom door / vestibule assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom door / vestibule assembly	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0051	Cleanroom door / vestibule assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pressure loss; door opening frequency; auto-close; evaluate recovery and separation integrity	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0052	Cleanroom door / vestibule assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0053	Cleanroom door / vestibule assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering recovery and separation integrity	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0054	Cleanroom door / vestibule assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pressure loss; door opening frequency; auto-close; define risk-based requalification triggers affecting recovery and separation integrity	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0055	Gowning facility	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses personnel flows; gown supply and change sequence; required outputs: contamination prevention	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0056	Gowning facility	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Gowning facility	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0057	Gowning facility	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for personnel flows; gown supply and change sequence; evaluate contamination prevention	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0058	Gowning facility	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0059	Gowning facility	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering contamination prevention	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0060	Gowning facility	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend personnel flows; gown supply and change sequence; define risk-based requalification triggers affecting contamination prevention	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0061	Recessed cleanroom lighting	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fixture seal; service access; particle shedding; required outputs: maintainable cleanroom envelope	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0062	Recessed cleanroom lighting	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Recessed cleanroom lighting	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0063	Recessed cleanroom lighting	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fixture seal; service access; particle shedding; evaluate maintainable cleanroom envelope	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0064	Recessed cleanroom lighting	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0065	Recessed cleanroom lighting	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering maintainable cleanroom envelope	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0066	Recessed cleanroom lighting	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fixture seal; service access; particle shedding; define risk-based requalification triggers affecting maintainable cleanroom envelope	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0067	Cleanroom floor finish	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses surface finish; chemical resistance; joint continuity; required outputs: cleanability and particle-shedding resistance	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0068	Cleanroom floor finish	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom floor finish	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0069	Cleanroom floor finish	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for surface finish; chemical resistance; joint continuity; evaluate cleanability and particle-shedding resistance	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0070	Cleanroom floor finish	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0071	Cleanroom floor finish	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cleanability and particle-shedding resistance	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0072	Cleanroom floor finish	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend surface finish; chemical resistance; joint continuity; define risk-based requalification triggers affecting cleanability and particle-shedding resistance	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0073	Wall service penetration	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses air leakage; cleaning access; seal integrity; required outputs: pressure cascade integrity	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0074	Wall service penetration	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wall service penetration	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0075	Wall service penetration	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for air leakage; cleaning access; seal integrity; evaluate pressure cascade integrity	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0076	Wall service penetration	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0077	Wall service penetration	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering pressure cascade integrity	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0078	Wall service penetration	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend air leakage; cleaning access; seal integrity; define risk-based requalification triggers affecting pressure cascade integrity	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0079	Clean bench / laminar flow cabinet	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses air velocity profile; filter scan; particle test; required outputs: specified work zone protection	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0080	Clean bench / laminar flow cabinet	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Clean bench / laminar flow cabinet	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0081	Clean bench / laminar flow cabinet	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for air velocity profile; filter scan; particle test; evaluate specified work zone protection	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0082	Clean bench / laminar flow cabinet	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0083	Clean bench / laminar flow cabinet	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specified work zone protection	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0084	Clean bench / laminar flow cabinet	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend air velocity profile; filter scan; particle test; define risk-based requalification triggers affecting specified work zone protection	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0085	Biosafety cabinet for IVD work	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses HEPA integrity; inflow/downflow; containment; required outputs: biological protection	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0086	Biosafety cabinet for IVD work	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Biosafety cabinet for IVD work	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0087	Biosafety cabinet for IVD work	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for HEPA integrity; inflow/downflow; containment; evaluate biological protection	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0088	Biosafety cabinet for IVD work	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-05-0089	Biosafety cabinet for IVD work	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biological protection	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0090	Biosafety cabinet for IVD work	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend HEPA integrity; inflow/downflow; containment; define risk-based requalification triggers affecting biological protection	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium
MDV-05-0091	Cleanroom housekeeping tools	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses particle generation; sanitization effectiveness; required outputs: environment contamination control	URS / DQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0092	Cleanroom housekeeping tools	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom housekeeping tools	IQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0093	Cleanroom housekeeping tools	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for particle generation; sanitization effectiveness; evaluate environment contamination control	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0094	Cleanroom housekeeping tools	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0095	Cleanroom housekeeping tools	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering environment contamination control	PQ	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	High
MDV-05-0096	Cleanroom housekeeping tools	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend particle generation; sanitization effectiveness; define risk-based requalification triggers affecting environment contamination control	Routine / Change	Sterile/nonsterile devices; implantables; clean assembly	M02 M05 M07 M15	Medium

06 HVAC, AHU, HEPA & MONITORING SYSTEMS

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0001	AHU supply fan and VFD	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses air volume; fan speed; trip recovery; required outputs: controlled airflow and alarms	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0002	AHU supply fan and VFD	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for AHU supply fan and VFD	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0003	AHU supply fan and VFD	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for air volume; fan speed; trip recovery; evaluate controlled airflow and alarms	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0004	AHU supply fan and VFD	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0005	AHU supply fan and VFD	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled airflow and alarms	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0006	AHU supply fan and VFD	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend air volume; fan speed; trip recovery; define risk-based requalification triggers affecting controlled airflow and alarms	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0007	HVAC duct balancing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses terminal flow; damper position; leakage; required outputs: airflow uniformity and clean/dirty zoning	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0008	HVAC duct balancing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for HVAC duct balancing	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0009	HVAC duct balancing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for terminal flow; damper position; leakage; evaluate airflow uniformity and clean/dirty zoning	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0010	HVAC duct balancing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0011	HVAC duct balancing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering airflow uniformity and clean/dirty zoning	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0012	HVAC duct balancing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend terminal flow; damper position; leakage; define risk-based requalification triggers affecting airflow uniformity and clean/dirty zoning	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0013	Pre-filter and fine filter train	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pressure drop; bypass leaks; change-out; required outputs: filter performance and alarm response	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0014	Pre-filter and fine filter train	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pre-filter and fine filter train	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0015	Pre-filter and fine filter train	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pressure drop; bypass leaks; change-out; evaluate filter performance and alarm response	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0016	Pre-filter and fine filter train	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0017	Pre-filter and fine filter train	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering filter performance and alarm response	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0018	Pre-filter and fine filter train	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pressure drop; bypass leaks; change-out; define risk-based requalification triggers affecting filter performance and alarm response	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0019	Terminal HEPA filter bank	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses installed filter leak integrity; static pressure; airflow; required outputs: airborne particle protection	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0020	Terminal HEPA filter bank	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Terminal HEPA filter bank	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0021	Terminal HEPA filter bank	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for installed filter leak integrity; static pressure; airflow; evaluate airborne particle protection	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0022	Terminal HEPA filter bank	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0023	Terminal HEPA filter bank	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering airborne particle protection	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0024	Terminal HEPA filter bank	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend installed filter leak integrity; static pressure; airflow; define risk-based requalification triggers affecting airborne particle protection	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0025	Cleanroom differential pressure controller	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses setpoint; sensor drift; door disturbances; required outputs: directional airflow stability	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0026	Cleanroom differential pressure controller	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom differential pressure controller	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0027	Cleanroom differential pressure controller	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for setpoint; sensor drift; door disturbances; evaluate directional airflow stability	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0028	Cleanroom differential pressure controller	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0029	Cleanroom differential pressure controller	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering directional airflow stability	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0030	Cleanroom differential pressure controller	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend setpoint; sensor drift; door disturbances; define risk-based requalification triggers affecting directional airflow stability	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0031	Room air change / recovery performance	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses recovery time; occupancy; particle challenge; required outputs: classified-zone recovery	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0032	Room air change / recovery performance	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Room air change / recovery performance	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0033	Room air change / recovery performance	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for recovery time; occupancy; particle challenge; evaluate classified-zone recovery	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0034	Room air change / recovery performance	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0035	Room air change / recovery performance	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering classified-zone recovery	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0036	Room air change / recovery performance	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend recovery time; occupancy; particle challenge; define risk-based requalification triggers affecting classified-zone recovery	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0037	Temperature conditioning coil	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses low/high load; sensor calibration; thermal response; required outputs: manufacturing process temperature stability	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0038	Temperature conditioning coil	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Temperature conditioning coil	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0039	Temperature conditioning coil	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for low/high load; sensor calibration; thermal response; evaluate manufacturing process temperature stability	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0040	Temperature conditioning coil	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0041	Temperature conditioning coil	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering manufacturing process temperature stability	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0042	Temperature conditioning coil	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend low/high load; sensor calibration; thermal response; define risk-based requalification triggers affecting manufacturing process temperature stability	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0043	Humidity conditioning/dehumidifier	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RH setpoint; worst-case season; condensate; required outputs: material and process humidity control	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0044	Humidity conditioning/dehumidifier	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Humidity conditioning/dehumidifier	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0045	Humidity conditioning/dehumidifier	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RH setpoint; worst-case season; condensate; evaluate material and process humidity control	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0046	Humidity conditioning/dehumidifier	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0047	Humidity conditioning/dehumidifier	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering material and process humidity control	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0048	Humidity conditioning/dehumidifier	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RH setpoint; worst-case season; condensate; define risk-based requalification triggers affecting material and process humidity control	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0049	Airflow visualization / smoke study	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses patterns at critical operation; operator positions; required outputs: no unacceptably adverse airflow to product	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0050	Airflow visualization / smoke study	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Airflow visualization / smoke study	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0051	Airflow visualization / smoke study	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for patterns at critical operation; operator positions; evaluate no unacceptably adverse airflow to product	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0052	Airflow visualization / smoke study	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0053	Airflow visualization / smoke study	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no unacceptably adverse airflow to product	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0054	Airflow visualization / smoke study	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend patterns at critical operation; operator positions; define risk-based requalification triggers affecting no unacceptably adverse airflow to product	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0055	Environmental monitoring viable air sampler	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses volume; flow metrology; recovery; required outputs: representative microbiological sampling	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0056	Environmental monitoring viable air sampler	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Environmental monitoring viable air sampler	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0057	Environmental monitoring viable air sampler	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for volume; flow metrology; recovery; evaluate representative microbiological sampling	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0058	Environmental monitoring viable air sampler	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0059	Environmental monitoring viable air sampler	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering representative microbiological sampling	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0060	Environmental monitoring viable air sampler	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend volume; flow metrology; recovery; define risk-based requalification triggers affecting representative microbiological sampling	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0061	Particle counter network	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses count efficiency; coincidence; tubing losses; required outputs: ISO particle counting accuracy	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0062	Particle counter network	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Particle counter network	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0063	Particle counter network	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for count efficiency; coincidence; tubing losses; evaluate ISO particle counting accuracy	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0064	Particle counter network	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0065	Particle counter network	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering ISO particle counting accuracy	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0066	Particle counter network	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend count efficiency; coincidence; tubing losses; define risk-based requalification triggers affecting ISO particle counting accuracy	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0067	Cleanroom building management system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sensors; trends; alarm escalation; backups; required outputs: environmental records integrity	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0068	Cleanroom building management system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom building management system	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0069	Cleanroom building management system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sensors; trends; alarm escalation; backups; evaluate environmental records integrity	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0070	Cleanroom building management system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0071	Cleanroom building management system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering environmental records integrity	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0072	Cleanroom building management system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sensors; trends; alarm escalation; backups; define risk-based requalification triggers affecting environmental records integrity	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0073	Local process exhaust system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses capture velocity; filter differential; negative pressure; required outputs: operator protection and cross-contamination prevention	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0074	Local process exhaust system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Local process exhaust system	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0075	Local process exhaust system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for capture velocity; filter differential; negative pressure; evaluate operator protection and cross-contamination prevention	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0076	Local process exhaust system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0077	Local process exhaust system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering operator protection and cross-contamination prevention	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0078	Local process exhaust system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend capture velocity; filter differential; negative pressure; define risk-based requalification triggers affecting operator protection and cross-contamination prevention	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0079	Critical HVAC emergency supply	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses power failure; restart sequencing; alarms; required outputs: safe facility state and data continuity	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0080	Critical HVAC emergency supply	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Critical HVAC emergency supply	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0081	Critical HVAC emergency supply	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for power failure; restart sequencing; alarms; evaluate safe facility state and data continuity	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0082	Critical HVAC emergency supply	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0083	Critical HVAC emergency supply	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe facility state and data continuity	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0084	Critical HVAC emergency supply	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend power failure; restart sequencing; alarms; define risk-based requalification triggers affecting safe facility state and data continuity	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0085	Fume hood	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses face velocity; sash positions; capture efficacy; required outputs: containment and exposure prevention	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0086	Fume hood	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Fume hood	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0087	Fume hood	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for face velocity; sash positions; capture efficacy; evaluate containment and exposure prevention	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0088	Fume hood	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-06-0089	Fume hood	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering containment and exposure prevention	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0090	Fume hood	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend face velocity; sash positions; capture efficacy; define risk-based requalification triggers affecting containment and exposure prevention	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium
MDV-06-0091	Air curtain at assembly transfer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses velocity uniformity; door opening disturbance; required outputs: contamination ingress protection	URS / DQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0092	Air curtain at assembly transfer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Air curtain at assembly transfer	IQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0093	Air curtain at assembly transfer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for velocity uniformity; door opening disturbance; evaluate contamination ingress protection	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0094	Air curtain at assembly transfer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0095	Air curtain at assembly transfer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering contamination ingress protection	PQ	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	High
MDV-06-0096	Air curtain at assembly transfer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend velocity uniformity; door opening disturbance; define risk-based requalification triggers affecting contamination ingress protection	Routine / Change	ISO-controlled areas; device assembly and laboratories	M02 M05 M07 M15	Medium

07 CRITICAL UTILITIES, GASES, WATER & PLANT SERVICES

108 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-07-0001	Purified water / RO loop	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses conductivity; TOC if relevant; microbial trend; required outputs: water suitability for cleaning/device contact	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0002	Purified water / RO loop	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Purified water / RO loop	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0003	Purified water / RO loop	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for conductivity; TOC if relevant; microbial trend; evaluate water suitability for cleaning/device contact	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0004	Purified water / RO loop	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0005	Purified water / RO loop	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering water suitability for cleaning/device contact	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0006	Purified water / RO loop	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend conductivity; TOC if relevant; microbial trend; define risk-based requalification triggers affecting water suitability for cleaning/device contact	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0007	WFI-grade water system if justified	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses microbiology; endotoxin; TOC; conductivity; required outputs: water compatible with sterile-contact processes	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0008	WFI-grade water system if justified	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for WFI-grade water system if justified	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0009	WFI-grade water system if justified	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for microbiology; endotoxin; TOC; conductivity; evaluate water compatible with sterile-contact processes	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0010	WFI-grade water system if justified	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0011	WFI-grade water system if justified	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering water compatible with sterile-contact processes	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0012	WFI-grade water system if justified	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend microbiology; endotoxin; TOC; conductivity; define risk-based requalification triggers affecting water compatible with sterile-contact processes	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0013	Water pretreatment softener	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses hardness; regeneration; breakthrough; required outputs: upstream feed-water control	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0014	Water pretreatment softener	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Water pretreatment softener	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0015	Water pretreatment softener	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for hardness; regeneration; breakthrough; evaluate upstream feed-water control	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0016	Water pretreatment softener	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0017	Water pretreatment softener	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering upstream feed-water control	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0018	Water pretreatment softener	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend hardness; regeneration; breakthrough; define risk-based requalification triggers affecting upstream feed-water control	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0019	UV treatment system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses UV dose; flow; lamp end-of-life; required outputs: microbial control capability	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0020	UV treatment system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UV treatment system	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0021	UV treatment system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for UV dose; flow; lamp end-of-life; evaluate microbial control capability	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0022	UV treatment system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-07-0023	UV treatment system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering microbial control capability	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0024	UV treatment system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend UV dose; flow; lamp end-of-life; define risk-based requalification triggers affecting microbial control capability	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0025	Compressed process air	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses oil aerosol; particulate; humidity; microbial risk; required outputs: process-contact air quality	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0026	Compressed process air	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Compressed process air	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0027	Compressed process air	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for oil aerosol; particulate; humidity; microbial risk; evaluate process-contact air quality	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0028	Compressed process air	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0029	Compressed process air	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering process-contact air quality	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0030	Compressed process air	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend oil aerosol; particulate; humidity; microbial risk; define risk-based requalification triggers affecting process-contact air quality	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0031	Instrument compressed air	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dew point; pressure; availability; required outputs: reliable actuation and control	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0032	Instrument compressed air	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Instrument compressed air	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0033	Instrument compressed air	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dew point; pressure; availability; evaluate reliable actuation and control	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0034	Instrument compressed air	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0035	Instrument compressed air	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reliable actuation and control	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0036	Instrument compressed air	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dew point; pressure; availability; define risk-based requalification triggers affecting reliable actuation and control	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0037	Process nitrogen supply	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses purity; pressure; moisture; alarm; required outputs: material and reagent protection	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0038	Process nitrogen supply	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Process nitrogen supply	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0039	Process nitrogen supply	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for purity; pressure; moisture; alarm; evaluate material and reagent protection	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0040	Process nitrogen supply	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0041	Process nitrogen supply	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering material and reagent protection	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0042	Process nitrogen supply	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend purity; pressure; moisture; alarm; define risk-based requalification triggers affecting material and reagent protection	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0043	Oxygen plant / medical gas interface	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses purity; line identity; cross-connection prevention; required outputs: specified gas quality and alarms	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0044	Oxygen plant / medical gas interface	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Oxygen plant / medical gas interface	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0045	Oxygen plant / medical gas interface	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for purity; line identity; cross-connection prevention; evaluate specified gas quality and alarms	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0046	Oxygen plant / medical gas interface	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-07-0047	Oxygen plant / medical gas interface	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specified gas quality and alarms	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0048	Oxygen plant / medical gas interface	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend purity; line identity; cross-connection prevention; define risk-based requalification triggers affecting specified gas quality and alarms	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0049	Process vacuum pump	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses vacuum range; cycle repeatability; backflow protection; required outputs: stable vacuum-enabled assembly	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0050	Process vacuum pump	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Process vacuum pump	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0051	Process vacuum pump	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for vacuum range; cycle repeatability; backflow protection; evaluate stable vacuum-enabled assembly	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0052	Process vacuum pump	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0053	Process vacuum pump	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering stable vacuum-enabled assembly	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0054	Process vacuum pump	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend vacuum range; cycle repeatability; backflow protection; define risk-based requalification triggers affecting stable vacuum-enabled assembly	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0055	Clean steam generator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses steam dryness; NCG and quality as justified; required outputs: sterilizer-compatible sterilant supply	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0056	Clean steam generator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Clean steam generator	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0057	Clean steam generator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for steam dryness; NCG and quality as justified; evaluate sterilizer-compatible sterilant supply	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0058	Clean steam generator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0059	Clean steam generator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterilizer-compatible sterilant supply	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0060	Clean steam generator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend steam dryness; NCG and quality as justified; define risk-based requalification triggers affecting sterilizer-compatible sterilant supply	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0061	Chilled water system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; flow; redundancy and load recovery; required outputs: process temperature control	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0062	Chilled water system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Chilled water system	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0063	Chilled water system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; flow; redundancy and load recovery; evaluate process temperature control	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0064	Chilled water system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0065	Chilled water system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering process temperature control	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0066	Chilled water system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; flow; redundancy and load recovery; define risk-based requalification triggers affecting process temperature control	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0067	Cooling tower / recirculation	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature performance; biological control; required outputs: cooling utility reliability	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0068	Cooling tower / recirculation	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cooling tower / recirculation	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0069	Cooling tower / recirculation	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature performance; biological control; evaluate cooling utility reliability	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0070	Cooling tower / recirculation	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-07-0071	Cooling tower / recirculation	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cooling utility reliability	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0072	Cooling tower / recirculation	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature performance; biological control; define risk-based requalification triggers affecting cooling utility reliability	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0073	Electrical transformer supply	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses phase stability; harmonics; brownout resilience; required outputs: power to critical manufacturing equipment	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0074	Electrical transformer supply	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electrical transformer supply	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0075	Electrical transformer supply	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for phase stability; harmonics; brownout resilience; evaluate power to critical manufacturing equipment	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0076	Electrical transformer supply	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0077	Electrical transformer supply	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering power to critical manufacturing equipment	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0078	Electrical transformer supply	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend phase stability; harmonics; brownout resilience; define risk-based requalification triggers affecting power to critical manufacturing equipment	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0079	UPS for critical PLC and data system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses load test; switchover; autonomy; required outputs: records and process continuity	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0080	UPS for critical PLC and data system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UPS for critical PLC and data system	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0081	UPS for critical PLC and data system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for load test; switchover; autonomy; evaluate records and process continuity	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0082	UPS for critical PLC and data system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0083	UPS for critical PLC and data system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering records and process continuity	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0084	UPS for critical PLC and data system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend load test; switchover; autonomy; define risk-based requalification triggers affecting records and process continuity	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0085	Diesel generator back-up	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses auto-start; transfer; critical load endurance; required outputs: controlled restart and alarms	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0086	Diesel generator back-up	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Diesel generator back-up	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0087	Diesel generator back-up	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for auto-start; transfer; critical load endurance; evaluate controlled restart and alarms	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0088	Diesel generator back-up	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0089	Diesel generator back-up	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled restart and alarms	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0090	Diesel generator back-up	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend auto-start; transfer; critical load endurance; define risk-based requalification triggers affecting controlled restart and alarms	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0091	Compressed gas manifold	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses gas identity; regulator; pressure cutover; required outputs: uninterrupted safe supply	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0092	Compressed gas manifold	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Compressed gas manifold	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0093	Compressed gas manifold	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for gas identity; regulator; pressure cutover; evaluate uninterrupted safe supply	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0094	Compressed gas manifold	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-07-0095	Compressed gas manifold	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering uninterrupted safe supply	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0096	Compressed gas manifold	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend gas identity; regulator; pressure cutover; define risk-based requalification triggers affecting uninterrupted safe supply	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0097	Industrial wastewater neutralization	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pH; flow; containment alarm; required outputs: compliant effluent control	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0098	Industrial wastewater neutralization	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Industrial wastewater neutralization	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0099	Industrial wastewater neutralization	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pH; flow; containment alarm; evaluate compliant effluent control	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0100	Industrial wastewater neutralization	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0101	Industrial wastewater neutralization	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering compliant effluent control	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0102	Industrial wastewater neutralization	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pH; flow; containment alarm; define risk-based requalification triggers affecting compliant effluent control	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium
MDV-07-0103	Critical water point-of-use filter	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses filter integrity; flow; service life; required outputs: process-contact water protection	URS / DQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0104	Critical water point-of-use filter	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Critical water point-of-use filter	IQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0105	Critical water point-of-use filter	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for filter integrity; flow; service life; evaluate process-contact water protection	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0106	Critical water point-of-use filter	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0107	Critical water point-of-use filter	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering process-contact water protection	PQ	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	High
MDV-07-0108	Critical water point-of-use filter	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend filter integrity; flow; service life; define risk-based requalification triggers affecting process-contact water protection	Routine / Change	Sterile/nonsterile medical device facilities	M02 M05 M07 M15	Medium

08 METROLOGY, AUTOMATED INSPECTION & QC INSTRUMENTS

162 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0001	Digital vernier caliper	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses linearity; repeatability; zero; jaw parallelism; required outputs: dimensional acceptance reliability	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0002	Digital vernier caliper	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Digital vernier caliper	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0003	Digital vernier caliper	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for linearity; repeatability; zero; jaw parallelism; evaluate dimensional acceptance reliability	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0004	Digital vernier caliper	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0005	Digital vernier caliper	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dimensional acceptance reliability	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0006	Digital vernier caliper	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend linearity; repeatability; zero; jaw parallelism; define risk-based requalification triggers affecting dimensional acceptance reliability	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0007	Micrometer / bore gauge	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses gauge blocks; linearity; user bias; required outputs: internal diameter / wall thickness control	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0008	Micrometer / bore gauge	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Micrometer / bore gauge	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0009	Micrometer / bore gauge	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for gauge blocks; linearity; user bias; evaluate internal diameter / wall thickness control	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0010	Micrometer / bore gauge	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0011	Micrometer / bore gauge	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering internal diameter / wall thickness control	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0012	Micrometer / bore gauge	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend gauge blocks; linearity; user bias; define risk-based requalification triggers affecting internal diameter / wall thickness control	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0013	Coordinate measuring machine CMM	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses probe calibration; axis geometry; thermal effects; required outputs: complex implant/component dimensional accuracy	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0014	Coordinate measuring machine CMM	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Coordinate measuring machine CMM	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0015	Coordinate measuring machine CMM	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for probe calibration; axis geometry; thermal effects; evaluate complex implant/component dimensional accuracy	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0016	Coordinate measuring machine CMM	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0017	Coordinate measuring machine CMM	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering complex implant/component dimensional accuracy	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0018	Coordinate measuring machine CMM	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend probe calibration; axis geometry; thermal effects; define risk-based requalification triggers affecting complex implant/component dimensional accuracy	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0019	Vision measuring microscope	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses camera calibration; magnification; lighting; required outputs: microfeature and geometry discrimination	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0020	Vision measuring microscope	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vision measuring microscope	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0021	Vision measuring microscope	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for camera calibration; magnification; lighting; evaluate microfeature and geometry discrimination	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0022	Vision measuring microscope	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0023	Vision measuring microscope	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering microfeature and geometry discrimination	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0024	Vision measuring microscope	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend camera calibration; magnification; lighting; define risk-based requalification triggers affecting microfeature and geometry discrimination	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0025	Optical comparator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses magnification; distortion; edge contrast; required outputs: profile inspection capability	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0026	Optical comparator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Optical comparator	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0027	Optical comparator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for magnification; distortion; edge contrast; evaluate profile inspection capability	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0028	Optical comparator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0029	Optical comparator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering profile inspection capability	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0030	Optical comparator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend magnification; distortion; edge contrast; define risk-based requalification triggers affecting profile inspection capability	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0031	Laser micrometer for tubing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses diameter range; laser alignment; speed; required outputs: online tube diameter measurement	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0032	Laser micrometer for tubing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser micrometer for tubing	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0033	Laser micrometer for tubing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for diameter range; laser alignment; speed; evaluate online tube diameter measurement	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0034	Laser micrometer for tubing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0035	Laser micrometer for tubing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering online tube diameter measurement	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0036	Laser micrometer for tubing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend diameter range; laser alignment; speed; define risk-based requalification triggers affecting online tube diameter measurement	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0037	Universal testing machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses force calibration; crosshead rate; grips; required outputs: tensile/compression test reliability	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0038	Universal testing machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Universal testing machine	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0039	Universal testing machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for force calibration; crosshead rate; grips; evaluate tensile/compression test reliability	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0040	Universal testing machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0041	Universal testing machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tensile/compression test reliability	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0042	Universal testing machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend force calibration; crosshead rate; grips; define risk-based requalification triggers affecting tensile/compression test reliability	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0043	Burst/leak pressure tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pressure traceability; leak threshold; fixture integrity; required outputs: pressure integrity test discrimination	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0044	Burst/leak pressure tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Burst/leak pressure tester	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0045	Burst/leak pressure tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pressure traceability; leak threshold; fixture integrity; evaluate pressure integrity test discrimination	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0046	Burst/leak pressure tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0047	Burst/leak pressure tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering pressure integrity test discrimination	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0048	Burst/leak pressure tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pressure traceability; leak threshold; fixture integrity; define risk-based requalification triggers affecting pressure integrity test discrimination	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0049	Torque meter / torque wrench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses torque accuracy; repeatability; fixture effect; required outputs: assembly torque control	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0050	Torque meter / torque wrench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Torque meter / torque wrench	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0051	Torque meter / torque wrench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for torque accuracy; repeatability; fixture effect; evaluate assembly torque control	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0052	Torque meter / torque wrench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0053	Torque meter / torque wrench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering assembly torque control	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0054	Torque meter / torque wrench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend torque accuracy; repeatability; fixture effect; define risk-based requalification triggers affecting assembly torque control	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0055	Flow meter / flow bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses low/high flows; fluid viscosity effects; required outputs: flow performance measurement	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0056	Flow meter / flow bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Flow meter / flow bench	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0057	Flow meter / flow bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for low/high flows; fluid viscosity effects; evaluate flow performance measurement	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0058	Flow meter / flow bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0059	Flow meter / flow bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flow performance measurement	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0060	Flow meter / flow bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend low/high flows; fluid viscosity effects; define risk-based requalification triggers affecting flow performance measurement	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0061	Differential pressure gauge	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses span; hysteresis; sensor drift; required outputs: cleanroom and HVAC pressure results	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0062	Differential pressure gauge	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Differential pressure gauge	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0063	Differential pressure gauge	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for span; hysteresis; sensor drift; evaluate cleanroom and HVAC pressure results	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0064	Differential pressure gauge	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0065	Differential pressure gauge	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cleanroom and HVAC pressure results	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0066	Differential pressure gauge	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend span; hysteresis; sensor drift; define risk-based requalification triggers affecting cleanroom and HVAC pressure results	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0067	Temperature logger	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses multi-point calibration; sampling interval; clock sync; required outputs: cold-chain mapping integrity	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0068	Temperature logger	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Temperature logger	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0069	Temperature logger	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for multi-point calibration; sampling interval; clock sync; evaluate cold-chain mapping integrity	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0070	Temperature logger	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0071	Temperature logger	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cold-chain mapping integrity	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0072	Temperature logger	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend multi-point calibration; sampling interval; clock sync; define risk-based requalification triggers affecting cold-chain mapping integrity	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0073	Humidity logger	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses calibration; response time; location bias; required outputs: warehouse and cleanroom humidity evidence	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0074	Humidity logger	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Humidity logger	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0075	Humidity logger	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for calibration; response time; location bias; evaluate warehouse and cleanroom humidity evidence	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0076	Humidity logger	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0077	Humidity logger	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering warehouse and cleanroom humidity evidence	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0078	Humidity logger	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend calibration; response time; location bias; define risk-based requalification triggers affecting warehouse and cleanroom humidity evidence	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0079	Balance and microbalance	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses linearity; repeatability; eccentricity; minimum weight; required outputs: mass/gravimetric accuracy	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0080	Balance and microbalance	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Balance and microbalance	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0081	Balance and microbalance	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for linearity; repeatability; eccentricity; minimum weight; evaluate mass/gravimetric accuracy	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0082	Balance and microbalance	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0083	Balance and microbalance	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering mass/gravimetric accuracy	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0084	Balance and microbalance	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend linearity; repeatability; eccentricity; minimum weight; define risk-based requalification triggers affecting mass/gravimetric accuracy	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0085	Spectrophotometer UV-Vis	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wavelength accuracy; photometric response; baseline; required outputs: IVD/reagent assay performance	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0086	Spectrophotometer UV-Vis	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Spectrophotometer UV-Vis	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0087	Spectrophotometer UV-Vis	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wavelength accuracy; photometric response; baseline; evaluate IVD/reagent assay performance	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0088	Spectrophotometer UV-Vis	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0089	Spectrophotometer UV-Vis	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering IVD/reagent assay performance	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0090	Spectrophotometer UV-Vis	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wavelength accuracy; photometric response; baseline; define risk-based requalification triggers affecting IVD/reagent assay performance	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0091	FTIR spectroscopy	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wavenumber; reference material; library matching; required outputs: polymer and compound identity	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0092	FTIR spectroscopy	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for FTIR spectroscopy	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0093	FTIR spectroscopy	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wavenumber; reference material; library matching; evaluate polymer and compound identity	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0094	FTIR spectroscopy	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0095	FTIR spectroscopy	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering polymer and compound identity	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0096	FTIR spectroscopy	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wavenumber; reference material; library matching; define risk-based requalification triggers affecting polymer and compound identity	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0097	HPLC system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pump precision; injection repeatability; detector response; required outputs: chemical analyte quantitation	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0098	HPLC system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for HPLC system	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0099	HPLC system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pump precision; injection repeatability; detector response; evaluate chemical analyte quantitation	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0100	HPLC system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0101	HPLC system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering chemical analyte quantitation	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0102	HPLC system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pump precision; injection repeatability; detector response; define risk-based requalification triggers affecting chemical analyte quantitation	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0103	GC / GC-MS system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses resolution; linearity; carryover; required outputs: EO residual/solvent quantitation	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0104	GC / GC-MS system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for GC / GC-MS system	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0105	GC / GC-MS system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for resolution; linearity; carryover; evaluate EO residual/solvent quantitation	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0106	GC / GC-MS system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0107	GC / GC-MS system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering EO residual/solvent quantitation	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0108	GC / GC-MS system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend resolution; linearity; carryover; define risk-based requalification triggers affecting EO residual/solvent quantitation	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0109	ICP-MS / OES	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses calibration drift; contamination blanks; sensitivity; required outputs: elemental impurities in implants	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0110	ICP-MS / OES	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for ICP-MS / OES	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0111	ICP-MS / OES	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for calibration drift; contamination blanks; sensitivity; evaluate elemental impurities in implants	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0112	ICP-MS / OES	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0113	ICP-MS / OES	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering elemental impurities in implants	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0114	ICP-MS / OES	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend calibration drift; contamination blanks; sensitivity; define risk-based requalification triggers affecting elemental impurities in implants	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0115	Endotoxin reader	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses standard curve; interference; reader reproducibility; required outputs: endotoxin assay integrity	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0116	Endotoxin reader	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Endotoxin reader	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0117	Endotoxin reader	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for standard curve; interference; reader reproducibility; evaluate endotoxin assay integrity	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0118	Endotoxin reader	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0119	Endotoxin reader	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering endotoxin assay integrity	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0120	Endotoxin reader	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend standard curve; interference; reader reproducibility; define risk-based requalification triggers affecting endotoxin assay integrity	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0121	Microscope image analysis software	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses edge detection; segmentation; repeatability; required outputs: surface and defect classification	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0122	Microscope image analysis software	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microscope image analysis software	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0123	Microscope image analysis software	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for edge detection; segmentation; repeatability; evaluate surface and defect classification	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0124	Microscope image analysis software	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0125	Microscope image analysis software	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering surface and defect classification	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0126	Microscope image analysis software	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend edge detection; segmentation; repeatability; define risk-based requalification triggers affecting surface and defect classification	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0127	Automated visual inspection camera	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses illumination; false accepts; reference defect set; required outputs: critical defect discrimination	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0128	Automated visual inspection camera	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated visual inspection camera	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0129	Automated visual inspection camera	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for illumination; false accepts; reference defect set; evaluate critical defect discrimination	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0130	Automated visual inspection camera	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0131	Automated visual inspection camera	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering critical defect discrimination	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0132	Automated visual inspection camera	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend illumination; false accepts; reference defect set; define risk-based requalification triggers affecting critical defect discrimination	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0133	Metal detector / X-ray contamination inspection	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses challenge pieces; product effect; sensitivity; required outputs: foreign material detection	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0134	Metal detector / X-ray contamination inspection	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Metal detector / X-ray contamination inspection	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0135	Metal detector / X-ray contamination inspection	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for challenge pieces; product effect; sensitivity; evaluate foreign material detection	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0136	Metal detector / X-ray contamination inspection	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0137	Metal detector / X-ray contamination inspection	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering foreign material detection	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0138	Metal detector / X-ray contamination inspection	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend challenge pieces; product effect; sensitivity; define risk-based requalification triggers affecting foreign material detection	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0139	Electrical safety analyzer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses accuracy; line/load conditions; test sequence; required outputs: device leakage and dielectric safety testing	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0140	Electrical safety analyzer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electrical safety analyzer	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0141	Electrical safety analyzer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for accuracy; line/load conditions; test sequence; evaluate device leakage and dielectric safety testing	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-08-0142	Electrical safety analyzer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0143	Electrical safety analyzer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering device leakage and dielectric safety testing	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0144	Electrical safety analyzer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend accuracy; line/load conditions; test sequence; define risk-based requalification triggers affecting device leakage and dielectric safety testing	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0145	Oscilloscope / DAQ acquisition system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bandwidth; trigger; timebase calibration; required outputs: electrical output measurement	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0146	Oscilloscope / DAQ acquisition system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Oscilloscope / DAQ acquisition system	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0147	Oscilloscope / DAQ acquisition system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bandwidth; trigger; timebase calibration; evaluate electrical output measurement	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0148	Oscilloscope / DAQ acquisition system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0149	Oscilloscope / DAQ acquisition system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering electrical output measurement	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0150	Oscilloscope / DAQ acquisition system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bandwidth; trigger; timebase calibration; define risk-based requalification triggers affecting electrical output measurement	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0151	Environmental test chamber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature/RH uniformity; sensor offset; recovery; required outputs: shelf-life / stress test reproducibility	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0152	Environmental test chamber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Environmental test chamber	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0153	Environmental test chamber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature/RH uniformity; sensor offset; recovery; evaluate shelf-life / stress test reproducibility	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0154	Environmental test chamber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0155	Environmental test chamber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering shelf-life / stress test reproducibility	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0156	Environmental test chamber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature/RH uniformity; sensor offset; recovery; define risk-based requalification triggers affecting shelf-life / stress test reproducibility	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0157	Vibration / drop test system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses amplitude; frequency; table response; required outputs: shipping/durability test representativeness	URS / DQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0158	Vibration / drop test system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vibration / drop test system	IQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0159	Vibration / drop test system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for amplitude; frequency; table response; evaluate shipping/durability test representativeness	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0160	Vibration / drop test system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0161	Vibration / drop test system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering shipping/durability test representativeness	PQ	All devices; critical product measurements	M02 M07 M18 M33	Medium
MDV-08-0162	Vibration / drop test system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend amplitude; frequency; table response; define risk-based requalification triggers affecting shipping/durability test representativeness	Routine / Change	All devices; critical product measurements	M02 M07 M18 M33	Medium

09 PLASTICS, EXTRUSION, MOLDING & POLYMER CONVERTING

132 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-09-0001	Injection molding press	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses melt temperature; hold pressure; clamp force; cooling time; required outputs: flash, short-shot, dimensions and tensile integrity	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0002	Injection molding press	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Injection molding press	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0003	Injection molding press	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for melt temperature; hold pressure; clamp force; cooling time; evaluate flash, short-shot, dimensions and tensile integrity	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0004	Injection molding press	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0005	Injection molding press	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flash, short-shot, dimensions and tensile integrity	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0006	Injection molding press	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend melt temperature; hold pressure; clamp force; cooling time; define risk-based requalification triggers affecting flash, short-shot, dimensions and tensile integrity	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0007	Multi-cavity injection mold	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cavity balance; gate freeze; ejector wear; required outputs: cavity-level dimensions and cosmetic defect rate	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0008	Multi-cavity injection mold	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Multi-cavity injection mold	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0009	Multi-cavity injection mold	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cavity balance; gate freeze; ejector wear; evaluate cavity-level dimensions and cosmetic defect rate	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0010	Multi-cavity injection mold	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0011	Multi-cavity injection mold	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cavity-level dimensions and cosmetic defect rate	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0012	Multi-cavity injection mold	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cavity balance; gate freeze; ejector wear; define risk-based requalification triggers affecting cavity-level dimensions and cosmetic defect rate	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0013	Extrusion line for medical tubing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses screw speed; melt pressure; puller speed; vacuum sizing; required outputs: inner/outer diameter, ovality and wall thickness	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0014	Extrusion line for medical tubing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Extrusion line for medical tubing	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0015	Extrusion line for medical tubing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for screw speed; melt pressure; puller speed; vacuum sizing; evaluate inner/outer diameter, ovality and wall thickness	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0016	Extrusion line for medical tubing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0017	Extrusion line for medical tubing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering inner/outer diameter, ovality and wall thickness	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0018	Extrusion line for medical tubing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend screw speed; melt pressure; puller speed; vacuum sizing; define risk-based requalification triggers affecting inner/outer diameter, ovality and wall thickness	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0019	Co-extrusion multilayer tubing line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses layer thickness; die centering; thermal profile; required outputs: layer bond and barrier performance	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0020	Co-extrusion multilayer tubing line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Co-extrusion multilayer tubing line	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0021	Co-extrusion multilayer tubing line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for layer thickness; die centering; thermal profile; evaluate layer bond and barrier performance	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High

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MDV-09-0022	Co-extrusion multilayer tubing line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0023	Co-extrusion multilayer tubing line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering layer bond and barrier performance	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0024	Co-extrusion multilayer tubing line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend layer thickness; die centering; thermal profile; define risk-based requalification triggers affecting layer bond and barrier performance	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0025	Film extrusion / cast film line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses line speed; chill roll temperature; thickness profile; required outputs: film thickness, clarity and strength	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0026	Film extrusion / cast film line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Film extrusion / cast film line	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0027	Film extrusion / cast film line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for line speed; chill roll temperature; thickness profile; evaluate film thickness, clarity and strength	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0028	Film extrusion / cast film line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0029	Film extrusion / cast film line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering film thickness, clarity and strength	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0030	Film extrusion / cast film line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend line speed; chill roll temperature; thickness profile; define risk-based requalification triggers affecting film thickness, clarity and strength	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0031	Blown film extrusion	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bubble stability; gauge profile; cooling air; required outputs: film uniformity and pinhole rate	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0032	Blown film extrusion	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Blown film extrusion	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0033	Blown film extrusion	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bubble stability; gauge profile; cooling air; evaluate film uniformity and pinhole rate	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0034	Blown film extrusion	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0035	Blown film extrusion	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering film uniformity and pinhole rate	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0036	Blown film extrusion	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bubble stability; gauge profile; cooling air; define risk-based requalification triggers affecting film uniformity and pinhole rate	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0037	Blow molding machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses parison profile; air pressure; mold temperature; required outputs: container volume, neck finish and burst strength	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0038	Blow molding machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Blow molding machine	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0039	Blow molding machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for parison profile; air pressure; mold temperature; evaluate container volume, neck finish and burst strength	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0040	Blow molding machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0041	Blow molding machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering container volume, neck finish and burst strength	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0042	Blow molding machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend parison profile; air pressure; mold temperature; define risk-based requalification triggers affecting container volume, neck finish and burst strength	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0043	Thermoforming machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses forming heat; vacuum; plug-assist timing; required outputs: tray cavity dimensions and material thinning	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0044	Thermoforming machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Thermoforming machine	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0045	Thermoforming machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for forming heat; vacuum; plug-assist timing; evaluate tray cavity dimensions and material thinning	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High

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MDV-09-0046	Thermoforming machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0047	Thermoforming machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tray cavity dimensions and material thinning	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0048	Thermoforming machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend forming heat; vacuum; plug-assist timing; define risk-based requalification triggers affecting tray cavity dimensions and material thinning	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0049	Vacuum forming process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses vacuum profile; sheet temperature; mold venting; required outputs: tray/part shape repeatability	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0050	Vacuum forming process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vacuum forming process	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0051	Vacuum forming process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for vacuum profile; sheet temperature; mold venting; evaluate tray/part shape repeatability	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0052	Vacuum forming process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0053	Vacuum forming process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tray/part shape repeatability	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0054	Vacuum forming process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend vacuum profile; sheet temperature; mold venting; define risk-based requalification triggers affecting tray/part shape repeatability	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0055	Hot embossing microfluidic mold	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses plate temperature; pressure; dwell; required outputs: microchannel geometry and bonding integrity	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0056	Hot embossing microfluidic mold	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Hot embossing microfluidic mold	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0057	Hot embossing microfluidic mold	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for plate temperature; pressure; dwell; evaluate microchannel geometry and bonding integrity	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0058	Hot embossing microfluidic mold	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0059	Hot embossing microfluidic mold	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering microchannel geometry and bonding integrity	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0060	Hot embossing microfluidic mold	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend plate temperature; pressure; dwell; define risk-based requalification triggers affecting microchannel geometry and bonding integrity	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0061	Polymer injection overmolding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses insert position; shot temperature; interface wetting; required outputs: seal adhesion and leak performance	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0062	Polymer injection overmolding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Polymer injection overmolding	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0063	Polymer injection overmolding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for insert position; shot temperature; interface wetting; evaluate seal adhesion and leak performance	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0064	Polymer injection overmolding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0065	Polymer injection overmolding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering seal adhesion and leak performance	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0066	Polymer injection overmolding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend insert position; shot temperature; interface wetting; define risk-based requalification triggers affecting seal adhesion and leak performance	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0067	Laser polymer trimming	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pulse power; focal offset; traverse speed; required outputs: edge quality and particulate	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0068	Laser polymer trimming	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser polymer trimming	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0069	Laser polymer trimming	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pulse power; focal offset; traverse speed; evaluate edge quality and particulate	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High

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MDV-09-0070	Laser polymer trimming	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0071	Laser polymer trimming	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering edge quality and particulate	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0072	Laser polymer trimming	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pulse power; focal offset; traverse speed; define risk-based requalification triggers affecting edge quality and particulate	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0073	Die cutting / punching of films	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses die clearance; stroke; registration; required outputs: hole dimensions and edge particulates	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0074	Die cutting / punching of films	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Die cutting / punching of films	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0075	Die cutting / punching of films	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for die clearance; stroke; registration; evaluate hole dimensions and edge particulates	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0076	Die cutting / punching of films	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0077	Die cutting / punching of films	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering hole dimensions and edge particulates	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0078	Die cutting / punching of films	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend die clearance; stroke; registration; define risk-based requalification triggers affecting hole dimensions and edge particulates	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0079	Ultrasonic polymer welding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses amplitude; energy; weld pressure; hold time; required outputs: weld strength, leak and flash	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0080	Ultrasonic polymer welding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ultrasonic polymer welding	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0081	Ultrasonic polymer welding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for amplitude; energy; weld pressure; hold time; evaluate weld strength, leak and flash	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0082	Ultrasonic polymer welding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0083	Ultrasonic polymer welding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering weld strength, leak and flash	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0084	Ultrasonic polymer welding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend amplitude; energy; weld pressure; hold time; define risk-based requalification triggers affecting weld strength, leak and flash	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0085	Thermal bonding / heat staking	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tip temperature; force; dwell; required outputs: retention force and polymer degradation	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0086	Thermal bonding / heat staking	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Thermal bonding / heat staking	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0087	Thermal bonding / heat staking	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tip temperature; force; dwell; evaluate retention force and polymer degradation	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0088	Thermal bonding / heat staking	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0089	Thermal bonding / heat staking	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering retention force and polymer degradation	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0090	Thermal bonding / heat staking	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tip temperature; force; dwell; define risk-based requalification triggers affecting retention force and polymer degradation	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0091	RF welding of plastic bags	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RF power; electrode pressure; weld dwell; required outputs: leak tightness and seal strength	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0092	RF welding of plastic bags	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for RF welding of plastic bags	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0093	RF welding of plastic bags	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RF power; electrode pressure; weld dwell; evaluate leak tightness and seal strength	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High

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MDV-09-0094	RF welding of plastic bags	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0095	RF welding of plastic bags	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering leak tightness and seal strength	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0096	RF welding of plastic bags	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RF power; electrode pressure; weld dwell; define risk-based requalification triggers affecting leak tightness and seal strength	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0097	Solvent bonding of tubing assemblies	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses solvent dose; cure time; insertion depth; required outputs: bond strength, solvent residue and passage patency	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0098	Solvent bonding of tubing assemblies	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Solvent bonding of tubing assemblies	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0099	Solvent bonding of tubing assemblies	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for solvent dose; cure time; insertion depth; evaluate bond strength, solvent residue and passage patency	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0100	Solvent bonding of tubing assemblies	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0101	Solvent bonding of tubing assemblies	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering bond strength, solvent residue and passage patency	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0102	Solvent bonding of tubing assemblies	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend solvent dose; cure time; insertion depth; define risk-based requalification triggers affecting bond strength, solvent residue and passage patency	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0103	Adhesive dispensing and curing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses viscosity; dispensed mass; cure energy; required outputs: bond strength, position and extractables	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0104	Adhesive dispensing and curing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Adhesive dispensing and curing	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0105	Adhesive dispensing and curing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for viscosity; dispensed mass; cure energy; evaluate bond strength, position and extractables	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0106	Adhesive dispensing and curing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0107	Adhesive dispensing and curing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering bond strength, position and extractables	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0108	Adhesive dispensing and curing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend viscosity; dispensed mass; cure energy; define risk-based requalification triggers affecting bond strength, position and extractables	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0109	UV-cure assembly station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses UV irradiance; exposure time; shadowing; required outputs: complete cure and bond reliability	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0110	UV-cure assembly station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UV-cure assembly station	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0111	UV-cure assembly station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for UV irradiance; exposure time; shadowing; evaluate complete cure and bond reliability	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0112	UV-cure assembly station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0113	UV-cure assembly station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering complete cure and bond reliability	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0114	UV-cure assembly station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend UV irradiance; exposure time; shadowing; define risk-based requalification triggers affecting complete cure and bond reliability	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0115	Heat-shrink assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses hot-air temperature; dwell; mandrel fit; required outputs: recovery, strain relief and connector seal	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0116	Heat-shrink assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Heat-shrink assembly	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0117	Heat-shrink assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for hot-air temperature; dwell; mandrel fit; evaluate recovery, strain relief and connector seal	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-09-0118	Heat-shrink assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0119	Heat-shrink assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering recovery, strain relief and connector seal	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0120	Heat-shrink assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend hot-air temperature; dwell; mandrel fit; define risk-based requalification triggers affecting recovery, strain relief and connector seal	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0121	Laser marking on polymer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses contrast; material interaction; code readability; required outputs: indelible UDI/traceability without damage	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0122	Laser marking on polymer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser marking on polymer	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0123	Laser marking on polymer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for contrast; material interaction; code readability; evaluate indelible UDI/traceability without damage	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0124	Laser marking on polymer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0125	Laser marking on polymer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering indelible UDI/traceability without damage	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0126	Laser marking on polymer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend contrast; material interaction; code readability; define risk-based requalification triggers affecting indelible UDI/traceability without damage	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium
MDV-09-0127	Automated robot pick-and-place	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pick vacuum; gripper force; vision alignment; required outputs: no damage, mix-up or part loss	URS / DQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0128	Automated robot pick-and-place	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated robot pick-and-place	IQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0129	Automated robot pick-and-place	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pick vacuum; gripper force; vision alignment; evaluate no damage, mix-up or part loss	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0130	Automated robot pick-and-place	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0131	Automated robot pick-and-place	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no damage, mix-up or part loss	PQ	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	High
MDV-09-0132	Automated robot pick-and-place	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pick vacuum; gripper force; vision alignment; define risk-based requalification triggers affecting no damage, mix-up or part loss	Routine / Change	Plastic disposable devices, housings and tubing	M01 M02 M05 M07	Medium

10 METALS, MACHINING, HEAT TREATMENT & FINISHING

132 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0001	CNC turning machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses spindle speed; feed; offset compensation; required outputs: shaft size, surface finish and concentricity	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0002	CNC turning machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for CNC turning machine	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0003	CNC turning machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for spindle speed; feed; offset compensation; evaluate shaft size, surface finish and concentricity	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0004	CNC turning machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0005	CNC turning machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering shaft size, surface finish and concentricity	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0006	CNC turning machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend spindle speed; feed; offset compensation; define risk-based requalification triggers affecting shaft size, surface finish and concentricity	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0007	Five-axis CNC machining center	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tool offsets; fixture repeatability; thermal drift; required outputs: complex implant contours and tolerance	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0008	Five-axis CNC machining center	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Five-axis CNC machining center	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0009	Five-axis CNC machining center	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tool offsets; fixture repeatability; thermal drift; evaluate complex implant contours and tolerance	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0010	Five-axis CNC machining center	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0011	Five-axis CNC machining center	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering complex implant contours and tolerance	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0012	Five-axis CNC machining center	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tool offsets; fixture repeatability; thermal drift; define risk-based requalification triggers affecting complex implant contours and tolerance	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0013	Wire EDM equipment	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wire tension; dielectric; speed; required outputs: cut accuracy and heat-affected zone	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0014	Wire EDM equipment	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wire EDM equipment	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0015	Wire EDM equipment	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wire tension; dielectric; speed; evaluate cut accuracy and heat-affected zone	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0016	Wire EDM equipment	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0017	Wire EDM equipment	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cut accuracy and heat-affected zone	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0018	Wire EDM equipment	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wire tension; dielectric; speed; define risk-based requalification triggers affecting cut accuracy and heat-affected zone	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0019	Laser cutting stainless tube	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pulse frequency; power; feed rate; required outputs: stent strut geometry and burrs	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0020	Laser cutting stainless tube	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser cutting stainless tube	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0021	Laser cutting stainless tube	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pulse frequency; power; feed rate; evaluate stent strut geometry and burrs	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0022	Laser cutting stainless tube	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0023	Laser cutting stainless tube	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering stent strut geometry and burrs	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0024	Laser cutting stainless tube	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pulse frequency; power; feed rate; define risk-based requalification triggers affecting stent strut geometry and burrs	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0025	Laser welding titanium/stainless components	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses beam focus; atmosphere; energy density; required outputs: weld penetration and fatigue strength	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0026	Laser welding titanium/stainless components	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser welding titanium/stainless components	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0027	Laser welding titanium/stainless components	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for beam focus; atmosphere; energy density; evaluate weld penetration and fatigue strength	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0028	Laser welding titanium/stainless components	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0029	Laser welding titanium/stainless components	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering weld penetration and fatigue strength	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0030	Laser welding titanium/stainless components	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend beam focus; atmosphere; energy density; define risk-based requalification triggers affecting weld penetration and fatigue strength	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0031	Spot welding / resistance welding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses electrode force; current; pulse time; required outputs: joint pull strength and continuity	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0032	Spot welding / resistance welding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Spot welding / resistance welding	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0033	Spot welding / resistance welding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for electrode force; current; pulse time; evaluate joint pull strength and continuity	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0034	Spot welding / resistance welding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0035	Spot welding / resistance welding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering joint pull strength and continuity	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0036	Spot welding / resistance welding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend electrode force; current; pulse time; define risk-based requalification triggers affecting joint pull strength and continuity	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0037	TIG micro-welding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses shielding gas; current; filler qualification; required outputs: joint porosity and mechanical strength	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0038	TIG micro-welding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for TIG micro-welding	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0039	TIG micro-welding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for shielding gas; current; filler qualification; evaluate joint porosity and mechanical strength	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0040	TIG micro-welding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0041	TIG micro-welding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering joint porosity and mechanical strength	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0042	TIG micro-welding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend shielding gas; current; filler qualification; define risk-based requalification triggers affecting joint porosity and mechanical strength	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0043	Metal additive manufacturing LPBF	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses powder lot; laser energy; hatch; oxygen; required outputs: density, fatigue and geometry	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0044	Metal additive manufacturing LPBF	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Metal additive manufacturing LPBF	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0045	Metal additive manufacturing LPBF	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for powder lot; laser energy; hatch; oxygen; evaluate density, fatigue and geometry	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0046	Metal additive manufacturing LPBF	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0047	Metal additive manufacturing LPBF	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering density, fatigue and geometry	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0048	Metal additive manufacturing LPBF	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend powder lot; laser energy; hatch; oxygen; define risk-based requalification triggers affecting density, fatigue and geometry	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0049	Metal powder handling/sieving	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses particle size; reuse cycles; contamination; required outputs: powder flow and critical impurity control	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0050	Metal powder handling/sieving	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Metal powder handling/sieving	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0051	Metal powder handling/sieving	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for particle size; reuse cycles; contamination; evaluate powder flow and critical impurity control	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0052	Metal powder handling/sieving	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0053	Metal powder handling/sieving	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering powder flow and critical impurity control	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0054	Metal powder handling/sieving	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend particle size; reuse cycles; contamination; define risk-based requalification triggers affecting powder flow and critical impurity control	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0055	Support removal and stress relieving	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses time; temperature; cutting method; required outputs: geometry, residual stress and strength	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0056	Support removal and stress relieving	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Support removal and stress relieving	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0057	Support removal and stress relieving	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for time; temperature; cutting method; evaluate geometry, residual stress and strength	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0058	Support removal and stress relieving	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0059	Support removal and stress relieving	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering geometry, residual stress and strength	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0060	Support removal and stress relieving	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend time; temperature; cutting method; define risk-based requalification triggers affecting geometry, residual stress and strength	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0061	Heat treatment / annealing furnace	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses soak time; load positions; temperature uniformity; required outputs: hardness, strength and microstructure	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0062	Heat treatment / annealing furnace	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Heat treatment / annealing furnace	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0063	Heat treatment / annealing furnace	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for soak time; load positions; temperature uniformity; evaluate hardness, strength and microstructure	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0064	Heat treatment / annealing furnace	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0065	Heat treatment / annealing furnace	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering hardness, strength and microstructure	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0066	Heat treatment / annealing furnace	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend soak time; load positions; temperature uniformity; define risk-based requalification triggers affecting hardness, strength and microstructure	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0067	Surface passivation tank	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses acid chemistry; exposure time; rinse quality; required outputs: corrosion resistance and surface cleanliness	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0068	Surface passivation tank	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surface passivation tank	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0069	Surface passivation tank	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for acid chemistry; exposure time; rinse quality; evaluate corrosion resistance and surface cleanliness	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0070	Surface passivation tank	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0071	Surface passivation tank	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering corrosion resistance and surface cleanliness	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0072	Surface passivation tank	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend acid chemistry; exposure time; rinse quality; define risk-based requalification triggers affecting corrosion resistance and surface cleanliness	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0073	Electropolishing line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses current density; bath concentration; dwell; required outputs: surface roughness and removal consistency	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0074	Electropolishing line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electropolishing line	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0075	Electropolishing line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for current density; bath concentration; dwell; evaluate surface roughness and removal consistency	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0076	Electropolishing line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0077	Electropolishing line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering surface roughness and removal consistency	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0078	Electropolishing line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend current density; bath concentration; dwell; define risk-based requalification triggers affecting surface roughness and removal consistency	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0079	Ultrasonic metal component deburr	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bath power; fixture loading; rinse; required outputs: burr-free features and particle removal	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0080	Ultrasonic metal component deburr	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ultrasonic metal component deburr	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0081	Ultrasonic metal component deburr	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bath power; fixture loading; rinse; evaluate burr-free features and particle removal	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0082	Ultrasonic metal component deburr	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0083	Ultrasonic metal component deburr	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering burr-free features and particle removal	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0084	Ultrasonic metal component deburr	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bath power; fixture loading; rinse; define risk-based requalification triggers affecting burr-free features and particle removal	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0085	Bead blasting / shot peening	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses blast media; pressure; standoff distance; required outputs: surface topography and fatigue response	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0086	Bead blasting / shot peening	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bead blasting / shot peening	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0087	Bead blasting / shot peening	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for blast media; pressure; standoff distance; evaluate surface topography and fatigue response	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0088	Bead blasting / shot peening	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0089	Bead blasting / shot peening	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering surface topography and fatigue response	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0090	Bead blasting / shot peening	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend blast media; pressure; standoff distance; define risk-based requalification triggers affecting surface topography and fatigue response	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0091	Anodizing or titanium surface treatment	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses current density; bath temperature; duration; required outputs: oxide film uniformity and corrosion resistance	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0092	Anodizing or titanium surface treatment	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Anodizing or titanium surface treatment	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0093	Anodizing or titanium surface treatment	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for current density; bath temperature; duration; evaluate oxide film uniformity and corrosion resistance	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0094	Anodizing or titanium surface treatment	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0095	Anodizing or titanium surface treatment	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering oxide film uniformity and corrosion resistance	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0096	Anodizing or titanium surface treatment	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend current density; bath temperature; duration; define risk-based requalification triggers affecting oxide film uniformity and corrosion resistance	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0097	Laser engraving / UDI marking	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses power; depth; contrast; readability; required outputs: permanent legible identification	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0098	Laser engraving / UDI marking	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser engraving / UDI marking	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0099	Laser engraving / UDI marking	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for power; depth; contrast; readability; evaluate permanent legible identification	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0100	Laser engraving / UDI marking	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0101	Laser engraving / UDI marking	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering permanent legible identification	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0102	Laser engraving / UDI marking	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend power; depth; contrast; readability; define risk-based requalification triggers affecting permanent legible identification	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0103	Precision grinding machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wheel condition; feed; coolant; required outputs: sharpness, dimensional tolerance and burn prevention	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0104	Precision grinding machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Precision grinding machine	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0105	Precision grinding machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wheel condition; feed; coolant; evaluate sharpness, dimensional tolerance and burn prevention	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0106	Precision grinding machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0107	Precision grinding machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sharpness, dimensional tolerance and burn prevention	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0108	Precision grinding machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wheel condition; feed; coolant; define risk-based requalification triggers affecting sharpness, dimensional tolerance and burn prevention	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0109	Surgical needle grinding / shaping	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bevel geometry; speed; coolant; required outputs: needle sharpness and penetration force	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0110	Surgical needle grinding / shaping	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surgical needle grinding / shaping	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0111	Surgical needle grinding / shaping	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bevel geometry; speed; coolant; evaluate needle sharpness and penetration force	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0112	Surgical needle grinding / shaping	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0113	Surgical needle grinding / shaping	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering needle sharpness and penetration force	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0114	Surgical needle grinding / shaping	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bevel geometry; speed; coolant; define risk-based requalification triggers affecting needle sharpness and penetration force	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0115	Stent crimping system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses crimp pressure; diameter; duration; required outputs: profile reduction without strut damage	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0116	Stent crimping system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Stent crimping system	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0117	Stent crimping system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for crimp pressure; diameter; duration; evaluate profile reduction without strut damage	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0118	Stent crimping system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0119	Stent crimping system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering profile reduction without strut damage	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0120	Stent crimping system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend crimp pressure; diameter; duration; define risk-based requalification triggers affecting profile reduction without strut damage	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0121	Implant surface coating / porous spray	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses surface prep; spray temperature; thickness; required outputs: coating adhesion, porosity and cleanliness	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0122	Implant surface coating / porous spray	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Implant surface coating / porous spray	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0123	Implant surface coating / porous spray	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for surface prep; spray temperature; thickness; evaluate coating adhesion, porosity and cleanliness	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0124	Implant surface coating / porous spray	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-10-0125	Implant surface coating / porous spray	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering coating adhesion, porosity and cleanliness	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0126	Implant surface coating / porous spray	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend surface prep; spray temperature; thickness; define risk-based requalification triggers affecting coating adhesion, porosity and cleanliness	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium
MDV-10-0127	Electrochemical polishing / etching	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses electrolyte composition; current; dwell; required outputs: surface defect reduction and corrosion resistance	URS / DQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0128	Electrochemical polishing / etching	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electrochemical polishing / etching	IQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0129	Electrochemical polishing / etching	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for electrolyte composition; current; dwell; evaluate surface defect reduction and corrosion resistance	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0130	Electrochemical polishing / etching	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0131	Electrochemical polishing / etching	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering surface defect reduction and corrosion resistance	PQ	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	High
MDV-10-0132	Electrochemical polishing / etching	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend electrolyte composition; current; dwell; define risk-based requalification triggers affecting surface defect reduction and corrosion resistance	Routine / Change	Surgical instruments; orthopedic/dental implants; components	M01 M02 M07 M32	Medium

11 CATHETERS, GUIDEWIRES, VASCULAR AND TUBING DEVICES

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0001	Catheter shaft reflow lamination	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reflow heat; tension; jacket thickness; required outputs: layer fusion and kink resistance	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0002	Catheter shaft reflow lamination	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter shaft reflow lamination	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0003	Catheter shaft reflow lamination	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reflow heat; tension; jacket thickness; evaluate layer fusion and kink resistance	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0004	Catheter shaft reflow lamination	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0005	Catheter shaft reflow lamination	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering layer fusion and kink resistance	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0006	Catheter shaft reflow lamination	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reflow heat; tension; jacket thickness; define risk-based requalification triggers affecting layer fusion and kink resistance	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0007	Catheter hub thermal bonding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses heat; force; cycle time; required outputs: hub tensile strength and leak integrity	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0008	Catheter hub thermal bonding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter hub thermal bonding	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0009	Catheter hub thermal bonding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for heat; force; cycle time; evaluate hub tensile strength and leak integrity	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0010	Catheter hub thermal bonding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0011	Catheter hub thermal bonding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering hub tensile strength and leak integrity	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0012	Catheter hub thermal bonding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend heat; force; cycle time; define risk-based requalification triggers affecting hub tensile strength and leak integrity	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0013	Catheter shaft laser weld	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses power; speed; weld position; required outputs: joint strength without lumen occlusion	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0014	Catheter shaft laser weld	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter shaft laser weld	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0015	Catheter shaft laser weld	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for power; speed; weld position; evaluate joint strength without lumen occlusion	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0016	Catheter shaft laser weld	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0017	Catheter shaft laser weld	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering joint strength without lumen occlusion	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0018	Catheter shaft laser weld	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend power; speed; weld position; define risk-based requalification triggers affecting joint strength without lumen occlusion	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0019	Catheter balloon forming	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses forming pressure; temperature; stretch ratio; required outputs: burst strength, diameter and compliance	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0020	Catheter balloon forming	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter balloon forming	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0021	Catheter balloon forming	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for forming pressure; temperature; stretch ratio; evaluate burst strength, diameter and compliance	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0022	Catheter balloon forming	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0023	Catheter balloon forming	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering burst strength, diameter and compliance	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0024	Catheter balloon forming	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend forming pressure; temperature; stretch ratio; define risk-based requalification triggers affecting burst strength, diameter and compliance	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0025	Balloon folding and pleating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fold count; tooling pressure; alignment; required outputs: profile and uniform expansion	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0026	Balloon folding and pleating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Balloon folding and pleating	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0027	Balloon folding and pleating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fold count; tooling pressure; alignment; evaluate profile and uniform expansion	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0028	Balloon folding and pleating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0029	Balloon folding and pleating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering profile and uniform expansion	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0030	Balloon folding and pleating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fold count; tooling pressure; alignment; define risk-based requalification triggers affecting profile and uniform expansion	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0031	Guidewire core grinding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses diameter taper; surface finish; coolant; required outputs: pushability, fatigue and torque transmission	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0032	Guidewire core grinding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Guidewire core grinding	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0033	Guidewire core grinding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for diameter taper; surface finish; coolant; evaluate pushability, fatigue and torque transmission	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0034	Guidewire core grinding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0035	Guidewire core grinding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering pushability, fatigue and torque transmission	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0036	Guidewire core grinding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend diameter taper; surface finish; coolant; define risk-based requalification triggers affecting pushability, fatigue and torque transmission	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0037	Guidewire coil winding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coil pitch; tension; distal weld; required outputs: coil retention and flexibility	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0038	Guidewire coil winding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Guidewire coil winding	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0039	Guidewire coil winding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coil pitch; tension; distal weld; evaluate coil retention and flexibility	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0040	Guidewire coil winding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0041	Guidewire coil winding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering coil retention and flexibility	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0042	Guidewire coil winding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coil pitch; tension; distal weld; define risk-based requalification triggers affecting coil retention and flexibility	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0043	Hydrophilic coating of catheter	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coating concentration; withdrawal rate; curing; required outputs: lubricity, coating adherence and particles	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0044	Hydrophilic coating of catheter	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Hydrophilic coating of catheter	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0045	Hydrophilic coating of catheter	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coating concentration; withdrawal rate; curing; evaluate lubricity, coating adherence and particles	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0046	Hydrophilic coating of catheter	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0047	Hydrophilic coating of catheter	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering lubricity, coating adherence and particles	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0048	Hydrophilic coating of catheter	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coating concentration; withdrawal rate; curing; define risk-based requalification triggers affecting lubricity, coating adherence and particles	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0049	Radiopaque marker band swaging	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses crimp force; position; tube deformation; required outputs: marker retention and lumen patency	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0050	Radiopaque marker band swaging	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Radiopaque marker band swaging	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0051	Radiopaque marker band swaging	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for crimp force; position; tube deformation; evaluate marker retention and lumen patency	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0052	Radiopaque marker band swaging	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0053	Radiopaque marker band swaging	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering marker retention and lumen patency	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0054	Radiopaque marker band swaging	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend crimp force; position; tube deformation; define risk-based requalification triggers affecting marker retention and lumen patency	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0055	Catheter tip thermoforming	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses heater temperature; mandrel; dwell; required outputs: atraumatic tip and lumen integrity	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0056	Catheter tip thermoforming	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter tip thermoforming	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0057	Catheter tip thermoforming	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for heater temperature; mandrel; dwell; evaluate atraumatic tip and lumen integrity	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0058	Catheter tip thermoforming	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0059	Catheter tip thermoforming	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering atraumatic tip and lumen integrity	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0060	Catheter tip thermoforming	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend heater temperature; mandrel; dwell; define risk-based requalification triggers affecting atraumatic tip and lumen integrity	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0061	Catheter flushing/leak test bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses test fluid; pressure; dwell; required outputs: fluid tightness and air ingress control	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0062	Catheter flushing/leak test bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter flushing/leak test bench	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0063	Catheter flushing/leak test bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for test fluid; pressure; dwell; evaluate fluid tightness and air ingress control	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0064	Catheter flushing/leak test bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0065	Catheter flushing/leak test bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fluid tightness and air ingress control	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0066	Catheter flushing/leak test bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend test fluid; pressure; dwell; define risk-based requalification triggers affecting fluid tightness and air ingress control	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0067	Burst pressure tester for balloon	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pressurization rate; endpoint threshold; required outputs: burst integrity and rated burst pressure	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0068	Burst pressure tester for balloon	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Burst pressure tester for balloon	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0069	Burst pressure tester for balloon	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pressurization rate; endpoint threshold; evaluate burst integrity and rated burst pressure	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0070	Burst pressure tester for balloon	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0071	Burst pressure tester for balloon	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering burst integrity and rated burst pressure	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0072	Burst pressure tester for balloon	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pressurization rate; endpoint threshold; define risk-based requalification triggers affecting burst integrity and rated burst pressure	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0073	Luer connector assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses torque; dimensional fit; leak test; required outputs: ISO 80369 compatibility as relevant	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0074	Luer connector assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Luer connector assembly	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0075	Luer connector assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for torque; dimensional fit; leak test; evaluate ISO 80369 compatibility as relevant	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0076	Luer connector assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0077	Luer connector assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering ISO 80369 compatibility as relevant	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0078	Luer connector assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend torque; dimensional fit; leak test; define risk-based requalification triggers affecting ISO 80369 compatibility as relevant	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0079	Needle-free connector assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses spring compression; diaphragm seating; required outputs: reflux, leakage and actuation performance	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0080	Needle-free connector assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Needle-free connector assembly	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0081	Needle-free connector assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for spring compression; diaphragm seating; evaluate reflux, leakage and actuation performance	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0082	Needle-free connector assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0083	Needle-free connector assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reflux, leakage and actuation performance	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0084	Needle-free connector assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend spring compression; diaphragm seating; define risk-based requalification triggers affecting reflux, leakage and actuation performance	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0085	Clamp / valve installation line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses clamp force; placement; material compatibility; required outputs: flow occlusion and durability	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0086	Clamp / valve installation line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Clamp / valve installation line	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0087	Clamp / valve installation line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for clamp force; placement; material compatibility; evaluate flow occlusion and durability	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0088	Clamp / valve installation line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-11-0089	Clamp / valve installation line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flow occlusion and durability	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0090	Clamp / valve installation line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend clamp force; placement; material compatibility; define risk-based requalification triggers affecting flow occlusion and durability	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium
MDV-11-0091	Drug-coated catheter process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses drug deposition; drying; coating uniformity; required outputs: dose accuracy and particulates; combination-product interface	URS / DQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0092	Drug-coated catheter process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Drug-coated catheter process	IQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0093	Drug-coated catheter process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for drug deposition; drying; coating uniformity; evaluate dose accuracy and particulates; combination-product interface	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0094	Drug-coated catheter process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0095	Drug-coated catheter process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose accuracy and particulates; combination-product interface	PQ	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	High
MDV-11-0096	Drug-coated catheter process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend drug deposition; drying; coating uniformity; define risk-based requalification triggers affecting dose accuracy and particulates; combination-product interface	Routine / Change	Intravascular catheters; guidewires; cannulae; tubing sets	M01 M02 M03 M07 M35	Medium

12 SYRINGES, NEEDLES, IV SETS, INFUSION AND BLOOD BAGS

108 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0001	Syringe barrel injection molding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cavity temperature; cycle time; plunger bore; required outputs: graduation accuracy and dimensional control	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0002	Syringe barrel injection molding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Syringe barrel injection molding	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0003	Syringe barrel injection molding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cavity temperature; cycle time; plunger bore; evaluate graduation accuracy and dimensional control	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0004	Syringe barrel injection molding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0005	Syringe barrel injection molding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering graduation accuracy and dimensional control	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0006	Syringe barrel injection molding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cavity temperature; cycle time; plunger bore; define risk-based requalification triggers affecting graduation accuracy and dimensional control	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0007	Plunger elastomer component molding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cure temperature; compression; cleaning; required outputs: friction, seal and extractables	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0008	Plunger elastomer component molding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Plunger elastomer component molding	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0009	Plunger elastomer component molding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cure temperature; compression; cleaning; evaluate friction, seal and extractables	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0010	Plunger elastomer component molding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0011	Plunger elastomer component molding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering friction, seal and extractables	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0012	Plunger elastomer component molding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cure temperature; compression; cleaning; define risk-based requalification triggers affecting friction, seal and extractables	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0013	Silicone lubricating station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses silicone dose; distribution; curing; required outputs: plunger glide force and particulate	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0014	Silicone lubricating station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Silicone lubricating station	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0015	Silicone lubricating station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for silicone dose; distribution; curing; evaluate plunger glide force and particulate	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0016	Silicone lubricating station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0017	Silicone lubricating station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering plunger glide force and particulate	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0018	Silicone lubricating station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend silicone dose; distribution; curing; define risk-based requalification triggers affecting plunger glide force and particulate	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0019	Syringe needle hub bonding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses adhesive dose; insertion depth; pull; required outputs: needle retention and leakage	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0020	Syringe needle hub bonding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Syringe needle hub bonding	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0021	Syringe needle hub bonding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for adhesive dose; insertion depth; pull; evaluate needle retention and leakage	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0022	Syringe needle hub bonding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0023	Syringe needle hub bonding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering needle retention and leakage	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0024	Syringe needle hub bonding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend adhesive dose; insertion depth; pull; define risk-based requalification triggers affecting needle retention and leakage	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0025	Needle cannula cut and grind	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bevel sharpness; burr; length; required outputs: penetration force and tissue trauma risk	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0026	Needle cannula cut and grind	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Needle cannula cut and grind	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0027	Needle cannula cut and grind	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bevel sharpness; burr; length; evaluate penetration force and tissue trauma risk	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0028	Needle cannula cut and grind	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0029	Needle cannula cut and grind	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering penetration force and tissue trauma risk	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0030	Needle cannula cut and grind	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bevel sharpness; burr; length; define risk-based requalification triggers affecting penetration force and tissue trauma risk	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0031	Needle cannula lubrication	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses silicone type; concentration; uniformity; required outputs: penetration characteristics and particle risk	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0032	Needle cannula lubrication	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Needle cannula lubrication	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0033	Needle cannula lubrication	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for silicone type; concentration; uniformity; evaluate penetration characteristics and particle risk	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0034	Needle cannula lubrication	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0035	Needle cannula lubrication	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering penetration characteristics and particle risk	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0036	Needle cannula lubrication	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend silicone type; concentration; uniformity; define risk-based requalification triggers affecting penetration characteristics and particle risk	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0037	Needle safety shield assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses locking force; deployment angle; cycle time; required outputs: needle-stick protection function	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0038	Needle safety shield assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Needle safety shield assembly	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0039	Needle safety shield assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for locking force; deployment angle; cycle time; evaluate needle-stick protection function	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0040	Needle safety shield assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0041	Needle safety shield assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering needle-stick protection function	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0042	Needle safety shield assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend locking force; deployment angle; cycle time; define risk-based requalification triggers affecting needle-stick protection function	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0043	Pre-filled syringe filling/closing (device component)	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill volume; stopper placement; CCI; required outputs: dose delivery and barrier performance	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0044	Pre-filled syringe filling/closing (device component)	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pre-filled syringe filling/closing (device component)	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0045	Pre-filled syringe filling/closing (device component)	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill volume; stopper placement; CCI; evaluate dose delivery and barrier performance	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0046	Pre-filled syringe filling/closing (device component)	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0047	Pre-filled syringe filling/closing (device component)	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose delivery and barrier performance	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0048	Pre-filled syringe filling/closing (device component)	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill volume; stopper placement; CCI; define risk-based requalification triggers affecting dose delivery and barrier performance	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0049	IV set tubing cut and fit	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cut length; bond engagement; end integrity; required outputs: secure and leak-free sets	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0050	IV set tubing cut and fit	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IV set tubing cut and fit	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0051	IV set tubing cut and fit	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cut length; bond engagement; end integrity; evaluate secure and leak-free sets	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0052	IV set tubing cut and fit	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0053	IV set tubing cut and fit	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering secure and leak-free sets	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0054	IV set tubing cut and fit	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cut length; bond engagement; end integrity; define risk-based requalification triggers affecting secure and leak-free sets	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0055	Drip chamber bonding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bond location; seal pressure; required outputs: chamber leak and flow control	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0056	Drip chamber bonding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Drip chamber bonding	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0057	Drip chamber bonding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bond location; seal pressure; evaluate chamber leak and flow control	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0058	Drip chamber bonding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0059	Drip chamber bonding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering chamber leak and flow control	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0060	Drip chamber bonding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bond location; seal pressure; define risk-based requalification triggers affecting chamber leak and flow control	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0061	Roller clamp assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses roller torque; track geometry; flow; required outputs: controlled IV flow and occlusion	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0062	Roller clamp assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Roller clamp assembly	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0063	Roller clamp assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for roller torque; track geometry; flow; evaluate controlled IV flow and occlusion	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0064	Roller clamp assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0065	Roller clamp assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled IV flow and occlusion	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0066	Roller clamp assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend roller torque; track geometry; flow; define risk-based requalification triggers affecting controlled IV flow and occlusion	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0067	Blood bag RF sealing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RF power; electrode force; seal width; required outputs: blood bag sterility integrity and burst strength	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0068	Blood bag RF sealing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Blood bag RF sealing	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0069	Blood bag RF sealing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RF power; electrode force; seal width; evaluate blood bag sterility integrity and burst strength	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0070	Blood bag RF sealing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0071	Blood bag RF sealing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering blood bag sterility integrity and burst strength	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0072	Blood bag RF sealing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RF power; electrode force; seal width; define risk-based requalification triggers affecting blood bag sterility integrity and burst strength	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0073	Blood collection set donor needle assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses needle retention; tubing connection; required outputs: leak and pull-out resistance	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0074	Blood collection set donor needle assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Blood collection set donor needle assembly	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0075	Blood collection set donor needle assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for needle retention; tubing connection; evaluate leak and pull-out resistance	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0076	Blood collection set donor needle assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0077	Blood collection set donor needle assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering leak and pull-out resistance	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0078	Blood collection set donor needle assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend needle retention; tubing connection; define risk-based requalification triggers affecting leak and pull-out resistance	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0079	Blood bag anticoagulant dosing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dose volume; homogeneity; mixing; required outputs: ratio assurance and preservation performance	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0080	Blood bag anticoagulant dosing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Blood bag anticoagulant dosing	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0081	Blood bag anticoagulant dosing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dose volume; homogeneity; mixing; evaluate ratio assurance and preservation performance	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0082	Blood bag anticoagulant dosing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0083	Blood bag anticoagulant dosing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering ratio assurance and preservation performance	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0084	Blood bag anticoagulant dosing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dose volume; homogeneity; mixing; define risk-based requalification triggers affecting ratio assurance and preservation performance	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0085	Infusion pump disposable cassette welding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses weld alignment; energy; leak threshold; required outputs: controlled pump flow and cassette seal	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0086	Infusion pump disposable cassette welding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Infusion pump disposable cassette welding	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0087	Infusion pump disposable cassette welding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for weld alignment; energy; leak threshold; evaluate controlled pump flow and cassette seal	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0088	Infusion pump disposable cassette welding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0089	Infusion pump disposable cassette welding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled pump flow and cassette seal	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0090	Infusion pump disposable cassette welding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend weld alignment; energy; leak threshold; define risk-based requalification triggers affecting controlled pump flow and cassette seal	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0091	Elastomeric infusion pump assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reservoir fill; elastomer stress; restrictor bore; required outputs: delivery rate and burst integrity	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0092	Elastomeric infusion pump assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Elastomeric infusion pump assembly	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0093	Elastomeric infusion pump assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reservoir fill; elastomer stress; restrictor bore; evaluate delivery rate and burst integrity	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0094	Elastomeric infusion pump assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0095	Elastomeric infusion pump assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering delivery rate and burst integrity	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0096	Elastomeric infusion pump assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reservoir fill; elastomer stress; restrictor bore; define risk-based requalification triggers affecting delivery rate and burst integrity	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0097	Syringe graduated marking/printing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses print alignment; ink adhesion; visibility; required outputs: scale legibility and dose accuracy	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0098	Syringe graduated marking/printing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Syringe graduated marking/printing	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0099	Syringe graduated marking/printing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for print alignment; ink adhesion; visibility; evaluate scale legibility and dose accuracy	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0100	Syringe graduated marking/printing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0101	Syringe graduated marking/printing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering scale legibility and dose accuracy	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0102	Syringe graduated marking/printing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend print alignment; ink adhesion; visibility; define risk-based requalification triggers affecting scale legibility and dose accuracy	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium
MDV-12-0103	Multi-way stopcock assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses torque; leakage; valve position; required outputs: switch integrity and flow control	URS / DQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0104	Multi-way stopcock assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Multi-way stopcock assembly	IQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0105	Multi-way stopcock assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for torque; leakage; valve position; evaluate switch integrity and flow control	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0106	Multi-way stopcock assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-12-0107	Multi-way stopcock assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering switch integrity and flow control	PQ	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	High
MDV-12-0108	Multi-way stopcock assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend torque; leakage; valve position; define risk-based requalification triggers affecting switch integrity and flow control	Routine / Change	Syringes; infusion sets; IV bags; blood collection products	M01 M02 M03 M07 M35	Medium

13 WOUND CARE, TEXTILE, SUTURES & SOFT GOODS

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-13-0001	Gauze weaving and fabric inspection	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses weave density; width; lint generation; required outputs: absorbency and particle release	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0002	Gauze weaving and fabric inspection	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Gauze weaving and fabric inspection	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0003	Gauze weaving and fabric inspection	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for weave density; width; lint generation; evaluate absorbency and particle release	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0004	Gauze weaving and fabric inspection	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0005	Gauze weaving and fabric inspection	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering absorbency and particle release	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0006	Gauze weaving and fabric inspection	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend weave density; width; lint generation; define risk-based requalification triggers affecting absorbency and particle release	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0007	Nonwoven spunbond line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fiber basis weight; thermal bond; web speed; required outputs: fabric tensile and uniformity	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0008	Nonwoven spunbond line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Nonwoven spunbond line	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0009	Nonwoven spunbond line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fiber basis weight; thermal bond; web speed; evaluate fabric tensile and uniformity	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0010	Nonwoven spunbond line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0011	Nonwoven spunbond line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fabric tensile and uniformity	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0012	Nonwoven spunbond line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fiber basis weight; thermal bond; web speed; define risk-based requalification triggers affecting fabric tensile and uniformity	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0013	Melt-blown filtration fabric process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses polymer melt; air draw; electrostatic charge; required outputs: particle filtration and pressure drop	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0014	Melt-blown filtration fabric process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Melt-blown filtration fabric process	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0015	Melt-blown filtration fabric process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for polymer melt; air draw; electrostatic charge; evaluate particle filtration and pressure drop	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0016	Melt-blown filtration fabric process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High

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MDV-13-0017	Melt-blown filtration fabric process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering particle filtration and pressure drop	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0018	Melt-blown filtration fabric process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend polymer melt; air draw; electrostatic charge; define risk-based requalification triggers affecting particle filtration and pressure drop	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0019	Hydrocolloid dressing coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coat thickness; drying time; solvent; required outputs: adhesion and fluid management	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0020	Hydrocolloid dressing coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Hydrocolloid dressing coating	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0021	Hydrocolloid dressing coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coat thickness; drying time; solvent; evaluate adhesion and fluid management	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0022	Hydrocolloid dressing coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0023	Hydrocolloid dressing coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering adhesion and fluid management	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0024	Hydrocolloid dressing coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coat thickness; drying time; solvent; define risk-based requalification triggers affecting adhesion and fluid management	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0025	Alginate dressing fiber formation	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses solution viscosity; wet spinning; calcium bath; required outputs: absorbency and tensile integrity	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0026	Alginate dressing fiber formation	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Alginate dressing fiber formation	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0027	Alginate dressing fiber formation	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for solution viscosity; wet spinning; calcium bath; evaluate absorbency and tensile integrity	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0028	Alginate dressing fiber formation	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0029	Alginate dressing fiber formation	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering absorbency and tensile integrity	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0030	Alginate dressing fiber formation	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend solution viscosity; wet spinning; calcium bath; define risk-based requalification triggers affecting absorbency and tensile integrity	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0031	Foam wound dressing lamination	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses laminate pressure; binder dose; required outputs: layer adhesion and fluid handling	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0032	Foam wound dressing lamination	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Foam wound dressing lamination	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0033	Foam wound dressing lamination	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for laminate pressure; binder dose; evaluate layer adhesion and fluid handling	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0034	Foam wound dressing lamination	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High

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MDV-13-0035	Foam wound dressing lamination	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering layer adhesion and fluid handling	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0036	Foam wound dressing lamination	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend laminate pressure; binder dose; define risk-based requalification triggers affecting layer adhesion and fluid handling	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0037	Adhesive medical tape coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coat weight; liner speed; tack; required outputs: peel adhesion and skin contact performance	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0038	Adhesive medical tape coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Adhesive medical tape coating	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0039	Adhesive medical tape coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coat weight; liner speed; tack; evaluate peel adhesion and skin contact performance	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0040	Adhesive medical tape coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0041	Adhesive medical tape coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering peel adhesion and skin contact performance	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0042	Adhesive medical tape coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coat weight; liner speed; tack; define risk-based requalification triggers affecting peel adhesion and skin contact performance	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0043	Bandage slitting/rewinding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tension; blade; lint; required outputs: width and edge quality	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0044	Bandage slitting/rewinding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bandage slitting/rewinding	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0045	Bandage slitting/rewinding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tension; blade; lint; evaluate width and edge quality	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0046	Bandage slitting/rewinding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0047	Bandage slitting/rewinding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering width and edge quality	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0048	Bandage slitting/rewinding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tension; blade; lint; define risk-based requalification triggers affecting width and edge quality	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0049	Surgical suture extrusion	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses diameter; orientation; anneal; required outputs: tensile and elongation	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0050	Surgical suture extrusion	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surgical suture extrusion	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0051	Surgical suture extrusion	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for diameter; orientation; anneal; evaluate tensile and elongation	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0052	Surgical suture extrusion	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High

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MDV-13-0053	Surgical suture extrusion	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tensile and elongation	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0054	Surgical suture extrusion	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend diameter; orientation; anneal; define risk-based requalification triggers affecting tensile and elongation	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0055	Suture needle swaging	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses swage force; needle barrel geometry; required outputs: needle-suture attachment strength	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0056	Suture needle swaging	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Suture needle swaging	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0057	Suture needle swaging	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for swage force; needle barrel geometry; evaluate needle-suture attachment strength	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0058	Suture needle swaging	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0059	Suture needle swaging	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering needle-suture attachment strength	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0060	Suture needle swaging	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend swage force; needle barrel geometry; define risk-based requalification triggers affecting needle-suture attachment strength	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0061	Suture knot pull tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses grip configuration; loading rate; required outputs: knot strength and test repeatability	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0062	Suture knot pull tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Suture knot pull tester	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0063	Suture knot pull tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for grip configuration; loading rate; evaluate knot strength and test repeatability	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0064	Suture knot pull tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0065	Suture knot pull tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering knot strength and test repeatability	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0066	Suture knot pull tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend grip configuration; loading rate; define risk-based requalification triggers affecting knot strength and test repeatability	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0067	Mesh knitting machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pore size; filament tension; required outputs: mesh geometry and burst resistance	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0068	Mesh knitting machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Mesh knitting machine	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0069	Mesh knitting machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pore size; filament tension; evaluate mesh geometry and burst resistance	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0070	Mesh knitting machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High

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MDV-13-0071	Mesh knitting machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering mesh geometry and burst resistance	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0072	Mesh knitting machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pore size; filament tension; define risk-based requalification triggers affecting mesh geometry and burst resistance	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0073	Surgical glove dipping line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses latex/nitrile thickness; cure; dwell; required outputs: barrier pinholes and tensile elongation	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0074	Surgical glove dipping line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surgical glove dipping line	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0075	Surgical glove dipping line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for latex/nitrile thickness; cure; dwell; evaluate barrier pinholes and tensile elongation	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0076	Surgical glove dipping line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0077	Surgical glove dipping line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering barrier pinholes and tensile elongation	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0078	Surgical glove dipping line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend latex/nitrile thickness; cure; dwell; define risk-based requalification triggers affecting barrier pinholes and tensile elongation	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0079	Glove leaching/washing line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses water exchange; temperature; dwell; required outputs: extractables/allergen or chemical residue	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0080	Glove leaching/washing line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Glove leaching/washing line	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0081	Glove leaching/washing line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for water exchange; temperature; dwell; evaluate extractables/allergen or chemical residue	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0082	Glove leaching/washing line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0083	Glove leaching/washing line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering extractables/allergen or chemical residue	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0084	Glove leaching/washing line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend water exchange; temperature; dwell; define risk-based requalification triggers affecting extractables/allergen or chemical residue	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0085	Medical mask pleating/seaming	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pleat depth; ultrasonic seam strength; required outputs: fit and airflow resistance	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0086	Medical mask pleating/seaming	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical mask pleating/seaming	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0087	Medical mask pleating/seaming	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pleat depth; ultrasonic seam strength; evaluate fit and airflow resistance	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0088	Medical mask pleating/seaming	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High

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MDV-13-0089	Medical mask pleating/seaming	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fit and airflow resistance	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0090	Medical mask pleating/seaming	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pleat depth; ultrasonic seam strength; define risk-based requalification triggers affecting fit and airflow resistance	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium
MDV-13-0091	Respirator electrostatic filtration process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses charging voltage; residence time; required outputs: filter efficiency and pressure drop	URS / DQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0092	Respirator electrostatic filtration process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Respirator electrostatic filtration process	IQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0093	Respirator electrostatic filtration process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for charging voltage; residence time; evaluate filter efficiency and pressure drop	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0094	Respirator electrostatic filtration process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0095	Respirator electrostatic filtration process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering filter efficiency and pressure drop	PQ	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	High
MDV-13-0096	Respirator electrostatic filtration process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend charging voltage; residence time; define risk-based requalification triggers affecting filter efficiency and pressure drop	Routine / Change	Dressings; bandages; sutures; meshes; gloves; PPE	M01 M02 M05 M07	Medium

14 ORTHOPEDIC, SPINAL, DENTAL & IMPLANTABLE DEVICES

96 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0001	Bone screw thread rolling	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses die force; alignment; pitch; required outputs: thread form and insertion torque	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0002	Bone screw thread rolling	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bone screw thread rolling	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0003	Bone screw thread rolling	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for die force; alignment; pitch; evaluate thread form and insertion torque	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0004	Bone screw thread rolling	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0005	Bone screw thread rolling	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering thread form and insertion torque	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0006	Bone screw thread rolling	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend die force; alignment; pitch; define risk-based requalification triggers affecting thread form and insertion torque	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0007	Orthopedic plate machining	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses thickness; hole position; profile; required outputs: bone plate strength and screw compatibility	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0008	Orthopedic plate machining	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Orthopedic plate machining	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0009	Orthopedic plate machining	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for thickness; hole position; profile; evaluate bone plate strength and screw compatibility	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0010	Orthopedic plate machining	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0011	Orthopedic plate machining	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering bone plate strength and screw compatibility	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0012	Orthopedic plate machining	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend thickness; hole position; profile; define risk-based requalification triggers affecting bone plate strength and screw compatibility	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0013	Intramedullary nail machining	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses length; curvature; bore; required outputs: fit, torsional strength and fatigue	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0014	Intramedullary nail machining	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Intramedullary nail machining	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0015	Intramedullary nail machining	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for length; curvature; bore; evaluate fit, torsional strength and fatigue	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0016	Intramedullary nail machining	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0017	Intramedullary nail machining	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fit, torsional strength and fatigue	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0018	Intramedullary nail machining	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend length; curvature; bore; define risk-based requalification triggers affecting fit, torsional strength and fatigue	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0019	Spinal cage additive production	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pore architecture; melt strategy; thermal cycle; required outputs: porosity and compression strength	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0020	Spinal cage additive production	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Spinal cage additive production	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0021	Spinal cage additive production	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pore architecture; melt strategy; thermal cycle; evaluate porosity and compression strength	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0022	Spinal cage additive production	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0023	Spinal cage additive production	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering porosity and compression strength	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0024	Spinal cage additive production	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pore architecture; melt strategy; thermal cycle; define risk-based requalification triggers affecting porosity and compression strength	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0025	Spinal screw/rod assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses set-screw torque; interface fit; required outputs: locking strength and mechanical stability	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0026	Spinal screw/rod assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Spinal screw/rod assembly	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0027	Spinal screw/rod assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for set-screw torque; interface fit; evaluate locking strength and mechanical stability	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0028	Spinal screw/rod assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0029	Spinal screw/rod assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering locking strength and mechanical stability	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0030	Spinal screw/rod assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend set-screw torque; interface fit; define risk-based requalification triggers affecting locking strength and mechanical stability	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0031	Dental implant thread machining	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pitch; form; microburrs; required outputs: insertion torque and fixation	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0032	Dental implant thread machining	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dental implant thread machining	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0033	Dental implant thread machining	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pitch; form; microburrs; evaluate insertion torque and fixation	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0034	Dental implant thread machining	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0035	Dental implant thread machining	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering insertion torque and fixation	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0036	Dental implant thread machining	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pitch; form; microburrs; define risk-based requalification triggers affecting insertion torque and fixation	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0037	Dental implant gritblast/etch	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses media; acid; rinse; drying; required outputs: surface texture and particulate cleanliness	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0038	Dental implant gritblast/etch	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dental implant gritblast/etch	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0039	Dental implant gritblast/etch	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for media; acid; rinse; drying; evaluate surface texture and particulate cleanliness	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0040	Dental implant gritblast/etch	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0041	Dental implant gritblast/etch	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering surface texture and particulate cleanliness	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0042	Dental implant gritblast/etch	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend media; acid; rinse; drying; define risk-based requalification triggers affecting surface texture and particulate cleanliness	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0043	Porous coating for joint replacement	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coating load; pore area; adhesion; required outputs: bone-ingrowth compatible surface	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0044	Porous coating for joint replacement	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Porous coating for joint replacement	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0045	Porous coating for joint replacement	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coating load; pore area; adhesion; evaluate bone-ingrowth compatible surface	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0046	Porous coating for joint replacement	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0047	Porous coating for joint replacement	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering bone-ingrowth compatible surface	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0048	Porous coating for joint replacement	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coating load; pore area; adhesion; define risk-based requalification triggers affecting bone-ingrowth compatible surface	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0049	Hip stem forge/heat treat	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temper; grain; hardness; required outputs: strength and fatigue performance	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0050	Hip stem forge/heat treat	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Hip stem forge/heat treat	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0051	Hip stem forge/heat treat	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temper; grain; hardness; evaluate strength and fatigue performance	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0052	Hip stem forge/heat treat	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0053	Hip stem forge/heat treat	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering strength and fatigue performance	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0054	Hip stem forge/heat treat	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temper; grain; hardness; define risk-based requalification triggers affecting strength and fatigue performance	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0055	Acetabular liner molding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses resin; melt history; crystallinity; required outputs: wear and component dimensions	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0056	Acetabular liner molding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Acetabular liner molding	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0057	Acetabular liner molding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for resin; melt history; crystallinity; evaluate wear and component dimensions	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0058	Acetabular liner molding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0059	Acetabular liner molding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering wear and component dimensions	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0060	Acetabular liner molding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend resin; melt history; crystallinity; define risk-based requalification triggers affecting wear and component dimensions	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0061	Ceramic femoral head polishing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses roughness; roundness; crack detection; required outputs: joint wear and fracture resistance	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0062	Ceramic femoral head polishing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ceramic femoral head polishing	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0063	Ceramic femoral head polishing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for roughness; roundness; crack detection; evaluate joint wear and fracture resistance	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0064	Ceramic femoral head polishing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0065	Ceramic femoral head polishing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering joint wear and fracture resistance	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0066	Ceramic femoral head polishing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend roughness; roundness; crack detection; define risk-based requalification triggers affecting joint wear and fracture resistance	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0067	Implant passivation and cleaning	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses rinse conductivity; residues; particulate; required outputs: corrosion resistance and surface cleanliness	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0068	Implant passivation and cleaning	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Implant passivation and cleaning	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0069	Implant passivation and cleaning	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for rinse conductivity; residues; particulate; evaluate corrosion resistance and surface cleanliness	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0070	Implant passivation and cleaning	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0071	Implant passivation and cleaning	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering corrosion resistance and surface cleanliness	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0072	Implant passivation and cleaning	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend rinse conductivity; residues; particulate; define risk-based requalification triggers affecting corrosion resistance and surface cleanliness	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0073	Implant final packaging line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses unit orientation; abrasion prevention; required outputs: preservation of clean implant surfaces	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0074	Implant final packaging line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Implant final packaging line	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0075	Implant final packaging line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for unit orientation; abrasion prevention; evaluate preservation of clean implant surfaces	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0076	Implant final packaging line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0077	Implant final packaging line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering preservation of clean implant surfaces	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0078	Implant final packaging line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend unit orientation; abrasion prevention; define risk-based requalification triggers affecting preservation of clean implant surfaces	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0079	Dental abutment interface milling	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses taper and screw bore; required outputs: retention and fit	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0080	Dental abutment interface milling	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dental abutment interface milling	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0081	Dental abutment interface milling	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for taper and screw bore; evaluate retention and fit	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0082	Dental abutment interface milling	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0083	Dental abutment interface milling	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering retention and fit	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0084	Dental abutment interface milling	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend taper and screw bore; define risk-based requalification triggers affecting retention and fit	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0085	Ophthalmic intraocular lens polishing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses lens optical power; surface defect; required outputs: visual optical performance	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0086	Ophthalmic intraocular lens polishing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ophthalmic intraocular lens polishing	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0087	Ophthalmic intraocular lens polishing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for lens optical power; surface defect; evaluate visual optical performance	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0088	Ophthalmic intraocular lens polishing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-14-0089	Ophthalmic intraocular lens polishing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering visual optical performance	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0090	Ophthalmic intraocular lens polishing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend lens optical power; surface defect; define risk-based requalification triggers affecting visual optical performance	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium
MDV-14-0091	Hydrogel contact lens molding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses polymer dose; curing; hydration; required outputs: refractive and mechanical attributes	URS / DQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0092	Hydrogel contact lens molding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Hydrogel contact lens molding	IQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0093	Hydrogel contact lens molding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for polymer dose; curing; hydration; evaluate refractive and mechanical attributes	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0094	Hydrogel contact lens molding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0095	Hydrogel contact lens molding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering refractive and mechanical attributes	PQ	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	High
MDV-14-0096	Hydrogel contact lens molding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend polymer dose; curing; hydration; define risk-based requalification triggers affecting refractive and mechanical attributes	Routine / Change	Implants; orthopedic, dental, spinal and ophthalmic components	M01 M02 M03 M07 M14 M32	Medium

15 ACTIVE ELECTROMECHANICAL & ELECTRICAL DEVICES

120 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0001	Printed circuit SMT soldering line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reflow profile; paste volume; stencil; required outputs: solder joint quality and shorts	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0002	Printed circuit SMT soldering line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Printed circuit SMT soldering line	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0003	Printed circuit SMT soldering line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reflow profile; paste volume; stencil; evaluate solder joint quality and shorts	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0004	Printed circuit SMT soldering line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0005	Printed circuit SMT soldering line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering solder joint quality and shorts	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0006	Printed circuit SMT soldering line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reflow profile; paste volume; stencil; define risk-based requalification triggers affecting solder joint quality and shorts	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0007	PCB AOI / AXI inspection system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses defect library; lighting; classification; required outputs: solder defect sensitivity/specificity	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0008	PCB AOI / AXI inspection system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for PCB AOI / AXI inspection system	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0009	PCB AOI / AXI inspection system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for defect library; lighting; classification; evaluate solder defect sensitivity/specificity	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0010	PCB AOI / AXI inspection system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0011	PCB AOI / AXI inspection system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering solder defect sensitivity/specificity	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0012	PCB AOI / AXI inspection system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend defect library; lighting; classification; define risk-based requalification triggers affecting solder defect sensitivity/specificity	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0013	Medical power supply assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses input range; ripple; overload protection; required outputs: essential performance and electrical safety	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0014	Medical power supply assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical power supply assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0015	Medical power supply assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for input range; ripple; overload protection; evaluate essential performance and electrical safety	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0016	Medical power supply assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0017	Medical power supply assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering essential performance and electrical safety	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0018	Medical power supply assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend input range; ripple; overload protection; define risk-based requalification triggers affecting essential performance and electrical safety	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0019	Battery cell welding / pack assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses weld current; force; thermal limits; required outputs: energy delivery and safe battery operation	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0020	Battery cell welding / pack assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Battery cell welding / pack assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0021	Battery cell welding / pack assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for weld current; force; thermal limits; evaluate energy delivery and safe battery operation	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0022	Battery cell welding / pack assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0023	Battery cell welding / pack assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering energy delivery and safe battery operation	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0024	Battery cell welding / pack assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend weld current; force; thermal limits; define risk-based requalification triggers affecting energy delivery and safe battery operation	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0025	Battery charger test bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses charge profile; cutoff; thermal rise; required outputs: battery safety and run time	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0026	Battery charger test bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Battery charger test bench	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0027	Battery charger test bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for charge profile; cutoff; thermal rise; evaluate battery safety and run time	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0028	Battery charger test bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0029	Battery charger test bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering battery safety and run time	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0030	Battery charger test bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend charge profile; cutoff; thermal rise; define risk-based requalification triggers affecting battery safety and run time	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0031	Infusion pump motor and gear calibration	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses drive steps; backlash; torque; required outputs: flow accuracy and occlusion alarm	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0032	Infusion pump motor and gear calibration	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Infusion pump motor and gear calibration	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0033	Infusion pump motor and gear calibration	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for drive steps; backlash; torque; evaluate flow accuracy and occlusion alarm	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0034	Infusion pump motor and gear calibration	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0035	Infusion pump motor and gear calibration	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flow accuracy and occlusion alarm	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0036	Infusion pump motor and gear calibration	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend drive steps; backlash; torque; define risk-based requalification triggers affecting flow accuracy and occlusion alarm	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0037	Patient monitor sensor assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses signal chain; connectors; calibration; required outputs: measurement accuracy and alarms	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0038	Patient monitor sensor assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Patient monitor sensor assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0039	Patient monitor sensor assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for signal chain; connectors; calibration; evaluate measurement accuracy and alarms	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0040	Patient monitor sensor assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0041	Patient monitor sensor assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering measurement accuracy and alarms	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0042	Patient monitor sensor assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend signal chain; connectors; calibration; define risk-based requalification triggers affecting measurement accuracy and alarms	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0043	ECG lead / cable assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses contact resistance; flex; insulation; required outputs: signal integrity and mechanical endurance	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0044	ECG lead / cable assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for ECG lead / cable assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0045	ECG lead / cable assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for contact resistance; flex; insulation; evaluate signal integrity and mechanical endurance	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0046	ECG lead / cable assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0047	ECG lead / cable assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering signal integrity and mechanical endurance	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0048	ECG lead / cable assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend contact resistance; flex; insulation; define risk-based requalification triggers affecting signal integrity and mechanical endurance	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0049	Pulse oximeter optical module	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses LED intensity; detector alignment; algorithm calibration; required outputs: SpO2 performance and error handling	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0050	Pulse oximeter optical module	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pulse oximeter optical module	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0051	Pulse oximeter optical module	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for LED intensity; detector alignment; algorithm calibration; evaluate SpO2 performance and error handling	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0052	Pulse oximeter optical module	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0053	Pulse oximeter optical module	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering SpO2 performance and error handling	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0054	Pulse oximeter optical module	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend LED intensity; detector alignment; algorithm calibration; define risk-based requalification triggers affecting SpO2 performance and error handling	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0055	Electrosurgical output calibration	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses frequency; power; load profile; required outputs: delivered power and safe cut/coagulate functions	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0056	Electrosurgical output calibration	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electrosurgical output calibration	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0057	Electrosurgical output calibration	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for frequency; power; load profile; evaluate delivered power and safe cut/coagulate functions	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0058	Electrosurgical output calibration	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0059	Electrosurgical output calibration	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering delivered power and safe cut/coagulate functions	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0060	Electrosurgical output calibration	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend frequency; power; load profile; define risk-based requalification triggers affecting delivered power and safe cut/coagulate functions	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0061	Ventilator blower assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flow; pressure; valve timing; required outputs: respiratory output performance	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0062	Ventilator blower assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ventilator blower assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0063	Ventilator blower assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flow; pressure; valve timing; evaluate respiratory output performance	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0064	Ventilator blower assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0065	Ventilator blower assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering respiratory output performance	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0066	Ventilator blower assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flow; pressure; valve timing; define risk-based requalification triggers affecting respiratory output performance	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0067	Anesthesia workstation leak test	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses circuit pressure; sensor response; required outputs: gas delivery integrity and alarms	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0068	Anesthesia workstation leak test	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Anesthesia workstation leak test	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0069	Anesthesia workstation leak test	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for circuit pressure; sensor response; evaluate gas delivery integrity and alarms	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0070	Anesthesia workstation leak test	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0071	Anesthesia workstation leak test	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering gas delivery integrity and alarms	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0072	Anesthesia workstation leak test	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend circuit pressure; sensor response; define risk-based requalification triggers affecting gas delivery integrity and alarms	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0073	Dialysis machine fluid path assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pump calibration; fluid mixing; leak control; required outputs: fluid safety and conductivity	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0074	Dialysis machine fluid path assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dialysis machine fluid path assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0075	Dialysis machine fluid path assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pump calibration; fluid mixing; leak control; evaluate fluid safety and conductivity	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0076	Dialysis machine fluid path assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0077	Dialysis machine fluid path assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fluid safety and conductivity	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0078	Dialysis machine fluid path assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pump calibration; fluid mixing; leak control; define risk-based requalification triggers affecting fluid safety and conductivity	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0079	Ultrasound transducer assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses acoustic coupling; bonding; element response; required outputs: image quality and element performance	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0080	Ultrasound transducer assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ultrasound transducer assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0081	Ultrasound transducer assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for acoustic coupling; bonding; element response; evaluate image quality and element performance	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0082	Ultrasound transducer assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0083	Ultrasound transducer assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering image quality and element performance	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0084	Ultrasound transducer assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend acoustic coupling; bonding; element response; define risk-based requalification triggers affecting image quality and element performance	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0085	Patient warming device assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses heater control; thermostat; fail-safe; required outputs: temperature uniformity and protection	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0086	Patient warming device assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Patient warming device assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0087	Patient warming device assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for heater control; thermostat; fail-safe; evaluate temperature uniformity and protection	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0088	Patient warming device assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0089	Patient warming device assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering temperature uniformity and protection	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0090	Patient warming device assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend heater control; thermostat; fail-safe; define risk-based requalification triggers affecting temperature uniformity and protection	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0091	Robotic surgical end effector	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses alignment; force sensing; movement range; required outputs: mechanical motion and safety controls	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0092	Robotic surgical end effector	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Robotic surgical end effector	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0093	Robotic surgical end effector	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for alignment; force sensing; movement range; evaluate mechanical motion and safety controls	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0094	Robotic surgical end effector	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0095	Robotic surgical end effector	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering mechanical motion and safety controls	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0096	Robotic surgical end effector	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend alignment; force sensing; movement range; define risk-based requalification triggers affecting mechanical motion and safety controls	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0097	Defibrillator charging system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses charge voltage; discharge energy; waveform; required outputs: therapeutic output integrity	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0098	Defibrillator charging system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Defibrillator charging system	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0099	Defibrillator charging system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for charge voltage; discharge energy; waveform; evaluate therapeutic output integrity	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0100	Defibrillator charging system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0101	Defibrillator charging system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering therapeutic output integrity	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0102	Defibrillator charging system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend charge voltage; discharge energy; waveform; define risk-based requalification triggers affecting therapeutic output integrity	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0103	Electromedical enclosure sealing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses gasket compression; liquid ingress; required outputs: IP protection and patient safety	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0104	Electromedical enclosure sealing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electromedical enclosure sealing	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0105	Electromedical enclosure sealing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for gasket compression; liquid ingress; evaluate IP protection and patient safety	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0106	Electromedical enclosure sealing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-15-0107	Electromedical enclosure sealing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering IP protection and patient safety	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0108	Electromedical enclosure sealing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend gasket compression; liquid ingress; define risk-based requalification triggers affecting IP protection and patient safety	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0109	Touchscreen and user interface line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses touch sensitivity; response; alarm display; required outputs: critical user function correctness	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0110	Touchscreen and user interface line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Touchscreen and user interface line	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0111	Touchscreen and user interface line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for touch sensitivity; response; alarm display; evaluate critical user function correctness	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0112	Touchscreen and user interface line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0113	Touchscreen and user interface line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering critical user function correctness	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0114	Touchscreen and user interface line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend touch sensitivity; response; alarm display; define risk-based requalification triggers affecting critical user function correctness	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium
MDV-15-0115	Mains isolation transformer assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dielectric withstand; leakage; grounding; required outputs: electrical isolation and protective earth	URS / DQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0116	Mains isolation transformer assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Mains isolation transformer assembly	IQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0117	Mains isolation transformer assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dielectric withstand; leakage; grounding; evaluate electrical isolation and protective earth	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0118	Mains isolation transformer assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0119	Mains isolation transformer assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering electrical isolation and protective earth	PQ	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	High
MDV-15-0120	Mains isolation transformer assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dielectric withstand; leakage; grounding; define risk-based requalification triggers affecting electrical isolation and protective earth	Routine / Change	Medical electronics; electrosurgical and electromechanical	M01 M02 M07 M18	Medium

16 IVD ASSAYS, REAGENTS, KITS & DIAGNOSTICS

147 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-16-0001	IVD buffer mixing tank	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pH; conductivity; stirring; hold time; required outputs: reagent concentration and stability	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0002	IVD buffer mixing tank	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IVD buffer mixing tank	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0003	IVD buffer mixing tank	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pH; conductivity; stirring; hold time; evaluate reagent concentration and stability	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0004	IVD buffer mixing tank	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0005	IVD buffer mixing tank	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reagent concentration and stability	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0006	IVD buffer mixing tank	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pH; conductivity; stirring; hold time; define risk-based requalification triggers affecting reagent concentration and stability	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0007	Reagent formulation filling line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill mass; nozzle pressure; carryover; required outputs: lot consistency and dispense accuracy	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0008	Reagent formulation filling line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Reagent formulation filling line	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0009	Reagent formulation filling line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill mass; nozzle pressure; carryover; evaluate lot consistency and dispense accuracy	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0010	Reagent formulation filling line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0011	Reagent formulation filling line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering lot consistency and dispense accuracy	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0012	Reagent formulation filling line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill mass; nozzle pressure; carryover; define risk-based requalification triggers affecting lot consistency and dispense accuracy	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0013	Lateral flow membrane dispensing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dispense volume; line width; nozzle alignment; required outputs: test line intensity and CV	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0014	Lateral flow membrane dispensing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Lateral flow membrane dispensing	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0015	Lateral flow membrane dispensing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dispense volume; line width; nozzle alignment; evaluate test line intensity and CV	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0016	Lateral flow membrane dispensing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-16-0017	Lateral flow membrane dispensing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering test line intensity and CV	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0018	Lateral flow membrane dispensing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dispense volume; line width; nozzle alignment; define risk-based requalification triggers affecting test line intensity and CV	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0019	Lateral flow membrane drying oven	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; airflow; humidity; required outputs: reagent activity and background	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0020	Lateral flow membrane drying oven	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Lateral flow membrane drying oven	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0021	Lateral flow membrane drying oven	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; airflow; humidity; evaluate reagent activity and background	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0022	Lateral flow membrane drying oven	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0023	Lateral flow membrane drying oven	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reagent activity and background	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0024	Lateral flow membrane drying oven	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; airflow; humidity; define risk-based requalification triggers affecting reagent activity and background	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0025	Conjugate pad impregnation/coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses solution loading; uniformity; drying; required outputs: sensitivity and lot consistency	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0026	Conjugate pad impregnation/coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Conjugate pad impregnation/coating	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0027	Conjugate pad impregnation/coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for solution loading; uniformity; drying; evaluate sensitivity and lot consistency	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0028	Conjugate pad impregnation/coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0029	Conjugate pad impregnation/coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sensitivity and lot consistency	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0030	Conjugate pad impregnation/coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend solution loading; uniformity; drying; define risk-based requalification triggers affecting sensitivity and lot consistency	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0031	Lateral flow strip lamination	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses layer overlap; pressure; pitch; required outputs: capillary migration and physical integrity	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0032	Lateral flow strip lamination	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Lateral flow strip lamination	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0033	Lateral flow strip lamination	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for layer overlap; pressure; pitch; evaluate capillary migration and physical integrity	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0034	Lateral flow strip lamination	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-16-0035	Lateral flow strip lamination	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering capillary migration and physical integrity	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0036	Lateral flow strip lamination	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend layer overlap; pressure; pitch; define risk-based requalification triggers affecting capillary migration and physical integrity	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0037	Lateral flow cassette assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses strip position; clamp pressure; required outputs: flow path and result window accuracy	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0038	Lateral flow cassette assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Lateral flow cassette assembly	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0039	Lateral flow cassette assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for strip position; clamp pressure; evaluate flow path and result window accuracy	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0040	Lateral flow cassette assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0041	Lateral flow cassette assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flow path and result window accuracy	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0042	Lateral flow cassette assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend strip position; clamp pressure; define risk-based requalification triggers affecting flow path and result window accuracy	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0043	Microplate coating process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coating concentration; time; blocking; required outputs: well-to-well binding consistency	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0044	Microplate coating process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microplate coating process	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0045	Microplate coating process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coating concentration; time; blocking; evaluate well-to-well binding consistency	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0046	Microplate coating process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0047	Microplate coating process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering well-to-well binding consistency	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0048	Microplate coating process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coating concentration; time; blocking; define risk-based requalification triggers affecting well-to-well binding consistency	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0049	ELISA plate washing/drying	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses residual fluid; cycle speed; required outputs: background and assay repeatability	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0050	ELISA plate washing/drying	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for ELISA plate washing/drying	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0051	ELISA plate washing/drying	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for residual fluid; cycle speed; evaluate background and assay repeatability	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0052	ELISA plate washing/drying	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

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MDV-16-0053	ELISA plate washing/drying	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering background and assay repeatability	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0054	ELISA plate washing/drying	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend residual fluid; cycle speed; define risk-based requalification triggers affecting background and assay repeatability	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0055	Molecular extraction kit filling	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses buffer volume; nuclease-free practices; required outputs: extraction recovery and contamination prevention	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0056	Molecular extraction kit filling	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Molecular extraction kit filling	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0057	Molecular extraction kit filling	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for buffer volume; nuclease-free practices; evaluate extraction recovery and contamination prevention	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0058	Molecular extraction kit filling	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0059	Molecular extraction kit filling	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering extraction recovery and contamination prevention	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0060	Molecular extraction kit filling	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend buffer volume; nuclease-free practices; define risk-based requalification triggers affecting extraction recovery and contamination prevention	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0061	PCR reagent dispense system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses microliter precision; mixing; contamination barrier; required outputs: amplification precision and false positive control	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0062	PCR reagent dispense system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for PCR reagent dispense system	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0063	PCR reagent dispense system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for microliter precision; mixing; contamination barrier; evaluate amplification precision and false positive control	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0064	PCR reagent dispense system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0065	PCR reagent dispense system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering amplification precision and false positive control	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0066	PCR reagent dispense system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend microliter precision; mixing; contamination barrier; define risk-based requalification triggers affecting amplification precision and false positive control	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0067	Lyophilized IVD reagent cycle	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses freeze profile; primary/secondary dry; moisture; required outputs: reagent stability and reconstitution	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0068	Lyophilized IVD reagent cycle	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Lyophilized IVD reagent cycle	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0069	Lyophilized IVD reagent cycle	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for freeze profile; primary/secondary dry; moisture; evaluate reagent stability and reconstitution	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0070	Lyophilized IVD reagent cycle	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

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MDV-16-0071	Lyophilized IVD reagent cycle	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reagent stability and reconstitution	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0072	Lyophilized IVD reagent cycle	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend freeze profile; primary/secondary dry; moisture; define risk-based requalification triggers affecting reagent stability and reconstitution	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0073	Liquid QC calibrator bottling	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill; mixing; lot traceability; required outputs: assigned concentration and homogeneity	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0074	Liquid QC calibrator bottling	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Liquid QC calibrator bottling	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0075	Liquid QC calibrator bottling	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill; mixing; lot traceability; evaluate assigned concentration and homogeneity	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0076	Liquid QC calibrator bottling	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0077	Liquid QC calibrator bottling	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering assigned concentration and homogeneity	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0078	Liquid QC calibrator bottling	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill; mixing; lot traceability; define risk-based requalification triggers affecting assigned concentration and homogeneity	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0079	Whole-blood hematology IVD cartridge sealing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fluid path geometry; bubble; seal; required outputs: cell count stability and sample containment	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0080	Whole-blood hematology IVD cartridge sealing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Whole-blood hematology IVD cartridge sealing	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0081	Whole-blood hematology IVD cartridge sealing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fluid path geometry; bubble; seal; evaluate cell count stability and sample containment	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0082	Whole-blood hematology IVD cartridge sealing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0083	Whole-blood hematology IVD cartridge sealing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cell count stability and sample containment	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0084	Whole-blood hematology IVD cartridge sealing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fluid path geometry; bubble; seal; define risk-based requalification triggers affecting cell count stability and sample containment	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0085	Immunoassay reader optical system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses wavelength; detector gain; stray light; required outputs: analytical accuracy and signal reproducibility	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0086	Immunoassay reader optical system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Immunoassay reader optical system	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0087	Immunoassay reader optical system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for wavelength; detector gain; stray light; evaluate analytical accuracy and signal reproducibility	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0088	Immunoassay reader optical system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

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MDV-16-0089	Immunoassay reader optical system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering analytical accuracy and signal reproducibility	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0090	Immunoassay reader optical system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend wavelength; detector gain; stray light; define risk-based requalification triggers affecting analytical accuracy and signal reproducibility	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0091	Point-of-care glucose strip printing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses enzyme loading; electrode geometry; required outputs: glucose bias, precision and linearity	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0092	Point-of-care glucose strip printing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Point-of-care glucose strip printing	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0093	Point-of-care glucose strip printing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for enzyme loading; electrode geometry; evaluate glucose bias, precision and linearity	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0094	Point-of-care glucose strip printing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0095	Point-of-care glucose strip printing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering glucose bias, precision and linearity	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0096	Point-of-care glucose strip printing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend enzyme loading; electrode geometry; define risk-based requalification triggers affecting glucose bias, precision and linearity	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0097	Microfluidic diagnostic cartridge bonding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bond temperature; pressure; channel deformation; required outputs: channel integrity and no cross-talk	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0098	Microfluidic diagnostic cartridge bonding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microfluidic diagnostic cartridge bonding	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0099	Microfluidic diagnostic cartridge bonding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bond temperature; pressure; channel deformation; evaluate channel integrity and no cross-talk	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0100	Microfluidic diagnostic cartridge bonding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0101	Microfluidic diagnostic cartridge bonding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering channel integrity and no cross-talk	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0102	Microfluidic diagnostic cartridge bonding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bond temperature; pressure; channel deformation; define risk-based requalification triggers affecting channel integrity and no cross-talk	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0103	Molecular cartridge fluidics assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses valve movement; inlet seals; sample path; required outputs: sample transfer and no carryover	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0104	Molecular cartridge fluidics assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Molecular cartridge fluidics assembly	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0105	Molecular cartridge fluidics assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for valve movement; inlet seals; sample path; evaluate sample transfer and no carryover	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0106	Molecular cartridge fluidics assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

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MDV-16-0107	Molecular cartridge fluidics assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sample transfer and no carryover	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0108	Molecular cartridge fluidics assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend valve movement; inlet seals; sample path; define risk-based requalification triggers affecting sample transfer and no carryover	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0109	Assay antibody conjugation line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pH; reaction time; separation; required outputs: specificity and activity	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0110	Assay antibody conjugation line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Assay antibody conjugation line	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0111	Assay antibody conjugation line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pH; reaction time; separation; evaluate specificity and activity	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0112	Assay antibody conjugation line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0113	Assay antibody conjugation line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specificity and activity	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0114	Assay antibody conjugation line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pH; reaction time; separation; define risk-based requalification triggers affecting specificity and activity	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0115	Diagnostic device RFID/calibration chip programming	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses ID write; lot mapping; checksum; required outputs: correct assay lot calibration	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0116	Diagnostic device RFID/calibration chip programming	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Diagnostic device RFID/calibration chip programming	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0117	Diagnostic device RFID/calibration chip programming	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for ID write; lot mapping; checksum; evaluate correct assay lot calibration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0118	Diagnostic device RFID/calibration chip programming	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0119	Diagnostic device RFID/calibration chip programming	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct assay lot calibration	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0120	Diagnostic device RFID/calibration chip programming	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend ID write; lot mapping; checksum; define risk-based requalification triggers affecting correct assay lot calibration	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0121	IVD automated liquid handler	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tip strategy; dispense repeatability; cross-contamination; required outputs: assay precision and carryover	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0122	IVD automated liquid handler	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IVD automated liquid handler	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0123	IVD automated liquid handler	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tip strategy; dispense repeatability; cross-contamination; evaluate assay precision and carryover	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0124	IVD automated liquid handler	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High

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MDV-16-0125	IVD automated liquid handler	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering assay precision and carryover	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0126	IVD automated liquid handler	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tip strategy; dispense repeatability; cross-contamination; define risk-based requalification triggers affecting assay precision and carryover	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0127	Colorimetric dipstick print/coating line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reagent distribution; color development; required outputs: clinical cutoff sensitivity and accuracy	URS / DQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0128	Colorimetric dipstick print/coating line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Colorimetric dipstick print/coating line	IQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0129	Colorimetric dipstick print/coating line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reagent distribution; color development; evaluate clinical cutoff sensitivity and accuracy	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0130	Colorimetric dipstick print/coating line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0131	Colorimetric dipstick print/coating line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering clinical cutoff sensitivity and accuracy	PQ	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	High
MDV-16-0132	Colorimetric dipstick print/coating line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reagent distribution; color development; define risk-based requalification triggers affecting clinical cutoff sensitivity and accuracy	Routine / Change	IVD test kits; clinical chemistry; immunoassay; molecular diagnostics	M01 M02 M04 M05 M07 M22 M23	Medium
MDV-16-0133	IVD analytical sensitivity	Establish LoB, LoD, LoQ where appropriate	Design-specific limits with sampling and uncertainty	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0134	IVD analytical specificity	Challenge cross-reactivity and interference	Evidence using relevant endogenous/exogenous interferents	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0135	IVD accuracy / method comparison	Compare against justified reference method	Bias, agreement and clinical decision limit analyses	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0136	IVD precision	Assess within-run, between-run, operator, instrument and lot	Repeatability and reproducibility across applicable conditions	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0137	IVD linearity / range	Challenge intended measuring interval	Linearity, reportable interval and hook-effect assessment	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0138	IVD lot-to-lot reproducibility	Compare production lots and calibration material	Clinical cutoff equivalence and allowable variation	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0139	IVD specimen handling	Validate anticoagulants, specimen containers and transport	Analyte stability, recovery and matrix equivalence	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0140	IVD calibrator traceability	Establish metrological traceability chain	Traceability to higher order references, uncertainty budget	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0141	IVD clinical performance	Validate clinical sensitivity/specificity or equivalent	Target population and intended purpose study evidence	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0142	IVD cut-off verification	Test near-cutoff specimens with expected variability	Misclassification probabilities and confidence limits	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0143	IVD reagent stability	Establish unopened, on-board, in-use and shipping stability	ISO 23640-based stability study with acceptance criteria	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0144	IVD reagent contamination controls	Challenge lot pooling, dispensing and rework	Prevention of false results and carryover	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0145	IVD controls / QC material	Assign ranges and lot acceptance	Traceable value assignment and stability	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-16-0146	IVD self-test usability	Evaluate untrained lay-users when intended	Correct steps, interpretation and IFU effectiveness	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High
MDV-16-0147	IVD software algorithm	Verify calculation, flags, invalid results and safeguards	Reference case test dataset and boundary challenges	Lifecycle	IVD assay and system validation	M04 M05 M06 M07 M22 M23 M24	High

17 OPHTHALMIC AND SPECIALIZED PRECISION DEVICES

72 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-17-0001	Intraocular lens injection molding / cast	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses lens curvature; thermal profile; optical homogeneity; required outputs: lens optic performance and dimensional integrity	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0002	Intraocular lens injection molding / cast	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Intraocular lens injection molding / cast	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0003	Intraocular lens injection molding / cast	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for lens curvature; thermal profile; optical homogeneity; evaluate lens optic performance and dimensional integrity	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0004	Intraocular lens injection molding / cast	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0005	Intraocular lens injection molding / cast	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering lens optic performance and dimensional integrity	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0006	Intraocular lens injection molding / cast	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend lens curvature; thermal profile; optical homogeneity; define risk-based requalification triggers affecting lens optic performance and dimensional integrity	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0007	IOL optical metrology bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses refractive power; resolution; alignment; required outputs: diopter and MTF verification	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0008	IOL optical metrology bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IOL optical metrology bench	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0009	IOL optical metrology bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for refractive power; resolution; alignment; evaluate diopter and MTF verification	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0010	IOL optical metrology bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0011	IOL optical metrology bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering diopter and MTF verification	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0012	IOL optical metrology bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend refractive power; resolution; alignment; define risk-based requalification triggers affecting diopter and MTF verification	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0013	IOL haptic forming and joining	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses haptic angle; weld energy; retention; required outputs: haptic flex and stability	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0014	IOL haptic forming and joining	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IOL haptic forming and joining	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0015	IOL haptic forming and joining	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for haptic angle; weld energy; retention; evaluate haptic flex and stability	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0016	IOL haptic forming and joining	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-17-0017	IOL haptic forming and joining	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering haptic flex and stability	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0018	IOL haptic forming and joining	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend haptic angle; weld energy; retention; define risk-based requalification triggers affecting haptic flex and stability	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0019	IOL ultrasonic cleaning line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bath quality; agitation; particle removal; required outputs: particle and endotoxin control	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0020	IOL ultrasonic cleaning line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IOL ultrasonic cleaning line	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0021	IOL ultrasonic cleaning line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bath quality; agitation; particle removal; evaluate particle and endotoxin control	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0022	IOL ultrasonic cleaning line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0023	IOL ultrasonic cleaning line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering particle and endotoxin control	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0024	IOL ultrasonic cleaning line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bath quality; agitation; particle removal; define risk-based requalification triggers affecting particle and endotoxin control	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0025	IOL final hydration storage	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses osmolarity; pH; time; required outputs: material geometry and optical stability	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0026	IOL final hydration storage	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IOL final hydration storage	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0027	IOL final hydration storage	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for osmolarity; pH; time; evaluate material geometry and optical stability	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0028	IOL final hydration storage	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0029	IOL final hydration storage	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering material geometry and optical stability	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0030	IOL final hydration storage	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend osmolarity; pH; time; define risk-based requalification triggers affecting material geometry and optical stability	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0031	IOL sterile packaging blister seal	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses seal temperature; pressure; aqueous fill; required outputs: container integrity and sterile barrier	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0032	IOL sterile packaging blister seal	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IOL sterile packaging blister seal	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0033	IOL sterile packaging blister seal	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for seal temperature; pressure; aqueous fill; evaluate container integrity and sterile barrier	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0034	IOL sterile packaging blister seal	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-17-0035	IOL sterile packaging blister seal	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering container integrity and sterile barrier	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0036	IOL sterile packaging blister seal	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend seal temperature; pressure; aqueous fill; define risk-based requalification triggers affecting container integrity and sterile barrier	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0037	Endoscope distal-tip assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses optics focus; waterproof seal; required outputs: image quality and leakage integrity	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0038	Endoscope distal-tip assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Endoscope distal-tip assembly	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0039	Endoscope distal-tip assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for optics focus; waterproof seal; evaluate image quality and leakage integrity	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0040	Endoscope distal-tip assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0041	Endoscope distal-tip assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering image quality and leakage integrity	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0042	Endoscope distal-tip assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend optics focus; waterproof seal; define risk-based requalification triggers affecting image quality and leakage integrity	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0043	Endoscope insertion-tube lamination	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tube hardness; bond; bend cycling; required outputs: flex life and structural integrity	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0044	Endoscope insertion-tube lamination	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Endoscope insertion-tube lamination	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0045	Endoscope insertion-tube lamination	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tube hardness; bond; bend cycling; evaluate flex life and structural integrity	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0046	Endoscope insertion-tube lamination	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0047	Endoscope insertion-tube lamination	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering flex life and structural integrity	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0048	Endoscope insertion-tube lamination	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tube hardness; bond; bend cycling; define risk-based requalification triggers affecting flex life and structural integrity	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0049	Surgical robotic instrument cable assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cable tension; repeated actuation; required outputs: grip output and fatigue life	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0050	Surgical robotic instrument cable assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surgical robotic instrument cable assembly	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0051	Surgical robotic instrument cable assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cable tension; repeated actuation; evaluate grip output and fatigue life	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0052	Surgical robotic instrument cable assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-17-0053	Surgical robotic instrument cable assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering grip output and fatigue life	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0054	Surgical robotic instrument cable assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cable tension; repeated actuation; define risk-based requalification triggers affecting grip output and fatigue life	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0055	Bipolar electrosurgical forceps coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses insulation film; pinhole test; required outputs: insulation and electrical isolation	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0056	Bipolar electrosurgical forceps coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bipolar electrosurgical forceps coating	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0057	Bipolar electrosurgical forceps coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for insulation film; pinhole test; evaluate insulation and electrical isolation	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0058	Bipolar electrosurgical forceps coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0059	Bipolar electrosurgical forceps coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering insulation and electrical isolation	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0060	Bipolar electrosurgical forceps coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend insulation film; pinhole test; define risk-based requalification triggers affecting insulation and electrical isolation	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0061	Endoscope channel cleaning/flush verification	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flow; detergent; lumen length; required outputs: soil extraction and no retained residues	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0062	Endoscope channel cleaning/flush verification	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Endoscope channel cleaning/flush verification	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0063	Endoscope channel cleaning/flush verification	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flow; detergent; lumen length; evaluate soil extraction and no retained residues	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0064	Endoscope channel cleaning/flush verification	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0065	Endoscope channel cleaning/flush verification	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering soil extraction and no retained residues	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0066	Endoscope channel cleaning/flush verification	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flow; detergent; lumen length; define risk-based requalification triggers affecting soil extraction and no retained residues	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium
MDV-17-0067	Micro-surgical blade sharpening	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bevel; edge profile; microburr; required outputs: cutting performance and particulate	URS / DQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0068	Micro-surgical blade sharpening	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Micro-surgical blade sharpening	IQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0069	Micro-surgical blade sharpening	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bevel; edge profile; microburr; evaluate cutting performance and particulate	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0070	Micro-surgical blade sharpening	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-17-0071	Micro-surgical blade sharpening	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cutting performance and particulate	PQ	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	High
MDV-17-0072	Micro-surgical blade sharpening	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bevel; edge profile; microburr; define risk-based requalification triggers affecting cutting performance and particulate	Routine / Change	IOL, ophthalmic devices, endoscopes and minimally invasive tools	M01 M02 M03 M07 M14	Medium

18 STERILIZATION - ETHYLENE OXIDE (EO)

70 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-18-0001	EO sterilizer chamber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses gas concentration; temperature; humidity; exposure; required outputs: reproducible lethality and load penetration	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0002	EO sterilizer chamber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO sterilizer chamber	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0003	EO sterilizer chamber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for gas concentration; temperature; humidity; exposure; evaluate reproducible lethality and load penetration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0004	EO sterilizer chamber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0005	EO sterilizer chamber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reproducible lethality and load penetration	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0006	EO sterilizer chamber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend gas concentration; temperature; humidity; exposure; define risk-based requalification triggers affecting reproducible lethality and load penetration	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0007	EO preconditioning room	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RH; temperature; load dwell; required outputs: specified product humidity and temperature	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0008	EO preconditioning room	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO preconditioning room	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0009	EO preconditioning room	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RH; temperature; load dwell; evaluate specified product humidity and temperature	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0010	EO preconditioning room	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0011	EO preconditioning room	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specified product humidity and temperature	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0012	EO preconditioning room	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RH; temperature; load dwell; define risk-based requalification triggers affecting specified product humidity and temperature	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0013	EO humidification system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RH rise; sensor response; humidification time; required outputs: adequate preconditioned load state	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0014	EO humidification system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO humidification system	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0015	EO humidification system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RH rise; sensor response; humidification time; evaluate adequate preconditioned load state	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0016	EO humidification system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0017	EO humidification system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering adequate preconditioned load state	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0018	EO humidification system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RH rise; sensor response; humidification time; define risk-based requalification triggers affecting adequate preconditioned load state	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0019	EO sterilant gas delivery skid	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses metering; concentration; leak detection; required outputs: controlled EO dose and interlocks	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0020	EO sterilant gas delivery skid	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO sterilant gas delivery skid	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0021	EO sterilant gas delivery skid	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for metering; concentration; leak detection; evaluate controlled EO dose and interlocks	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-18-0022	EO sterilant gas delivery skid	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0023	EO sterilant gas delivery skid	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled EO dose and interlocks	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0024	EO sterilant gas delivery skid	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend metering; concentration; leak detection; define risk-based requalification triggers affecting controlled EO dose and interlocks	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0025	EO evacuation/air-wash process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses vacuum pulses; air exchange; cycle duration; required outputs: controlled sterilant removal and safety	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0026	EO evacuation/air-wash process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO evacuation/air-wash process	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0027	EO evacuation/air-wash process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for vacuum pulses; air exchange; cycle duration; evaluate controlled sterilant removal and safety	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0028	EO evacuation/air-wash process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0029	EO evacuation/air-wash process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled sterilant removal and safety	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0030	EO evacuation/air-wash process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend vacuum pulses; air exchange; cycle duration; define risk-based requalification triggers affecting controlled sterilant removal and safety	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0031	EO aeration room	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses aeration temperature; airflow; time; required outputs: acceptable EO/ECH residuals	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0032	EO aeration room	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO aeration room	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0033	EO aeration room	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for aeration temperature; airflow; time; evaluate acceptable EO/ECH residuals	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0034	EO aeration room	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0035	EO aeration room	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering acceptable EO/ECH residuals	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0036	EO aeration room	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend aeration temperature; airflow; time; define risk-based requalification triggers affecting acceptable EO/ECH residuals	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0037	EO load cart / pallet configuration	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses spacing; carton orientation; product density; required outputs: reproducible worst-case penetration	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0038	EO load cart / pallet configuration	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO load cart / pallet configuration	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0039	EO load cart / pallet configuration	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for spacing; carton orientation; product density; evaluate reproducible worst-case penetration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0040	EO load cart / pallet configuration	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0041	EO load cart / pallet configuration	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reproducible worst-case penetration	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0042	EO load cart / pallet configuration	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend spacing; carton orientation; product density; define risk-based requalification triggers affecting reproducible worst-case penetration	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0043	EO chamber temperature/RH probes	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sensor placement; range; recorder calibration; required outputs: cycle independent monitoring	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0044	EO chamber temperature/RH probes	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO chamber temperature/RH probes	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0045	EO chamber temperature/RH probes	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sensor placement; range; recorder calibration; evaluate cycle independent monitoring	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-18-0046	EO chamber temperature/RH probes	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0047	EO chamber temperature/RH probes	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cycle independent monitoring	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0048	EO chamber temperature/RH probes	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sensor placement; range; recorder calibration; define risk-based requalification triggers affecting cycle independent monitoring	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0049	EO BI/PCD positioning	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses worst-case location; penetration; resistance; required outputs: challenge equivalent to validated process	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0050	EO BI/PCD positioning	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO BI/PCD positioning	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0051	EO BI/PCD positioning	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for worst-case location; penetration; resistance; evaluate challenge equivalent to validated process	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0052	EO BI/PCD positioning	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0053	EO BI/PCD positioning	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering challenge equivalent to validated process	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0054	EO BI/PCD positioning	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend worst-case location; penetration; resistance; define risk-based requalification triggers affecting challenge equivalent to validated process	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0055	EO scrubber / abatement unit	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flow; destruction efficiency; emission alarms; required outputs: occupational/environmental control	URS / DQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0056	EO scrubber / abatement unit	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO scrubber / abatement unit	IQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0057	EO scrubber / abatement unit	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flow; destruction efficiency; emission alarms; evaluate occupational/environmental control	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0058	EO scrubber / abatement unit	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0059	EO scrubber / abatement unit	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering occupational/environmental control	PQ	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	High
MDV-18-0060	EO scrubber / abatement unit	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flow; destruction efficiency; emission alarms; define risk-based requalification triggers affecting occupational/environmental control	Routine / Change	EO terminal sterilization	M01 M02 M07 M09 M13 M25 M27	Medium
MDV-18-0061	EO microbiological cycle development	Demonstrate validated lethality with product/PCD	Protocol determines applicable overkill/bioburden-based approach	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0062	EO PQ load matrix	Qualify min/max product mass, packaging and pallet density	Worst-case dimensional and thermal/humidity evidence	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0063	EO residual limits	Validate ISO 10993-7 EO/ECH extraction and release limits	Patient exposure assessment by device type and contact duration	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0064	EO half-cycle study	Challenge worst-case load with qualified BI/PCDs where selected	Sterilization cycle efficacy evidence	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0065	EO aeration duration	Verify residuals after maximum load/packing	Release criteria based on extraction data	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0066	EO parametric release	Validate parametric release only if justified and eligible	Defined variables and capability to assure sterilization outcome	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0067	EO sterilization subcontracting	Verify split roles and review external validation package	Authorized release with sterilizer lot and cycle linkage	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0068	EO biological indicator tests	Validate BI incubation growth and positives/negatives	Organism challenge and incubation suitability	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0069	EO sterilization requalification	Review product/packaging/plant/process changes	Change-specific repeat PQ or maintenance rationale	Lifecycle	EO sterilized products	M09 M13 M25 M27	High
MDV-18-0070	EO safety controls	Challenge chamber door interlock / leak alarms	EO occupational safety and rescue safeguards	Lifecycle	EO sterilized products	M09 M13 M25 M27	High

19 STERILIZATION - RADIATION (GAMMA, E-BEAM, X-RAY)

56 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-19-0001	Gamma irradiator process interface	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses conveyor route; dwell time; source configuration; required outputs: dose delivery integrity	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0002	Gamma irradiator process interface	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Gamma irradiator process interface	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0003	Gamma irradiator process interface	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for conveyor route; dwell time; source configuration; evaluate dose delivery integrity	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0004	Gamma irradiator process interface	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0005	Gamma irradiator process interface	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose delivery integrity	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0006	Gamma irradiator process interface	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend conveyor route; dwell time; source configuration; define risk-based requalification triggers affecting dose delivery integrity	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0007	Electron-beam accelerator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses beam energy; scan width; current; belt speed; required outputs: dose distribution across product	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0008	Electron-beam accelerator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electron-beam accelerator	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0009	Electron-beam accelerator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for beam energy; scan width; current; belt speed; evaluate dose distribution across product	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0010	Electron-beam accelerator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0011	Electron-beam accelerator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose distribution across product	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0012	Electron-beam accelerator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend beam energy; scan width; current; belt speed; define risk-based requalification triggers affecting dose distribution across product	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0013	X-ray irradiation line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses converter energy; source uniformity; product positioning; required outputs: dose consistency and penetration	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0014	X-ray irradiation line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for X-ray irradiation line	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0015	X-ray irradiation line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for converter energy; source uniformity; product positioning; evaluate dose consistency and penetration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0016	X-ray irradiation line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0017	X-ray irradiation line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose consistency and penetration	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0018	X-ray irradiation line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend converter energy; source uniformity; product positioning; define risk-based requalification triggers affecting dose consistency and penetration	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0019	Radiation product tote/carton configuration	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses mass density; fill level; orientation; required outputs: worst-case dose distribution	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0020	Radiation product tote/carton configuration	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Radiation product tote/carton configuration	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0021	Radiation product tote/carton configuration	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for mass density; fill level; orientation; evaluate worst-case dose distribution	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0022	Radiation product tote/carton configuration	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-19-0023	Radiation product tote/carton configuration	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering worst-case dose distribution	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0024	Radiation product tote/carton configuration	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend mass density; fill level; orientation; define risk-based requalification triggers affecting worst-case dose distribution	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0025	Dosimeter batch mapping and reader	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses calibration; response curve; positioning; required outputs: dose measurements traceability	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0026	Dosimeter batch mapping and reader	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dosimeter batch mapping and reader	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0027	Dosimeter batch mapping and reader	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for calibration; response curve; positioning; evaluate dose measurements traceability	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0028	Dosimeter batch mapping and reader	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0029	Dosimeter batch mapping and reader	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose measurements traceability	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0030	Dosimeter batch mapping and reader	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend calibration; response curve; positioning; define risk-based requalification triggers affecting dose measurements traceability	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0031	Temperature-sensitive device irradiation profile	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dose heating; process dwell; cooling; required outputs: no adverse material change	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0032	Temperature-sensitive device irradiation profile	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Temperature-sensitive device irradiation profile	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0033	Temperature-sensitive device irradiation profile	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dose heating; process dwell; cooling; evaluate no adverse material change	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0034	Temperature-sensitive device irradiation profile	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0035	Temperature-sensitive device irradiation profile	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no adverse material change	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0036	Temperature-sensitive device irradiation profile	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dose heating; process dwell; cooling; define risk-based requalification triggers affecting no adverse material change	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0037	Irradiated polymer aging study	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dose range; embrittlement; oxidation; required outputs: maintenance of performance over shelf life	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0038	Irradiated polymer aging study	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Irradiated polymer aging study	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0039	Irradiated polymer aging study	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dose range; embrittlement; oxidation; evaluate maintenance of performance over shelf life	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0040	Irradiated polymer aging study	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0041	Irradiated polymer aging study	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering maintenance of performance over shelf life	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0042	Irradiated polymer aging study	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dose range; embrittlement; oxidation; define risk-based requalification triggers affecting maintenance of performance over shelf life	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0043	Radiation mapping phantom	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses worst geometry; density; pack patterns; required outputs: Dmin/Dmax identification	URS / DQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0044	Radiation mapping phantom	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Radiation mapping phantom	IQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0045	Radiation mapping phantom	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for worst geometry; density; pack patterns; evaluate Dmin/Dmax identification	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0046	Radiation mapping phantom	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-19-0047	Radiation mapping phantom	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering Dmin/Dmax identification	PQ	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	High
MDV-19-0048	Radiation mapping phantom	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend worst geometry; density; pack patterns; define risk-based requalification triggers affecting Dmin/Dmax identification	Routine / Change	Radiation-sterilized terminal sterile devices	M02 M07 M10 M13 M25	Medium
MDV-19-0049	Radiation sterilization dose establishment	Justify minimum sterilization dose and verification approach	ISO 11137 dose evidence for product/bioburden family	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0050	Radiation dose audit	Perform periodic dose verification/audit as applicable	Audit outcome and corrective action	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0051	Radiation bioburden method	Validate recovery, suitability and representativeness	Bioburden method qualification	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0052	Radiation material compatibility	Challenge maximum credible dose and cumulative dose	Mechanical, optical and biological property retention	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0053	Radiation product-family grouping	Demonstrate equivalence in bioburden and device configuration	Technical family/verification rationales	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0054	Radiation reprocessing / multiple passes	Set controls for re-exposure and maximum cumulative dose	Validated reprocessing disposition where permissible	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0055	Radiation outsourced release	Verify independent dosimetry and certificate review	Traceable dose / load / lot links	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High
MDV-19-0056	Radiation microbiological audits	Confirm bioburden trend consistent with dose method	Action thresholds and change impact decision	Lifecycle	Radiation sterilization	M10 M13 M25 M14	High

20 STERILIZATION - MOIST HEAT, DRY HEAT & VHP

68 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-20-0001	Steam autoclave for medical devices	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; pressure; air removal; exposure; required outputs: sterilant penetration and reproducible cycle	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0002	Steam autoclave for medical devices	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Steam autoclave for medical devices	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0003	Steam autoclave for medical devices	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; pressure; air removal; exposure; evaluate sterilant penetration and reproducible cycle	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0004	Steam autoclave for medical devices	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0005	Steam autoclave for medical devices	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterilant penetration and reproducible cycle	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0006	Steam autoclave for medical devices	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; pressure; air removal; exposure; define risk-based requalification triggers affecting sterilant penetration and reproducible cycle	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0007	Pre-vacuum steam cycle	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses vacuum depth; pulse count; condensate; required outputs: air removal and lethality	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0008	Pre-vacuum steam cycle	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pre-vacuum steam cycle	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0009	Pre-vacuum steam cycle	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for vacuum depth; pulse count; condensate; evaluate air removal and lethality	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0010	Pre-vacuum steam cycle	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0011	Pre-vacuum steam cycle	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering air removal and lethality	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0012	Pre-vacuum steam cycle	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend vacuum depth; pulse count; condensate; define risk-based requalification triggers affecting air removal and lethality	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0013	Steam sterilizer load racks	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses loading pattern; orientation; wrap configuration; required outputs: worst-case heat penetration	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0014	Steam sterilizer load racks	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Steam sterilizer load racks	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0015	Steam sterilizer load racks	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for loading pattern; orientation; wrap configuration; evaluate worst-case heat penetration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0016	Steam sterilizer load racks	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0017	Steam sterilizer load racks	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering worst-case heat penetration	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0018	Steam sterilizer load racks	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend loading pattern; orientation; wrap configuration; define risk-based requalification triggers affecting worst-case heat penetration	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0019	Steam sterilizer F0/thermal mapping	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cold spots; load density; logger placement; required outputs: defined thermal lethality	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0020	Steam sterilizer F0/thermal mapping	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Steam sterilizer F0/thermal mapping	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0021	Steam sterilizer F0/thermal mapping	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cold spots; load density; logger placement; evaluate defined thermal lethality	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0022	Steam sterilizer F0/thermal mapping	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-20-0023	Steam sterilizer F0/thermal mapping	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering defined thermal lethality	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0024	Steam sterilizer F0/thermal mapping	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cold spots; load density; logger placement; define risk-based requalification triggers affecting defined thermal lethality	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0025	Moist heat sterilizer steam quality	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses NCG; dryness; superheat where applicable; required outputs: steam suitability	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0026	Moist heat sterilizer steam quality	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Moist heat sterilizer steam quality	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0027	Moist heat sterilizer steam quality	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for NCG; dryness; superheat where applicable; evaluate steam suitability	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0028	Moist heat sterilizer steam quality	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0029	Moist heat sterilizer steam quality	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering steam suitability	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0030	Moist heat sterilizer steam quality	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend NCG; dryness; superheat where applicable; define risk-based requalification triggers affecting steam suitability	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0031	Dry heat sterilizer for device components	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses setpoint; load heat-up; exposure time; required outputs: validated dry heat treatment and materials	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0032	Dry heat sterilizer for device components	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dry heat sterilizer for device components	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0033	Dry heat sterilizer for device components	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for setpoint; load heat-up; exposure time; evaluate validated dry heat treatment and materials	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0034	Dry heat sterilizer for device components	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0035	Dry heat sterilizer for device components	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering validated dry heat treatment and materials	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0036	Dry heat sterilizer for device components	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend setpoint; load heat-up; exposure time; define risk-based requalification triggers affecting validated dry heat treatment and materials	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0037	Dry heat depyrogenation tunnel (if justified)	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses belt speed; cold point; endotoxin challenge; required outputs: endotoxin reduction and relevant product protection	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0038	Dry heat depyrogenation tunnel (if justified)	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dry heat depyrogenation tunnel (if justified)	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0039	Dry heat depyrogenation tunnel (if justified)	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for belt speed; cold point; endotoxin challenge; evaluate endotoxin reduction and relevant product protection	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0040	Dry heat depyrogenation tunnel (if justified)	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0041	Dry heat depyrogenation tunnel (if justified)	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering endotoxin reduction and relevant product protection	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0042	Dry heat depyrogenation tunnel (if justified)	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend belt speed; cold point; endotoxin challenge; define risk-based requalification triggers affecting endotoxin reduction and relevant product protection	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0043	Vaporized H2O2 sterilizer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses H2O2 concentration; pressure; dwell; humidity; required outputs: sterilant penetration and effective cycle	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0044	Vaporized H2O2 sterilizer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vaporized H2O2 sterilizer	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0045	Vaporized H2O2 sterilizer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for H2O2 concentration; pressure; dwell; humidity; evaluate sterilant penetration and effective cycle	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0046	Vaporized H2O2 sterilizer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-20-0047	Vaporized H2O2 sterilizer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterilant penetration and effective cycle	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0048	Vaporized H2O2 sterilizer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend H2O2 concentration; pressure; dwell; humidity; define risk-based requalification triggers affecting sterilant penetration and effective cycle	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0049	VHP load presentation and lumen challenge	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses lumen length; ID; pack orientation; required outputs: worst-case sterilant access	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0050	VHP load presentation and lumen challenge	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for VHP load presentation and lumen challenge	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0051	VHP load presentation and lumen challenge	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for lumen length; ID; pack orientation; evaluate worst-case sterilant access	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0052	VHP load presentation and lumen challenge	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0053	VHP load presentation and lumen challenge	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering worst-case sterilant access	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0054	VHP load presentation and lumen challenge	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend lumen length; ID; pack orientation; define risk-based requalification triggers affecting worst-case sterilant access	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0055	VHP aeration process	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses air exchange; residual oxidant; required outputs: safe residues and product compatibility	URS / DQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0056	VHP aeration process	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for VHP aeration process	IQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0057	VHP aeration process	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for air exchange; residual oxidant; evaluate safe residues and product compatibility	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0058	VHP aeration process	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0059	VHP aeration process	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe residues and product compatibility	PQ	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	High
MDV-20-0060	VHP aeration process	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend air exchange; residual oxidant; define risk-based requalification triggers affecting safe residues and product compatibility	Routine / Change	Heat/VHP sterilization as suitable to device/material	M02 M07 M11 M12 M13 M25	Medium
MDV-20-0061	Steam PQ thermal mapping	Challenge minimum/maximum load and cold spot	Validated thermal lethality and heat distribution	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0062	Steam microbiological PQ	Apply BI/physical monitoring as justified by cycle	Worst-case lethality evidence and rationale	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0063	Steam package integrity	Verify moisture and post-sterilization integrity	Dryness, barrier preservation and opening suitability	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0064	Steam cycle requalification	Evaluate maintenance, load, chamber, sensor changes	Repeat-validation plan based on documented risk	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0065	VHP material compatibility	Challenge worst-case repeats and oxidative changes	Function, label/ink and polymer integrity	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0066	VHP sterility validation	Verify BI/PCD performance and worst-case exposure	ISO 22441-based validation report	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0067	Dry heat compatibility	Check dimensional distortion and polymer instability	Mechanical/performance properties maintained	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High
MDV-20-0068	Dry heat endotoxin controls	Where depyrogenation claimed, validate worst-case challenge	Endotoxin recovery and log reduction evidence	Lifecycle	Moist heat and alternative sterilization	M11 M12 M13 M25	High

21 ASEPTIC PROCESSES, STERILE FILLING & CLEAN TRANSFER

69 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-21-0001	Aseptic assembly workstation	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses unidirectional airflow; intervention effects; hold time; required outputs: contamination control under operational conditions	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0002	Aseptic assembly workstation	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic assembly workstation	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0003	Aseptic assembly workstation	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for unidirectional airflow; intervention effects; hold time; evaluate contamination control under operational conditions	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0004	Aseptic assembly workstation	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0005	Aseptic assembly workstation	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering contamination control under operational conditions	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0006	Aseptic assembly workstation	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend unidirectional airflow; intervention effects; hold time; define risk-based requalification triggers affecting contamination control under operational conditions	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0007	Aseptic device fill line	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill weight; container closure; aseptic interventions; required outputs: fill accuracy and contamination assurance	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0008	Aseptic device fill line	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic device fill line	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0009	Aseptic device fill line	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill weight; container closure; aseptic interventions; evaluate fill accuracy and contamination assurance	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0010	Aseptic device fill line	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0011	Aseptic device fill line	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering fill accuracy and contamination assurance	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0012	Aseptic device fill line	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill weight; container closure; aseptic interventions; define risk-based requalification triggers affecting fill accuracy and contamination assurance	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0013	Aseptic liquid transfer tubing/connector	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses connection technique; leak; sanitization; required outputs: closed system transfer integrity	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0014	Aseptic liquid transfer tubing/connector	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic liquid transfer tubing/connector	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0015	Aseptic liquid transfer tubing/connector	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for connection technique; leak; sanitization; evaluate closed system transfer integrity	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0016	Aseptic liquid transfer tubing/connector	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-21-0017	Aseptic liquid transfer tubing/connector	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering closed system transfer integrity	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0018	Aseptic liquid transfer tubing/connector	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend connection technique; leak; sanitization; define risk-based requalification triggers affecting closed system transfer integrity	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0019	Aseptic peristaltic pump and tubing set	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tubing fatigue; pump accuracy; contact time; required outputs: repeatable aseptic dispensing and product compatibility	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0020	Aseptic peristaltic pump and tubing set	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic peristaltic pump and tubing set	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0021	Aseptic peristaltic pump and tubing set	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tubing fatigue; pump accuracy; contact time; evaluate repeatable aseptic dispensing and product compatibility	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0022	Aseptic peristaltic pump and tubing set	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0023	Aseptic peristaltic pump and tubing set	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering repeatable aseptic dispensing and product compatibility	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0024	Aseptic peristaltic pump and tubing set	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tubing fatigue; pump accuracy; contact time; define risk-based requalification triggers affecting repeatable aseptic dispensing and product compatibility	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0025	Aseptic syringe plunger stoppering station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses stopper depth; vacuum; positional alignment; required outputs: integral seal and contamination control	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0026	Aseptic syringe plunger stoppering station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic syringe plunger stoppering station	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0027	Aseptic syringe plunger stoppering station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for stopper depth; vacuum; positional alignment; evaluate integral seal and contamination control	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0028	Aseptic syringe plunger stoppering station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0029	Aseptic syringe plunger stoppering station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering integral seal and contamination control	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0030	Aseptic syringe plunger stoppering station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend stopper depth; vacuum; positional alignment; define risk-based requalification triggers affecting integral seal and contamination control	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0031	Aseptic barrier isolator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses leak rate; decontamination cycle; glove integrity; required outputs: barrier integrity and microbial control	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0032	Aseptic barrier isolator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic barrier isolator	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0033	Aseptic barrier isolator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for leak rate; decontamination cycle; glove integrity; evaluate barrier integrity and microbial control	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0034	Aseptic barrier isolator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-21-0035	Aseptic barrier isolator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering barrier integrity and microbial control	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0036	Aseptic barrier isolator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend leak rate; decontamination cycle; glove integrity; define risk-based requalification triggers affecting barrier integrity and microbial control	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0037	Aseptic RABS barrier system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses airflow; access interventions; glove/door integrity; required outputs: risk controls for aseptic operations	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0038	Aseptic RABS barrier system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic RABS barrier system	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0039	Aseptic RABS barrier system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for airflow; access interventions; glove/door integrity; evaluate risk controls for aseptic operations	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0040	Aseptic RABS barrier system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0041	Aseptic RABS barrier system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering risk controls for aseptic operations	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0042	Aseptic RABS barrier system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend airflow; access interventions; glove/door integrity; define risk-based requalification triggers affecting risk controls for aseptic operations	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0043	Sterile components depyrogenation/transfer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses exposure; endotoxin controls; transfer sequence; required outputs: sterile/clean component transfer	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0044	Sterile components depyrogenation/transfer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile components depyrogenation/transfer	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0045	Sterile components depyrogenation/transfer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for exposure; endotoxin controls; transfer sequence; evaluate sterile/clean component transfer	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0046	Sterile components depyrogenation/transfer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0047	Sterile components depyrogenation/transfer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterile/clean component transfer	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0048	Sterile components depyrogenation/transfer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend exposure; endotoxin controls; transfer sequence; define risk-based requalification triggers affecting sterile/clean component transfer	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0049	Aseptic robotic assembly cell	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses robot motions; critical zone disturbance; required outputs: no product contamination from movements	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0050	Aseptic robotic assembly cell	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Aseptic robotic assembly cell	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0051	Aseptic robotic assembly cell	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for robot motions; critical zone disturbance; evaluate no product contamination from movements	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0052	Aseptic robotic assembly cell	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-21-0053	Aseptic robotic assembly cell	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no product contamination from movements	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0054	Aseptic robotic assembly cell	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend robot motions; critical zone disturbance; define risk-based requalification triggers affecting no product contamination from movements	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0055	Sterile filtration train where used	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses filter integrity; load/compatibility; aseptic connections; required outputs: sterility assurance of device-associated liquid	URS / DQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0056	Sterile filtration train where used	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile filtration train where used	IQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0057	Sterile filtration train where used	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for filter integrity; load/compatibility; aseptic connections; evaluate sterility assurance of device-associated liquid	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0058	Sterile filtration train where used	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0059	Sterile filtration train where used	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterility assurance of device-associated liquid	PQ	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	High
MDV-21-0060	Sterile filtration train where used	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend filter integrity; load/compatibility; aseptic connections; define risk-based requalification triggers affecting sterility assurance of device-associated liquid	Routine / Change	Aseptically manufactured devices/combination products	M01 M02 M03 M07 M13 M15 M26	Medium
MDV-21-0061	Aseptic process simulation APS	Simulate worst interventions, durations, shifts and line speed	Contamination detection study design appropriate to process	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0062	APS growth promotion	Demonstrate growth capability of selected medium/organisms	Approved test showing media suitability	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0063	APS personnel interventions	Include typical and non-routine planned interventions	Intervention qualification and rationale	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0064	Aseptic personnel qualification	Gowning and microbiological monitoring capability	Documented qualification and periodic reassessment	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0065	Isolator leak / glove testing	Challenge leak detection and barrier breaches	Approved leak detection sensitivity limits	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0066	Airflow visualization at aseptic operations	Challenge actual operator and machine obstructions	Protective flow evidence	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0067	Sterile tubing connection qualification	Test aseptic connector integrity across rework conditions	Microbiological or physical integrity demonstration	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0068	Aseptic holding study	Validate max sterile component exposure and queue time	Chemical and microbiological risk-based limits	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High
MDV-21-0069	APS repeat triggers	Define line, shift, personnel, process change triggers	Risk-based APS requalification and trending	Lifecycle	Aseptic manufacturing	M02 M07 M13 M15 M26	High

22 STERILE BARRIER PACKAGING - FORMING, SEALING & ASSEMBLY

101 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0001	Rotary pouch heat sealer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses seal temperature; pressure; dwell; line speed; required outputs: seal width, strength and channel-free integrity	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0002	Rotary pouch heat sealer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Rotary pouch heat sealer	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0003	Rotary pouch heat sealer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for seal temperature; pressure; dwell; line speed; evaluate seal width, strength and channel-free integrity	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0004	Rotary pouch heat sealer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0005	Rotary pouch heat sealer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering seal width, strength and channel-free integrity	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0006	Rotary pouch heat sealer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend seal temperature; pressure; dwell; line speed; define risk-based requalification triggers affecting seal width, strength and channel-free integrity	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0007	Continuous band heat sealer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature distribution; roller speed; pressure; required outputs: seal uniformity across start/end and edges	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0008	Continuous band heat sealer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Continuous band heat sealer	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0009	Continuous band heat sealer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature distribution; roller speed; pressure; evaluate seal uniformity across start/end and edges	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0010	Continuous band heat sealer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0011	Continuous band heat sealer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering seal uniformity across start/end and edges	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0012	Continuous band heat sealer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature distribution; roller speed; pressure; define risk-based requalification triggers affecting seal uniformity across start/end and edges	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0013	Tyvek-to-film tray sealer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses tool temperature; force; sealing time; required outputs: sterile tray seal strength and integrity	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0014	Tyvek-to-film tray sealer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Tyvek-to-film tray sealer	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0015	Tyvek-to-film tray sealer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for tool temperature; force; sealing time; evaluate sterile tray seal strength and integrity	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0016	Tyvek-to-film tray sealer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0017	Tyvek-to-film tray sealer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterile tray seal strength and integrity	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0018	Tyvek-to-film tray sealer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend tool temperature; force; sealing time; define risk-based requalification triggers affecting sterile tray seal strength and integrity	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0019	Vacuum blister packaging machine	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses vacuum level; film forming; index; required outputs: tray fit and deformation prevention	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0020	Vacuum blister packaging machine	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vacuum blister packaging machine	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0021	Vacuum blister packaging machine	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for vacuum level; film forming; index; evaluate tray fit and deformation prevention	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0022	Vacuum blister packaging machine	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0023	Vacuum blister packaging machine	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tray fit and deformation prevention	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0024	Vacuum blister packaging machine	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend vacuum level; film forming; index; define risk-based requalification triggers affecting tray fit and deformation prevention	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0025	Form-fill-seal device packer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses forming temperature; seal registration; tension; required outputs: package integrity and part placement	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0026	Form-fill-seal device packer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Form-fill-seal device packer	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0027	Form-fill-seal device packer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for forming temperature; seal registration; tension; evaluate package integrity and part placement	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0028	Form-fill-seal device packer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0029	Form-fill-seal device packer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering package integrity and part placement	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0030	Form-fill-seal device packer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend forming temperature; seal registration; tension; define risk-based requalification triggers affecting package integrity and part placement	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0031	Medical paper pouch sealer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; web alignment; peel characteristics; required outputs: seal strength without fiber tear	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0032	Medical paper pouch sealer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical paper pouch sealer	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0033	Medical paper pouch sealer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; web alignment; peel characteristics; evaluate seal strength without fiber tear	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0034	Medical paper pouch sealer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0035	Medical paper pouch sealer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering seal strength without fiber tear	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0036	Medical paper pouch sealer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; web alignment; peel characteristics; define risk-based requalification triggers affecting seal strength without fiber tear	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0037	RF seal for sterile flexible pack	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses power; electrode pressure; weld line; required outputs: sterile barrier leak resistance	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0038	RF seal for sterile flexible pack	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for RF seal for sterile flexible pack	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0039	RF seal for sterile flexible pack	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for power; electrode pressure; weld line; evaluate sterile barrier leak resistance	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0040	RF seal for sterile flexible pack	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0041	RF seal for sterile flexible pack	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterile barrier leak resistance	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0042	RF seal for sterile flexible pack	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend power; electrode pressure; weld line; define risk-based requalification triggers affecting sterile barrier leak resistance	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0043	Ultrasonic bag sealing station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses weld energy; pressure; speed; required outputs: continuous robust weld without pinholes	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0044	Ultrasonic bag sealing station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ultrasonic bag sealing station	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0045	Ultrasonic bag sealing station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for weld energy; pressure; speed; evaluate continuous robust weld without pinholes	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0046	Ultrasonic bag sealing station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0047	Ultrasonic bag sealing station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering continuous robust weld without pinholes	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0048	Ultrasonic bag sealing station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend weld energy; pressure; speed; define risk-based requalification triggers affecting continuous robust weld without pinholes	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0049	Peelable lid application station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses seal dwell; pressure; peel interface; required outputs: controlled peelability and integrity	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0050	Peelable lid application station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Peelable lid application station	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0051	Peelable lid application station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for seal dwell; pressure; peel interface; evaluate controlled peelability and integrity	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0052	Peelable lid application station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0053	Peelable lid application station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled peelability and integrity	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0054	Peelable lid application station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend seal dwell; pressure; peel interface; define risk-based requalification triggers affecting controlled peelability and integrity	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0055	Protective thermoformed tray assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses formed cavities; product support; closure; required outputs: device restraint and package protection	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0056	Protective thermoformed tray assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Protective thermoformed tray assembly	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0057	Protective thermoformed tray assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for formed cavities; product support; closure; evaluate device restraint and package protection	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0058	Protective thermoformed tray assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0059	Protective thermoformed tray assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering device restraint and package protection	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0060	Protective thermoformed tray assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend formed cavities; product support; closure; define risk-based requalification triggers affecting device restraint and package protection	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0061	Automated pouch product insertion	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses orientation; rubbing; reject logic; required outputs: no punctures or package damage	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0062	Automated pouch product insertion	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated pouch product insertion	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0063	Automated pouch product insertion	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for orientation; rubbing; reject logic; evaluate no punctures or package damage	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0064	Automated pouch product insertion	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0065	Automated pouch product insertion	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no punctures or package damage	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0066	Automated pouch product insertion	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend orientation; rubbing; reject logic; define risk-based requalification triggers affecting no punctures or package damage	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0067	Desiccant / humidity-control pack out	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses desiccant amount; RH exposure; timing; required outputs: product stability and moisture control	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0068	Desiccant / humidity-control pack out	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Desiccant / humidity-control pack out	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0069	Desiccant / humidity-control pack out	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for desiccant amount; RH exposure; timing; evaluate product stability and moisture control	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0070	Desiccant / humidity-control pack out	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0071	Desiccant / humidity-control pack out	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering product stability and moisture control	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0072	Desiccant / humidity-control pack out	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend desiccant amount; RH exposure; timing; define risk-based requalification triggers affecting product stability and moisture control	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0073	Sterile barrier package printing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses print pressure; ink cure; location; required outputs: label legibility with no barrier damage	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0074	Sterile barrier package printing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile barrier package printing	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0075	Sterile barrier package printing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for print pressure; ink cure; location; evaluate label legibility with no barrier damage	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0076	Sterile barrier package printing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0077	Sterile barrier package printing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering label legibility with no barrier damage	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0078	Sterile barrier package printing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend print pressure; ink cure; location; define risk-based requalification triggers affecting label legibility with no barrier damage	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0079	Sterile pack vision integrity inspection	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses defect library; seal wrinkles; detection limits; required outputs: reliable channel/void detection	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0080	Sterile pack vision integrity inspection	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile pack vision integrity inspection	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0081	Sterile pack vision integrity inspection	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for defect library; seal wrinkles; detection limits; evaluate reliable channel/void detection	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0082	Sterile pack vision integrity inspection	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0083	Sterile pack vision integrity inspection	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reliable channel/void detection	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0084	Sterile pack vision integrity inspection	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend defect library; seal wrinkles; detection limits; define risk-based requalification triggers affecting reliable channel/void detection	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0085	Multi-lumen device protective packaging	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses secure winding; bend radius; retention; required outputs: no kinking and sterile barrier preservation	URS / DQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0086	Multi-lumen device protective packaging	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Multi-lumen device protective packaging	IQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0087	Multi-lumen device protective packaging	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for secure winding; bend radius; retention; evaluate no kinking and sterile barrier preservation	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0088	Multi-lumen device protective packaging	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-22-0089	Multi-lumen device protective packaging	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no kinking and sterile barrier preservation	PQ	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	High
MDV-22-0090	Multi-lumen device protective packaging	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend secure winding; bend radius; retention; define risk-based requalification triggers affecting no kinking and sterile barrier preservation	Routine / Change	Terminally sterilized device packaging; sterile barrier systems	M01 M02 M07 M08 M28	Medium
MDV-22-0091	Packaging material qualification	Verify porosity, strength, microbial barrier and sealing range	Incoming material and shelf-life qualified specification	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0092	Sterile barrier seal window	OQ low/nominal/high parameter combinations	Acceptable seal strength and integrity under edges	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0093	Worst-case product load	PQ challenge maximum bulk, rigid edges and operator	Product size/tool/pack worst-case study	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0094	Seal tensile test	Qualify testing method/sample geometry	ASTM F88 or justified alternative with GR&R	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0095	Dye penetration or bubble leak test	Validate method capability and suitability for package type	Defect detection near risk-defined limit	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0096	Visual seal inspection	Validate operator qualification and defect reference standards	False-accept/false-reject rates and reproducibility	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0097	Package shelf-life	Age package and repeat strength/integrity tests	Sterile barrier maintained through labeled shelf-life	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0098	Package distribution	Test distribution simulation and post-ship integrity	Handling and transport robustness	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0099	Opening / aseptic presentation	Verify peel characteristics and aseptic presentation	Usability evaluation and damage control	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0100	Reprocessed pack out	Control rework/reseal and potential damage	Rework validation with prohibition where appropriate	Lifecycle	Sterile barrier validation	M08 M28 M07	High
MDV-22-0101	Packaging change assessment	Challenge paper/film supplier, thickness, format changes	Requalification matrix and equivalence study	Lifecycle	Sterile barrier validation	M08 M28 M07	High

23 LABELING, UDI, VISION & FINAL PACKAGING

78 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-23-0001	UDI inkjet coder	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses ink drying; print position; scanning; required outputs: durable code readability and traceability	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0002	UDI inkjet coder	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UDI inkjet coder	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0003	UDI inkjet coder	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for ink drying; print position; scanning; evaluate durable code readability and traceability	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0004	UDI inkjet coder	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0005	UDI inkjet coder	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering durable code readability and traceability	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0006	UDI inkjet coder	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend ink drying; print position; scanning; define risk-based requalification triggers affecting durable code readability and traceability	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0007	Laser UDI marking station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses mark depth; contrast; image quality; required outputs: permanent label accuracy without material degradation	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0008	Laser UDI marking station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser UDI marking station	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0009	Laser UDI marking station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for mark depth; contrast; image quality; evaluate permanent label accuracy without material degradation	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0010	Laser UDI marking station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0011	Laser UDI marking station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering permanent label accuracy without material degradation	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0012	Laser UDI marking station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend mark depth; contrast; image quality; define risk-based requalification triggers affecting permanent label accuracy without material degradation	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0013	Thermal transfer label printer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses ribbon; print density; smear resistance; required outputs: readability after abrasion and aging	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0014	Thermal transfer label printer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Thermal transfer label printer	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0015	Thermal transfer label printer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for ribbon; print density; smear resistance; evaluate readability after abrasion and aging	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0016	Thermal transfer label printer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0017	Thermal transfer label printer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering readability after abrasion and aging	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0018	Thermal transfer label printer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend ribbon; print density; smear resistance; define risk-based requalification triggers affecting readability after abrasion and aging	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0019	Automated label applicator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses label location; pressure; adhesive; required outputs: correct label placement and adhesion	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0020	Automated label applicator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated label applicator	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0021	Automated label applicator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for label location; pressure; adhesive; evaluate correct label placement and adhesion	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0022	Automated label applicator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-23-0023	Automated label applicator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct label placement and adhesion	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0024	Automated label applicator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend label location; pressure; adhesive; define risk-based requalification triggers affecting correct label placement and adhesion	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0025	Barcode and QR verifier	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses symbol grade; scanner calibration; required outputs: UDI scannability and data matching	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0026	Barcode and QR verifier	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Barcode and QR verifier	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0027	Barcode and QR verifier	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for symbol grade; scanner calibration; evaluate UDI scannability and data matching	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0028	Barcode and QR verifier	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0029	Barcode and QR verifier	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering UDI scannability and data matching	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0030	Barcode and QR verifier	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend symbol grade; scanner calibration; define risk-based requalification triggers affecting UDI scannability and data matching	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0031	Cartoner	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses carton handling; placement; fill; required outputs: correct device and IFU inclusion	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0032	Cartoner	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cartoner	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0033	Cartoner	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for carton handling; placement; fill; evaluate correct device and IFU inclusion	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0034	Cartoner	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0035	Cartoner	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct device and IFU inclusion	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0036	Cartoner	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend carton handling; placement; fill; define risk-based requalification triggers affecting correct device and IFU inclusion	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0037	IFU leaflet insertion station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fold sequence; quantity; reader detection; required outputs: complete device instructions	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0038	IFU leaflet insertion station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IFU leaflet insertion station	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0039	IFU leaflet insertion station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fold sequence; quantity; reader detection; evaluate complete device instructions	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0040	IFU leaflet insertion station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0041	IFU leaflet insertion station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering complete device instructions	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0042	IFU leaflet insertion station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fold sequence; quantity; reader detection; define risk-based requalification triggers affecting complete device instructions	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0043	Serialization and aggregation system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses lot; serial; pack hierarchy; rejection; required outputs: traceability integrity	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0044	Serialization and aggregation system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Serialization and aggregation system	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0045	Serialization and aggregation system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for lot; serial; pack hierarchy; rejection; evaluate traceability integrity	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0046	Serialization and aggregation system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-23-0047	Serialization and aggregation system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering traceability integrity	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0048	Serialization and aggregation system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend lot; serial; pack hierarchy; rejection; define risk-based requalification triggers affecting traceability integrity	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0049	Multi-lingual artwork control workflow	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses artwork version; translations; target market; required outputs: correct claims and symbols per market	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0050	Multi-lingual artwork control workflow	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Multi-lingual artwork control workflow	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0051	Multi-lingual artwork control workflow	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for artwork version; translations; target market; evaluate correct claims and symbols per market	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0052	Multi-lingual artwork control workflow	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0053	Multi-lingual artwork control workflow	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct claims and symbols per market	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0054	Multi-lingual artwork control workflow	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend artwork version; translations; target market; define risk-based requalification triggers affecting correct claims and symbols per market	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0055	Weight checkweigher for finished packs	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reference weights; false rejects; underweight; required outputs: component completeness detection	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0056	Weight checkweigher for finished packs	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Weight checkweigher for finished packs	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0057	Weight checkweigher for finished packs	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reference weights; false rejects; underweight; evaluate component completeness detection	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0058	Weight checkweigher for finished packs	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0059	Weight checkweigher for finished packs	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering component completeness detection	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0060	Weight checkweigher for finished packs	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reference weights; false rejects; underweight; define risk-based requalification triggers affecting component completeness detection	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0061	Automated tamper evident labeler	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses seal tamper evidence; adhesive cure; required outputs: tamper evidence retained through shipment	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0062	Automated tamper evident labeler	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated tamper evident labeler	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0063	Automated tamper evident labeler	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for seal tamper evidence; adhesive cure; evaluate tamper evidence retained through shipment	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0064	Automated tamper evident labeler	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0065	Automated tamper evident labeler	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering tamper evidence retained through shipment	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0066	Automated tamper evident labeler	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend seal tamper evidence; adhesive cure; define risk-based requalification triggers affecting tamper evidence retained through shipment	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0067	Final carton seal application	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses adhesive/case tape settings; carton compression; required outputs: safe transport containment	URS / DQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0068	Final carton seal application	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Final carton seal application	IQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0069	Final carton seal application	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for adhesive/case tape settings; carton compression; evaluate safe transport containment	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0070	Final carton seal application	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-23-0071	Final carton seal application	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe transport containment	PQ	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	High
MDV-23-0072	Final carton seal application	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend adhesive/case tape settings; carton compression; define risk-based requalification triggers affecting safe transport containment	Routine / Change	All devices and IVDs; sterile/nonsterile	M01 M02 M03 M04 M05 M20 M21	Medium
MDV-23-0073	UDI data consistency	Cross-check label, ERP, device master and regulatory database	Accurate UDI-DI/PI assignments and pack hierarchy	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High
MDV-23-0074	Label adhesion challenge	Test humidity, sterilization and shelf-life effects	No loss of critical warnings/expiry/UDI	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High
MDV-23-0075	IFU comprehension	Verify critical warnings and steps are understandable	User-oriented validation where risk requires	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High
MDV-23-0076	Expiry-date calculation	Verify validated shelf life and system date logic	No release beyond qualified age	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High
MDV-23-0077	Electronic labeling	Validate retrieval, version control and offline access	Correct approved version accessible to intended users	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High
MDV-23-0078	Market language control	Challenge translations and symbol interpretations	Regional labeling compliance review	Lifecycle	Medical devices / IVD	M03 M04 M05 M20 M21	High

24 CLEANING, DISINFECTION, RESIDUE & CONTAMINATION CONTROL

95 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0001	Ultrasonic cleaning bath	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses frequency; power; loading; solution age; required outputs: particulate and oil removal without damage	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0002	Ultrasonic cleaning bath	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ultrasonic cleaning bath	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0003	Ultrasonic cleaning bath	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for frequency; power; loading; solution age; evaluate particulate and oil removal without damage	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0004	Ultrasonic cleaning bath	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0005	Ultrasonic cleaning bath	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering particulate and oil removal without damage	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0006	Ultrasonic cleaning bath	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend frequency; power; loading; solution age; define risk-based requalification triggers affecting particulate and oil removal without damage	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0007	Multistage aqueous washer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses spray pressure; rinse conductivity; cycle time; required outputs: soil removal and controlled residues	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0008	Multistage aqueous washer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Multistage aqueous washer	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0009	Multistage aqueous washer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for spray pressure; rinse conductivity; cycle time; evaluate soil removal and controlled residues	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0010	Multistage aqueous washer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0011	Multistage aqueous washer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering soil removal and controlled residues	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0012	Multistage aqueous washer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend spray pressure; rinse conductivity; cycle time; define risk-based requalification triggers affecting soil removal and controlled residues	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0013	Solvent cleaning workstation	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses solvent type; contact time; exchange; required outputs: organic residue and material compatibility	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0014	Solvent cleaning workstation	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Solvent cleaning workstation	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0015	Solvent cleaning workstation	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for solvent type; contact time; exchange; evaluate organic residue and material compatibility	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0016	Solvent cleaning workstation	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0017	Solvent cleaning workstation	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering organic residue and material compatibility	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0018	Solvent cleaning workstation	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend solvent type; contact time; exchange; define risk-based requalification triggers affecting organic residue and material compatibility	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0019	CIP skid for IVD reagent tanks	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flow; time; temperature; conductivity; required outputs: reproducible wet cleaning performance	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0020	CIP skid for IVD reagent tanks	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for CIP skid for IVD reagent tanks	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0021	CIP skid for IVD reagent tanks	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flow; time; temperature; conductivity; evaluate reproducible wet cleaning performance	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0022	CIP skid for IVD reagent tanks	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0023	CIP skid for IVD reagent tanks	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reproducible wet cleaning performance	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0024	CIP skid for IVD reagent tanks	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flow; time; temperature; conductivity; define risk-based requalification triggers affecting reproducible wet cleaning performance	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0025	Automated glass/metal component washer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses rack geometry; spray shadowing; rinse; required outputs: worst-case contact surface cleanliness	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0026	Automated glass/metal component washer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated glass/metal component washer	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0027	Automated glass/metal component washer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for rack geometry; spray shadowing; rinse; evaluate worst-case contact surface cleanliness	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0028	Automated glass/metal component washer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0029	Automated glass/metal component washer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering worst-case contact surface cleanliness	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0030	Automated glass/metal component washer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend rack geometry; spray shadowing; rinse; define risk-based requalification triggers affecting worst-case contact surface cleanliness	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0031	Manual cleaning of implant tools	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses brush type; technique; operators; required outputs: residue/bioburden within approved limits	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0032	Manual cleaning of implant tools	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Manual cleaning of implant tools	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0033	Manual cleaning of implant tools	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for brush type; technique; operators; evaluate residue/bioburden within approved limits	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0034	Manual cleaning of implant tools	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0035	Manual cleaning of implant tools	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering residue/bioburden within approved limits	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0036	Manual cleaning of implant tools	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend brush type; technique; operators; define risk-based requalification triggers affecting residue/bioburden within approved limits	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0037	Cleanroom sanitization / fogging system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses disinfectant concentration; coverage; dwell; required outputs: environment microbial reduction and material compatibility	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0038	Cleanroom sanitization / fogging system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleanroom sanitization / fogging system	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0039	Cleanroom sanitization / fogging system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for disinfectant concentration; coverage; dwell; evaluate environment microbial reduction and material compatibility	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0040	Cleanroom sanitization / fogging system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0041	Cleanroom sanitization / fogging system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering environment microbial reduction and material compatibility	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0042	Cleanroom sanitization / fogging system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend disinfectant concentration; coverage; dwell; define risk-based requalification triggers affecting environment microbial reduction and material compatibility	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0043	Vaporized H2O2 bio-decontamination of isolator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses dose; humidity; distribution; catalysis; required outputs: biological decontamination cycle efficacy	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0044	Vaporized H2O2 bio-decontamination of isolator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vaporized H2O2 bio-decontamination of isolator	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0045	Vaporized H2O2 bio-decontamination of isolator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for dose; humidity; distribution; catalysis; evaluate biological decontamination cycle efficacy	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0046	Vaporized H2O2 bio-decontamination of isolator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0047	Vaporized H2O2 bio-decontamination of isolator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biological decontamination cycle efficacy	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0048	Vaporized H2O2 bio-decontamination of isolator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend dose; humidity; distribution; catalysis; define risk-based requalification triggers affecting biological decontamination cycle efficacy	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0049	Micro-cleaning of lumened devices	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flush volume; flow; lumen geometry; required outputs: cleaning of hardest-to-reach internal surfaces	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0050	Micro-cleaning of lumened devices	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Micro-cleaning of lumened devices	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0051	Micro-cleaning of lumened devices	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flush volume; flow; lumen geometry; evaluate cleaning of hardest-to-reach internal surfaces	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0052	Micro-cleaning of lumened devices	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0053	Micro-cleaning of lumened devices	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cleaning of hardest-to-reach internal surfaces	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0054	Micro-cleaning of lumened devices	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flush volume; flow; lumen geometry; define risk-based requalification triggers affecting cleaning of hardest-to-reach internal surfaces	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0055	Automated air blowoff/particle removal	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses air quality; flow; fixture spacing; required outputs: particle removal without redeposition	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0056	Automated air blowoff/particle removal	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated air blowoff/particle removal	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0057	Automated air blowoff/particle removal	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for air quality; flow; fixture spacing; evaluate particle removal without redeposition	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0058	Automated air blowoff/particle removal	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0059	Automated air blowoff/particle removal	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering particle removal without redeposition	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0060	Automated air blowoff/particle removal	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend air quality; flow; fixture spacing; define risk-based requalification triggers affecting particle removal without redeposition	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0061	Pure-water final rinse station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses water microbial quality; rinse volume; drainage; required outputs: residual cleaning agent removal	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0062	Pure-water final rinse station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Pure-water final rinse station	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0063	Pure-water final rinse station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for water microbial quality; rinse volume; drainage; evaluate residual cleaning agent removal	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0064	Pure-water final rinse station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0065	Pure-water final rinse station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering residual cleaning agent removal	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0066	Pure-water final rinse station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend water microbial quality; rinse volume; drainage; define risk-based requalification triggers affecting residual cleaning agent removal	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0067	Drying oven / nitrogen blowdown	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; dwell; gas quality; required outputs: residual moisture and recontamination prevention	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0068	Drying oven / nitrogen blowdown	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Drying oven / nitrogen blowdown	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0069	Drying oven / nitrogen blowdown	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; dwell; gas quality; evaluate residual moisture and recontamination prevention	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0070	Drying oven / nitrogen blowdown	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0071	Drying oven / nitrogen blowdown	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering residual moisture and recontamination prevention	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0072	Drying oven / nitrogen blowdown	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; dwell; gas quality; define risk-based requalification triggers affecting residual moisture and recontamination prevention	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0073	Environmental surface disinfection	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses contact time; frequency; hard-to-wet surfaces; required outputs: disinfection effectiveness in controlled areas	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0074	Environmental surface disinfection	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Environmental surface disinfection	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0075	Environmental surface disinfection	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for contact time; frequency; hard-to-wet surfaces; evaluate disinfection effectiveness in controlled areas	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0076	Environmental surface disinfection	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0077	Environmental surface disinfection	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering disinfection effectiveness in controlled areas	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0078	Environmental surface disinfection	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend contact time; frequency; hard-to-wet surfaces; define risk-based requalification triggers affecting disinfection effectiveness in controlled areas	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0079	Cleaned component protected holding cabinet	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses hold time; airflow; humidity; required outputs: cleanliness maintenance before pack-out	URS / DQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0080	Cleaned component protected holding cabinet	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cleaned component protected holding cabinet	IQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0081	Cleaned component protected holding cabinet	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for hold time; airflow; humidity; evaluate cleanliness maintenance before pack-out	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0082	Cleaned component protected holding cabinet	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0083	Cleaned component protected holding cabinet	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cleanliness maintenance before pack-out	PQ	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	High
MDV-24-0084	Cleaned component protected holding cabinet	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend hold time; airflow; humidity; define risk-based requalification triggers affecting cleanliness maintenance before pack-out	Routine / Change	Device-contact tools; reusable tooling; sterile components	M01 M02 M07 M13 M14 M32	Medium
MDV-24-0085	Cleaning limit derivation	Set scientifically justified particulate, chemical, microbial and endotoxin limits	Biological risk/material suitability based limits rather than default pharma PDE	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0086	Worst-case device geometry	Select lumens, hinges, rough and porous surfaces	Approved cleanability challenge model	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0087	Residue sampling recovery	Validate swab/rinse extraction efficiency	Recovery by soil, material and location	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0088	Particulate measurement method	Set particle size, counting and sample extraction capability	ISO 19227 where orthopedic implants applicable	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0089	Bioburden method post-cleaning	Demonstrate recovery and material neutralization	ISO 11737-1 method validation data	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0090	Cleaning agent residues	Validate analytical method for surfactant / solvent	Sensitive method with material-related limits	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0091	Disinfectant rotation	Evaluate efficacy against facility isolates where justified	Approved selection and periodic monitoring	Lifecycle	Device cleanliness	M07 M13 M14 M32	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-24-0092	Clean hold time	Validate maximum time before packaging/sterilization	Relevant contamination and residue stability	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0093	Dirty hold time	Assess residue aging and dried-on soils	Worst-case cleaning challenge	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0094	Reprocessing/reusable device IFU	Validate manufacturer cleaning and reprocessing instructions	Simulated-use soil / repeated cycles and risk controls	Lifecycle	Device cleanliness	M07 M13 M14 M32	High
MDV-24-0095	Device rinse-water suitability	Assess water microbiology, endotoxin and material contamination	Process-specific acceptance and trends	Lifecycle	Device cleanliness	M07 M13 M14 M32	High

25 MICROBIOLOGY, STERILITY, ENDOTOXIN & LAB METHODS

85 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-25-0001	Bioburden filtration apparatus	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses filter lot; extraction recovery; inhibition; required outputs: accurate device bioburden enumeration	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0002	Bioburden filtration apparatus	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bioburden filtration apparatus	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0003	Bioburden filtration apparatus	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for filter lot; extraction recovery; inhibition; evaluate accurate device bioburden enumeration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0004	Bioburden filtration apparatus	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0005	Bioburden filtration apparatus	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering accurate device bioburden enumeration	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0006	Bioburden filtration apparatus	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend filter lot; extraction recovery; inhibition; define risk-based requalification triggers affecting accurate device bioburden enumeration	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0007	Bioburden incubation system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature; time; culture recovery; required outputs: microorganism recovery and traceable monitoring	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0008	Bioburden incubation system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Bioburden incubation system	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0009	Bioburden incubation system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature; time; culture recovery; evaluate microorganism recovery and traceable monitoring	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0010	Bioburden incubation system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0011	Bioburden incubation system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering microorganism recovery and traceable monitoring	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0012	Bioburden incubation system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature; time; culture recovery; define risk-based requalification triggers affecting microorganism recovery and traceable monitoring	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0013	Sterility test isolator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses leak; decontamination; airflow; required outputs: testing area asepsis and false-positive prevention	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0014	Sterility test isolator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterility test isolator	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0015	Sterility test isolator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for leak; decontamination; airflow; evaluate testing area asepsis and false-positive prevention	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0016	Sterility test isolator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0017	Sterility test isolator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering testing area asepsis and false-positive prevention	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0018	Sterility test isolator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend leak; decontamination; airflow; define risk-based requalification triggers affecting testing area asepsis and false-positive prevention	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0019	Sterility test membrane filtration rig	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sterilization; fluid compatibility; flushing; required outputs: test method validity for device extracts	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0020	Sterility test membrane filtration rig	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterility test membrane filtration rig	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0021	Sterility test membrane filtration rig	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sterilization; fluid compatibility; flushing; evaluate test method validity for device extracts	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0022	Sterility test membrane filtration rig	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-25-0023	Sterility test membrane filtration rig	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering test method validity for device extracts	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0024	Sterility test membrane filtration rig	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sterilization; fluid compatibility; flushing; define risk-based requalification triggers affecting test method validity for device extracts	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0025	LAL/BET kinetic reader	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses calibration curve; endotoxin interference; required outputs: endotoxin detection in device rinses	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0026	LAL/BET kinetic reader	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for LAL/BET kinetic reader	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0027	LAL/BET kinetic reader	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for calibration curve; endotoxin interference; evaluate endotoxin detection in device rinses	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0028	LAL/BET kinetic reader	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0029	LAL/BET kinetic reader	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering endotoxin detection in device rinses	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0030	LAL/BET kinetic reader	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend calibration curve; endotoxin interference; define risk-based requalification triggers affecting endotoxin detection in device rinses	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0031	Incubator for microbiological media	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature uniformity; recovery; data logging; required outputs: reproducible incubation	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0032	Incubator for microbiological media	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Incubator for microbiological media	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0033	Incubator for microbiological media	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature uniformity; recovery; data logging; evaluate reproducible incubation	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0034	Incubator for microbiological media	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0035	Incubator for microbiological media	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reproducible incubation	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0036	Incubator for microbiological media	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature uniformity; recovery; data logging; define risk-based requalification triggers affecting reproducible incubation	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0037	Autoclave for lab decontamination	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cycle penetration; load distribution; required outputs: biosafety waste decontamination	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0038	Autoclave for lab decontamination	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Autoclave for lab decontamination	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0039	Autoclave for lab decontamination	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cycle penetration; load distribution; evaluate biosafety waste decontamination	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0040	Autoclave for lab decontamination	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0041	Autoclave for lab decontamination	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biosafety waste decontamination	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0042	Autoclave for lab decontamination	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cycle penetration; load distribution; define risk-based requalification triggers affecting biosafety waste decontamination	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0043	Laminar-flow microbiology cabinet	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses HEPA leak; airflow; particle counts; required outputs: controlled sample manipulations	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0044	Laminar-flow microbiology cabinet	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laminar-flow microbiology cabinet	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0045	Laminar-flow microbiology cabinet	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for HEPA leak; airflow; particle counts; evaluate controlled sample manipulations	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0046	Laminar-flow microbiology cabinet	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-25-0047	Laminar-flow microbiology cabinet	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled sample manipulations	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0048	Laminar-flow microbiology cabinet	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend HEPA leak; airflow; particle counts; define risk-based requalification triggers affecting controlled sample manipulations	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0049	Microbial identification analyzer	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses ID database; QC challenge; result interpretation; required outputs: organism identification reliability	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0050	Microbial identification analyzer	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microbial identification analyzer	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0051	Microbial identification analyzer	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for ID database; QC challenge; result interpretation; evaluate organism identification reliability	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0052	Microbial identification analyzer	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0053	Microbial identification analyzer	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering organism identification reliability	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0054	Microbial identification analyzer	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend ID database; QC challenge; result interpretation; define risk-based requalification triggers affecting organism identification reliability	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0055	Air sampler and settle plate exposure program	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sampler volume; placement; incubation; required outputs: reproducible facility microbiological results	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0056	Air sampler and settle plate exposure program	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Air sampler and settle plate exposure program	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0057	Air sampler and settle plate exposure program	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sampler volume; placement; incubation; evaluate reproducible facility microbiological results	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0058	Air sampler and settle plate exposure program	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0059	Air sampler and settle plate exposure program	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reproducible facility microbiological results	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0060	Air sampler and settle plate exposure program	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sampler volume; placement; incubation; define risk-based requalification triggers affecting reproducible facility microbiological results	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0061	Media prep vessel / autoclave	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pH; sterilization; growth promotion; required outputs: media performance and batch consistency	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0062	Media prep vessel / autoclave	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Media prep vessel / autoclave	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0063	Media prep vessel / autoclave	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pH; sterilization; growth promotion; evaluate media performance and batch consistency	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0064	Media prep vessel / autoclave	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0065	Media prep vessel / autoclave	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering media performance and batch consistency	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0066	Media prep vessel / autoclave	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pH; sterilization; growth promotion; define risk-based requalification triggers affecting media performance and batch consistency	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0067	Rapid microbiology assay system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses false positive/negative; matrix effects; required outputs: suitability for test item and intended use	URS / DQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0068	Rapid microbiology assay system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Rapid microbiology assay system	IQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0069	Rapid microbiology assay system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for false positive/negative; matrix effects; evaluate suitability for test item and intended use	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0070	Rapid microbiology assay system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-25-0071	Rapid microbiology assay system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering suitability for test item and intended use	PQ	Sterility assurance and microbiological testing	M02 M07 M13 M14	High
MDV-25-0072	Rapid microbiology assay system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend false positive/negative; matrix effects; define risk-based requalification triggers affecting suitability for test item and intended use	Routine / Change	Sterility assurance and microbiological testing	M02 M07 M13 M14	Medium
MDV-25-0073	Bioburden recovery efficiency	Validate recovery from representative difficult device geometries	Method suitability and recovery correction / rationale	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0074	Bioburden method inhibitory substances	Demonstrate neutralization and test portion effects	No false low counts from product matrix	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0075	Sterility test suitability	Demonstrate inhibition/neutralization and method applicability	Growth recovery with device extracts	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0076	Sterility assurance linkage	Link process capability to sterile claim, not just finished test	Validated sterilization process and routine control evidence	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0077	Endotoxin extract method	Validate extraction time, volume, temperature and interference	Suitable endotoxin limits tied to patient exposure	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0078	Endotoxin pooling	Demonstrate risk-based pooling and sensitivity	No masked contamination at release decision	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0079	Environmental monitoring locations	Justify surface, air, glove and personnel samples	Facility microbiological contamination risk mapping	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0080	Environmental alert / action levels	Build rational site-specific limits and excursion response	Trending and CAPA protocols	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0081	Microbial ID trending	Track objectionable organisms and sterile-zone flora	Risk-based investigation and control plan	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0082	Disinfectant efficacy test	Challenge relevant surfaces and environmental isolates	Validated contact time and efficacy	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0083	Media growth promotion	Perform acceptance for microbiology media batches	Qualified challenge organisms and recovery	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0084	Sample transport	Validate time, temperature and containers for viable organisms	Sample stability and recovery	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High
MDV-25-0085	Rapid microbiology vs compendial	Validate method equivalence with reference method	Sensitivity, specificity, robust detection limits	Lifecycle	Sterile/nonsterile device products	M07 M13 M26	High

26 ANALYTICAL, PHYSICAL & MATERIALS TEST METHOD VALIDATION

22 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-26-0001	Tensile strength method	Determine repeatability, grips, loading rate, specimen preparation	Fit-for-purpose precision and bias	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0002	Peel / bond test method	Validate grip alignment and peeling speed	Sensitivity to low-strength bonded joints	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0003	Pressure leak test method	Establish detection threshold, fixtures and limits	Leak reference artifacts and false accepts	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0004	Burst strength method	Verify pressure ramp and end-point repeatability	Accuracy near acceptance criterion	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0005	Dimensional measurement system	GR&R for multiple users/cavities and tolerances	Capability relative to product tolerance	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0006	Surface roughness method	Validate stylus/camera and surface prep	Measurement uncertainty and repeatability	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0007	Corrosion test method	Define solution, exposure and visual criteria	Discriminatory test reproducibility	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0008	Chemical extractables/leachables test	Assess extraction conditions, identification and quantitation	Reproducible analytical measurement and toxicological relevance	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0009	GC-MS EO residuals method	Method linearity, recovery, detection, matrix carryover	ISO 10993-7 compatible limits and reliability	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0010	ICP-MS trace metal method	Selectivity, blank controls and recovery	Quantitation of elemental residues	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0011	FTIR material identity method	Discriminatory spectral matching	Accept/reject polymer identity at site conditions	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0012	Optical clarity / power testing	Verify sample alignment and temperature	Optical accuracy at performance thresholds	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0013	Electrical output test	Determine uncertainty, calibration and load conditions	Essential performance verification accuracy	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0014	Software test script qualification	Verify automation script can detect seeded defects	Versioned test fixtures and reference outputs	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0015	Microleak test for lumens	Challenge known microdefects across sizes	Leak sensitivity and material applicability	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0016	Sterile package integrity test	Set defect detectability and package suitability	Appropriate deterministic/probabilistic method validation	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0017	Bacterial retention test method	Demonstrate method/device combination suitability	Validated challenge and controls when applicable	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0018	Clinical chemistry assay validation	Precision, bias, range and interference	IVD intended-use performance targets	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0019	Analytical method transfer	Establish source/receiver method equivalence	Cross-laboratory reproducibility and competence	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0020	Instrument firmware measurement logic	Verify calculations, rounding, alarms and stored outputs	Traceable input-to-result verification	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0021	Reference standard qualification	Assess stability, identity and traceability	Certificates/assigned value uncertainty	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High
MDV-26-0022	Laboratory sampling plans	Verify reproducibility and sample representativeness	Appropriate sampling and acceptance operating characteristics	Lifecycle	Raw material, process and final device testing	M02 M07 M14 M18 M28 M32	High

27 BIOCOMPATIBILITY, CHEMICAL CHARACTERIZATION & MATERIAL RISK

18 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-27-0001	Biological evaluation plan	Document contact type, duration and relevant endpoints	ISO 10993 strategy and testing/rationale	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0002	Material characterization	Assess polymer metals coatings adhesives and processing aids	Formulation and supplier composition evidence	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0003	Chemical characterization	Characterize extractables under justified extraction conditions	ISO 10993-18 approach as applicable	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0004	Toxicological risk assessment	Assess patient exposure and toxicological thresholds	ISO 10993-17 approach and qualified expert review	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0005	Cytotoxicity assessment	Choose test method suitable to test article	ISO 10993-5 data and risk assessment	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0006	Sensitization assessment	Select endpoint based on contact and chemistry	ISO 10993-10 or applicable current edition	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0007	Irritation assessment	Evaluate intended contact route and exposure	ISO 10993-23 or appropriate endpoint	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0008	Systemic toxicity	Evaluate chemical hazard and exposure	Applicable ISO 10993 endpoint plan	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0009	Implantation and histopathology	Design representative implant site/duration if required	Biological response and histopathology	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0010	Hemocompatibility	Assess thrombogenicity, hemolysis and complement when relevant	ISO 10993-4 evaluation	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0011	Genotoxicity	Test/rationale based on chemicals and contact risk	ISO 10993-3 evaluation when applicable	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0012	Sterilant residues	Evaluate EO, ECH and alternative sterilant residuals	ISO 10993-7/device-specific toxicology	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0013	Respiratory gas pathway	Evaluate volatile/particulate emissions	ISO 18562 series when relevant	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0014	Reprocessing cumulative toxicity	Assess effects of multiple cleaning/sterilization cycles	Biocompatibility retained at end of claimed reuse	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0015	Colorants and additives	Qualify changes and potential new leachables	Comparability and toxicological assessment	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0016	Manufacturing residue contribution	Consider oils, solvents, release agents and lubricants	Process residue risk controls	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0017	Package leachables transfer	Assess interactions during aging and sterilization	Device/package chemical risk evaluation	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High
MDV-27-0018	Biocompatibility bridging	Justify family/material/process comparisons	Documented scientific equivalence and residual risk	Lifecycle	Patient-contact devices / implants	M07 M14 M34	High

28 SOFTWARE, SAMD, CYBERSECURITY & ELECTRONIC SYSTEMS

38 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-28-0001	Software development plan	Establish safety classification and lifecycle process	IEC 62304 compliant plan and traceability	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0002	Software requirements	Translate functional and risk-control inputs into testable requirements	Bidirectional test coverage matrix	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0003	Software architecture verification	Check modularity, interfaces and risk separation	Architecture reviews / traceability	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0004	Unit testing	Validate edge/boundary logic and exceptions	Automated unit test evidence and controlled code	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0005	Integration testing	Verify communication failures and data exchange	Interface testing with simulated faults	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0006	System software verification	Test full device functions against requirements	Representative software/hardware configurations	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0007	Software validation	Demonstrate intended user goals and operating environment	Risk-based user acceptance and real-world scenarios	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0008	Software anomaly management	Triage open anomalies and field risk	Release decision with known defect residual risk	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0009	Software build and release	Verify controlled toolchain, checksum and SBOM	Reproducible version and configuration baseline	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0010	SOUP/open source assessment	Qualify third-party component risk and updates	Software item inventory and known vulnerabilities	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0011	Cybersecurity threat model	Identify attack surface, misuse and patient-harm chain	Documented threat assessment and mitigations	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0012	Authentication / authorization	Challenge least privilege and role escalation	Access control testing and audit records	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0013	Audit trail / log integrity	Test time stamps, tamper resistance and exception logs	Reliable forensic records	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0014	Data encryption / transfer	Verify data in transit and storage protections	Approved threat-appropriate cryptographic tests	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0015	Secure update mechanism	Verify signed update/rollback and interrupted installation	No unsafe device state from patch failure	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0016	Network stress / resilience	Challenge packet loss, latency, outages and reconnection	Safe essential performance and recovery	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-28-0017	Interoperability	Validate HL7/FHIR/DICOM/device interfaces if applicable	Accurate message mapping and error handling	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0018	Algorithm performance	Verify analytical validity on representative independent test data	Bias, subgroup performance and clinical limits	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0019	AI/ML dataset governance	Evaluate representativeness, leakage, labeling and drift	Versioned dataset/ground truth controls	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0020	AI/ML locked-model release	Verify frozen weights, performance and inference traceability	Controlled model version and reproducible outputs	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0021	Human factors software UI	Summative testing of high-risk functions	Correct user interpretation of alerts and prompts	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0022	Cybersecurity penetration testing	Use test scope derived from threat model	Pen-test findings and documented closure	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0023	Vulnerability management	Define monitoring, disclosure and patch pathways	Postmarket cyber lifecycle evidence	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0024	Manufacturing ERP	Validate lot status, release blocks and traceability	GxP computerized system requirements	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0025	MES electronic batch record	Challenge permissions, recipes, exceptions and revisions	Accurate manufacture and traceability records	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0026	Electronic DHR / device history	Verify completeness and immutable approvals	Device production record integrity	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0027	LIMS	Validate results calculations, sample IDs and audit trail	Correct sample-to-report traceability	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0028	QMS software	Validate change control, CAPA, training approvals	Workflow rights and records retention	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0029	BMS/EMS	Verify sensors, alarm escalations and audit trails	Electronic environmental data reliability	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0030	PLC machine recipes	Lock/unlock access, checksum and controlled change	Stable validated recipes and error recovery	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0031	SCADA/HMI	Validate alarms, trends, edit restrictions and fail-safe	Process output and records integrity	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0032	Backup and disaster recovery	Test restoration including user permissions and raw data	Recoverability under plausible loss scenarios	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0033	Date/time synchronization	Verify clock sync and daylight time changes	Trusted time stamps for traceability	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0034	Electronic signature	Verify unique identity, manifestation and link to records	Applicable 21 CFR Part 11 / EU electronic record criteria when relevant	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-28-0035	Cloud validation	Qualify hosted vendor, regions and disaster recovery	SLA, security, data ownership and access	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0036	Remote maintenance	Challenge session authorization and traceability	Controlled vendor access and logging	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0037	Software production burn-in	Validate repeated power cycles and functional sequence	No latent failures in finished device	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High
MDV-28-0038	Device cybersecurity labeling	Verify support lifetime, update routes and user steps	Tested user cybersecurity instructions	Lifecycle	SaMD; embedded device software; GxP manufacturing systems	M01 M02 M03 M04 M07 M16 M17 M19 M29	High

29 STABILITY, AGING, TRANSPORT, SHELF-LIFE & DURABILITY

94 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0001	Accelerated aging stability chamber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses thermal uniformity; humidity; sampling intervals; required outputs: representative accelerated aging conditions	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0002	Accelerated aging stability chamber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Accelerated aging stability chamber	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0003	Accelerated aging stability chamber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for thermal uniformity; humidity; sampling intervals; evaluate representative accelerated aging conditions	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0004	Accelerated aging stability chamber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0005	Accelerated aging stability chamber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering representative accelerated aging conditions	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0006	Accelerated aging stability chamber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend thermal uniformity; humidity; sampling intervals; define risk-based requalification triggers affecting representative accelerated aging conditions	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0007	Real-time aging storage room	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses temperature mapping; sensor calibration; humidity; required outputs: valid shelf life time-point conditions	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0008	Real-time aging storage room	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Real-time aging storage room	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0009	Real-time aging storage room	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for temperature mapping; sensor calibration; humidity; evaluate valid shelf life time-point conditions	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0010	Real-time aging storage room	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0011	Real-time aging storage room	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering valid shelf life time-point conditions	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0012	Real-time aging storage room	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend temperature mapping; sensor calibration; humidity; define risk-based requalification triggers affecting valid shelf life time-point conditions	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0013	Thermal cycling chamber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses thermal extremes; ramp rate; dwell; required outputs: device function after environmental cycling	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0014	Thermal cycling chamber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Thermal cycling chamber	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0015	Thermal cycling chamber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for thermal extremes; ramp rate; dwell; evaluate device function after environmental cycling	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0016	Thermal cycling chamber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0017	Thermal cycling chamber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering device function after environmental cycling	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0018	Thermal cycling chamber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend thermal extremes; ramp rate; dwell; define risk-based requalification triggers affecting device function after environmental cycling	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0019	Vibration table for package testing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses PSD profile; duration; load mounting; required outputs: distribution stress fidelity	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0020	Vibration table for package testing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Vibration table for package testing	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0021	Vibration table for package testing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for PSD profile; duration; load mounting; evaluate distribution stress fidelity	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0022	Vibration table for package testing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0023	Vibration table for package testing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering distribution stress fidelity	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0024	Vibration table for package testing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend PSD profile; duration; load mounting; define risk-based requalification triggers affecting distribution stress fidelity	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0025	Drop tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses height; orientation; impact surface; required outputs: physical product/package damage response	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0026	Drop tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Drop tester	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0027	Drop tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for height; orientation; impact surface; evaluate physical product/package damage response	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0028	Drop tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0029	Drop tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering physical product/package damage response	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0030	Drop tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend height; orientation; impact surface; define risk-based requalification triggers affecting physical product/package damage response	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0031	Compression testing apparatus	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses stack loading; load dwell; required outputs: shipping carton and device resilience	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0032	Compression testing apparatus	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Compression testing apparatus	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0033	Compression testing apparatus	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for stack loading; load dwell; evaluate shipping carton and device resilience	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0034	Compression testing apparatus	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0035	Compression testing apparatus	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering shipping carton and device resilience	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0036	Compression testing apparatus	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend stack loading; load dwell; define risk-based requalification triggers affecting shipping carton and device resilience	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0037	Shipping temperature profiler	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses logger sample rate; location; alarms; required outputs: product temperature exposure evidence	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0038	Shipping temperature profiler	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Shipping temperature profiler	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0039	Shipping temperature profiler	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for logger sample rate; location; alarms; evaluate product temperature exposure evidence	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0040	Shipping temperature profiler	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0041	Shipping temperature profiler	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering product temperature exposure evidence	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0042	Shipping temperature profiler	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend logger sample rate; location; alarms; define risk-based requalification triggers affecting product temperature exposure evidence	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0043	UV/weathering exposure chamber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses light spectrum; irradiance; duration; required outputs: label/polymer degradation assessment	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0044	UV/weathering exposure chamber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UV/weathering exposure chamber	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0045	UV/weathering exposure chamber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for light spectrum; irradiance; duration; evaluate label/polymer degradation assessment	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0046	UV/weathering exposure chamber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0047	UV/weathering exposure chamber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering label/polymer degradation assessment	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0048	UV/weathering exposure chamber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend light spectrum; irradiance; duration; define risk-based requalification triggers affecting label/polymer degradation assessment	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0049	Mechanical fatigue simulator	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cycle frequency; amplitude; load profile; required outputs: expected device service-life reliability	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0050	Mechanical fatigue simulator	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Mechanical fatigue simulator	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0051	Mechanical fatigue simulator	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cycle frequency; amplitude; load profile; evaluate expected device service-life reliability	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0052	Mechanical fatigue simulator	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0053	Mechanical fatigue simulator	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering expected device service-life reliability	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0054	Mechanical fatigue simulator	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cycle frequency; amplitude; load profile; define risk-based requalification triggers affecting expected device service-life reliability	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0055	Flex/bend durability tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bend radius; speed; cycle count; required outputs: catheter/cable endurance	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0056	Flex/bend durability tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Flex/bend durability tester	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0057	Flex/bend durability tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bend radius; speed; cycle count; evaluate catheter/cable endurance	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0058	Flex/bend durability tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0059	Flex/bend durability tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering catheter/cable endurance	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0060	Flex/bend durability tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bend radius; speed; cycle count; define risk-based requalification triggers affecting catheter/cable endurance	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0061	Ingress protection test apparatus	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses water/dust challenge; device orientation; required outputs: claimed enclosure ingress resistance	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0062	Ingress protection test apparatus	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ingress protection test apparatus	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0063	Ingress protection test apparatus	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for water/dust challenge; device orientation; evaluate claimed enclosure ingress resistance	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0064	Ingress protection test apparatus	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0065	Ingress protection test apparatus	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering claimed enclosure ingress resistance	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0066	Ingress protection test apparatus	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend water/dust challenge; device orientation; define risk-based requalification triggers affecting claimed enclosure ingress resistance	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0067	Battery runtime cycling test	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses charge/discharge; ambient temperature; required outputs: battery health and service life	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0068	Battery runtime cycling test	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Battery runtime cycling test	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0069	Battery runtime cycling test	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for charge/discharge; ambient temperature; evaluate battery health and service life	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0070	Battery runtime cycling test	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0071	Battery runtime cycling test	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering battery health and service life	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0072	Battery runtime cycling test	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend charge/discharge; ambient temperature; define risk-based requalification triggers affecting battery health and service life	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0073	IVD onboard reagent stability rig	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses open-vial life; analyte drift; calibration; required outputs: clinical assay performance through use period	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0074	IVD onboard reagent stability rig	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IVD onboard reagent stability rig	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0075	IVD onboard reagent stability rig	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for open-vial life; analyte drift; calibration; evaluate clinical assay performance through use period	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0076	IVD onboard reagent stability rig	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0077	IVD onboard reagent stability rig	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering clinical assay performance through use period	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0078	IVD onboard reagent stability rig	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend open-vial life; analyte drift; calibration; define risk-based requalification triggers affecting clinical assay performance through use period	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0079	Wearable adhesive aging study	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses humidity; perspiration; adhesion duration; required outputs: skin retention and performance	URS / DQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0080	Wearable adhesive aging study	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wearable adhesive aging study	IQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0081	Wearable adhesive aging study	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for humidity; perspiration; adhesion duration; evaluate skin retention and performance	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0082	Wearable adhesive aging study	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0083	Wearable adhesive aging study	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering skin retention and performance	PQ	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0084	Wearable adhesive aging study	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend humidity; perspiration; adhesion duration; define risk-based requalification triggers affecting skin retention and performance	Routine / Change	Aged and distributed medical devices, IVDs, implants	M02 M07 M08 M22 M28	Medium
MDV-29-0085	Device shelf life rationale	Establish expiry endpoint for material/function/barrier	Scientific aging plan linked to risk	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0086	Aged electrical reliability	Check essential performance after aging exposure	Functional tests on aged representative devices	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0087	Aged sterile barrier integrity	Verify seal integrity and barrier after aging	Post-aging package test pass	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0088	Accelerated-aging correlation	Confirm material-specific activation assumptions	No unsupported simple equivalence	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0089	Shipping route qualification	Choose worst-case geographic/transport exposures	Representative profile and monitoring	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-29-0090	Temperature excursion assessment	Set excursion duration / severity and release controls	Stability data supports disposition	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0091	IVD in-use stability	Test multiple opening/closing and day-to-day use	Assay precision at labeled in-use period	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0092	IVD shipping hold	Assess freeze/thaw, vibration and temperature stress	Retained analytical performance	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0093	Device mechanical life-cycle	Perform fatigue and wear on critical load elements	Meets declared service-life performance	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High
MDV-29-0094	Aged label/UDI readability	Test ink/barcode after sterilization and aging	Scannable UDI and safety instructions	Lifecycle	Devices with expiry or service-life claims	M02 M07 M08 M22 M28	High

30 PRODUCTION INSPECTION, RELEASE & PERFORMANCE VERIFICATION

103 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-30-0001	In-line laser diameter inspection	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses laser geometry; product motion; alarm threshold; required outputs: accurate identification of out-of-tolerance tubing	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0002	In-line laser diameter inspection	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for In-line laser diameter inspection	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0003	In-line laser diameter inspection	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for laser geometry; product motion; alarm threshold; evaluate accurate identification of out-of-tolerance tubing	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0004	In-line laser diameter inspection	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0005	In-line laser diameter inspection	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering accurate identification of out-of-tolerance tubing	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0006	In-line laser diameter inspection	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend laser geometry; product motion; alarm threshold; define risk-based requalification triggers affecting accurate identification of out-of-tolerance tubing	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0007	100 percent camera inspection system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reference defects; lighting; part orientation; required outputs: validated detectability and rejects	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0008	100 percent camera inspection system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for 100 percent camera inspection system	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0009	100 percent camera inspection system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reference defects; lighting; part orientation; evaluate validated detectability and rejects	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0010	100 percent camera inspection system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0011	100 percent camera inspection system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering validated detectability and rejects	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0012	100 percent camera inspection system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reference defects; lighting; part orientation; define risk-based requalification triggers affecting validated detectability and rejects	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0013	Syringe glide force tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses plunger speed; fixture; force profile; required outputs: reliable break-loose/glide force measurement	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0014	Syringe glide force tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Syringe glide force tester	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0015	Syringe glide force tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for plunger speed; fixture; force profile; evaluate reliable break-loose/glide force measurement	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0016	Syringe glide force tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0017	Syringe glide force tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reliable break-loose/glide force measurement	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0018	Syringe glide force tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend plunger speed; fixture; force profile; define risk-based requalification triggers affecting reliable break-loose/glide force measurement	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0019	Needle penetration tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses puncture medium; loading speed; required outputs: sharpness and repeatability	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0020	Needle penetration tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Needle penetration tester	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0021	Needle penetration tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for puncture medium; loading speed; evaluate sharpness and repeatability	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0022	Needle penetration tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-30-0023	Needle penetration tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sharpness and repeatability	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0024	Needle penetration tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend puncture medium; loading speed; define risk-based requalification triggers affecting sharpness and repeatability	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0025	Catheter leak / kink tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pressure; bend radius; response; required outputs: leak and kink failure discrimination	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0026	Catheter leak / kink tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Catheter leak / kink tester	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0027	Catheter leak / kink tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pressure; bend radius; response; evaluate leak and kink failure discrimination	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0028	Catheter leak / kink tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0029	Catheter leak / kink tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering leak and kink failure discrimination	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0030	Catheter leak / kink tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pressure; bend radius; response; define risk-based requalification triggers affecting leak and kink failure discrimination	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0031	Implant pull-off / torque bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses load rate; clamp/alignment; required outputs: construct strength and fixation	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0032	Implant pull-off / torque bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Implant pull-off / torque bench	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0033	Implant pull-off / torque bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for load rate; clamp/alignment; evaluate construct strength and fixation	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0034	Implant pull-off / torque bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0035	Implant pull-off / torque bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering construct strength and fixation	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0036	Implant pull-off / torque bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend load rate; clamp/alignment; define risk-based requalification triggers affecting construct strength and fixation	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0037	Electrical medical device final functional test	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses test sequence; input voltage; fault capture; required outputs: complete essential performance test	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0038	Electrical medical device final functional test	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electrical medical device final functional test	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0039	Electrical medical device final functional test	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for test sequence; input voltage; fault capture; evaluate complete essential performance test	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0040	Electrical medical device final functional test	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0041	Electrical medical device final functional test	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering complete essential performance test	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0042	Electrical medical device final functional test	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend test sequence; input voltage; fault capture; define risk-based requalification triggers affecting complete essential performance test	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0043	Patient monitor calibration station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reference signal; channel mapping; required outputs: accuracy of alarms and readings	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0044	Patient monitor calibration station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Patient monitor calibration station	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0045	Patient monitor calibration station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reference signal; channel mapping; evaluate accuracy of alarms and readings	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0046	Patient monitor calibration station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-30-0047	Patient monitor calibration station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering accuracy of alarms and readings	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0048	Patient monitor calibration station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reference signal; channel mapping; define risk-based requalification triggers affecting accuracy of alarms and readings	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0049	Surgical tool sharpness test bench	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reference medium; blade trajectory; required outputs: cutting performance and consistency	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0050	Surgical tool sharpness test bench	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Surgical tool sharpness test bench	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0051	Surgical tool sharpness test bench	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reference medium; blade trajectory; evaluate cutting performance and consistency	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0052	Surgical tool sharpness test bench	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0053	Surgical tool sharpness test bench	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering cutting performance and consistency	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0054	Surgical tool sharpness test bench	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reference medium; blade trajectory; define risk-based requalification triggers affecting cutting performance and consistency	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0055	Disposable mask filtration tester	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses challenge aerosol; air flow; seal; required outputs: filtration efficiency and resistance	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0056	Disposable mask filtration tester	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Disposable mask filtration tester	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0057	Disposable mask filtration tester	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for challenge aerosol; air flow; seal; evaluate filtration efficiency and resistance	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0058	Disposable mask filtration tester	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0059	Disposable mask filtration tester	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering filtration efficiency and resistance	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0060	Disposable mask filtration tester	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend challenge aerosol; air flow; seal; define risk-based requalification triggers affecting filtration efficiency and resistance	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0061	Medical glove water-leak test system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill pressure; hold time; pinhole detection; required outputs: barrier integrity and AQL control	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0062	Medical glove water-leak test system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical glove water-leak test system	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0063	Medical glove water-leak test system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill pressure; hold time; pinhole detection; evaluate barrier integrity and AQL control	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0064	Medical glove water-leak test system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0065	Medical glove water-leak test system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering barrier integrity and AQL control	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0066	Medical glove water-leak test system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill pressure; hold time; pinhole detection; define risk-based requalification triggers affecting barrier integrity and AQL control	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0067	IVD reader final verification station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses optical standards; software config; temperature; required outputs: correct reference results and calibration	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0068	IVD reader final verification station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IVD reader final verification station	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0069	IVD reader final verification station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for optical standards; software config; temperature; evaluate correct reference results and calibration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0070	IVD reader final verification station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-30-0071	IVD reader final verification station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct reference results and calibration	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0072	IVD reader final verification station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend optical standards; software config; temperature; define risk-based requalification triggers affecting correct reference results and calibration	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0073	Automated reject verification gate	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses reject timing; missing air; sensor fault; required outputs: no unrejected defective units	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0074	Automated reject verification gate	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Automated reject verification gate	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0075	Automated reject verification gate	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for reject timing; missing air; sensor fault; evaluate no unrejected defective units	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0076	Automated reject verification gate	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0077	Automated reject verification gate	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no unrejected defective units	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0078	Automated reject verification gate	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend reject timing; missing air; sensor fault; define risk-based requalification triggers affecting no unrejected defective units	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0079	Electronic UDI final scan station	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses symbology grade; code data match; required outputs: final labeling/lot traceability	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0080	Electronic UDI final scan station	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Electronic UDI final scan station	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0081	Electronic UDI final scan station	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for symbology grade; code data match; evaluate final labeling/lot traceability	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0082	Electronic UDI final scan station	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0083	Electronic UDI final scan station	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering final labeling/lot traceability	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0084	Electronic UDI final scan station	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend symbology grade; code data match; define risk-based requalification triggers affecting final labeling/lot traceability	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0085	In-line checkweigher	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses underweight threshold; challenge reference; required outputs: missing parts detection	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0086	In-line checkweigher	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for In-line checkweigher	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0087	In-line checkweigher	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for underweight threshold; challenge reference; evaluate missing parts detection	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0088	In-line checkweigher	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0089	In-line checkweigher	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering missing parts detection	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0090	In-line checkweigher	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend underweight threshold; challenge reference; define risk-based requalification triggers affecting missing parts detection	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0091	Batch release software / ERP disposition	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses release permission; expired lot lock; recall retrieval; required outputs: authorized disposition and traceability	URS / DQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0092	Batch release software / ERP disposition	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Batch release software / ERP disposition	IQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0093	Batch release software / ERP disposition	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for release permission; expired lot lock; recall retrieval; evaluate authorized disposition and traceability	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0094	Batch release software / ERP disposition	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	All medical devices; release verification	M01 M02 M03 M05 M07	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-30-0095	Batch release software / ERP disposition	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering authorized disposition and traceability	PQ	All medical devices; release verification	M01 M02 M03 M05 M07	High
MDV-30-0096	Batch release software / ERP disposition	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend release permission; expired lot lock; recall retrieval; define risk-based requalification triggers affecting authorized disposition and traceability	Routine / Change	All medical devices; release verification	M01 M02 M03 M05 M07	Medium
MDV-30-0097	Critical characteristic sampling plan	Justify sampling vs 100-percent test and risk	Statistical operating characteristic / severity rationale	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0098	Nonconforming product segregation	Challenge mislabeling and unauthorized release	System access, scan and physical controls	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0099	First article inspection	Confirm first-run changeover or new tools meet drawing	Approved first-article results	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0100	Tool/cavity traceability	Trace failures to tool cavity and shift	Device history and defect trending	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0101	Product release review	Check sterile cycle, lab, packaging and manufacturing evidence	Controlled acceptance decision	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0102	Test method change	Evaluate impact of new sensors and software	Reverification / revalidation of final acceptance process	Lifecycle	All devices	M01 M02 M07	High
MDV-30-0103	SPC for critical output	Determine process capability and trending limits	Stable and capable routine process or control strategy	Lifecycle	All devices	M01 M02 M07	High

31 HR, PERSONNEL QUALIFICATION & GOWNING

18 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-31-0001	Training system	Verify employee role-matrix coverage of critical validated processes	Training/authorization traceable to tasks	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0002	Machine setup qualification	Challenge independent operator changeover execution	Observed competence and documented assessment	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0003	Cleanroom gowning qualification	Verify gowning technique with particle/viable monitoring as appropriate	Personnel contamination controls	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0004	Aseptic interventions training	Assess deviations and critical interventions in simulation	Qualified people for aseptic line tasks	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0005	Visual inspection qualification	Challenge defect library, false pass and false fail rates	Inspection sensitivity and reproducibility	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0006	Weld/bond operator qualification	Execute low/high parameter work and adverse samples	Operator skill evidence and requalification plan	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0007	Micromachining operator qualification	Test tool offsets and defect recognition	Documented precision manufacturing competence	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0008	Sterilizer loading qualification	Challenge load pattern and PCD/dosimeter location	Operator compliance with validated loading	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0009	Cleanroom sanitation personnel	Observe prescribed chemical, concentration and contact time	Effective cleaning and safe handling	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0010	Maintenance engineer qualification	Ensure intervention control, safe state and release	Authorized repair/requalification sign-off	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0011	Metrology technician competence	Witness calibration and uncertainty calculation	Verified measurement competence	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0012	Software release engineer qualification	Assess configuration management, cyber controls and traceability	Controlled software build/release competence	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0013	Supplier quality auditor	Assess sterile/device critical-process supplier audit skill	Record of auditor competency	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0014	Warehouse pack-out operator	Demonstrate product orientation, scan and temperature rules	Traceable shipping process competency	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0015	EHS emergency team	Simulate EO/chemical/spill/exposure response	Readiness and incident communication	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0016	HR onboarding/exit role changes	Validate access provisioning and removal	Role-based permissions with segregation of duties	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0017	Training effectiveness	Evaluate proficiency after training, not only attendance	Effectiveness sampling and corrective coaching	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium
MDV-31-0018	Personnel requalification	Define training refresh after errors or prolonged absence	Risk-based reassessment and signed authorizations	Lifecycle	All facilities; clean/sterile operations	M01 M02 M05 M07 M15	Medium

32 EHS, CONTAINMENT, WASTE & EMERGENCY CONTROLS

114 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0001	EO gas detection network	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sensor span; alarm thresholds; evacuation interface; required outputs: early gas leak detection and documented response	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0002	EO gas detection network	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO gas detection network	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0003	EO gas detection network	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sensor span; alarm thresholds; evacuation interface; evaluate early gas leak detection and documented response	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0004	EO gas detection network	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0005	EO gas detection network	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering early gas leak detection and documented response	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0006	EO gas detection network	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sensor span; alarm thresholds; evacuation interface; define risk-based requalification triggers affecting early gas leak detection and documented response	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0007	EO abatement / scrubber	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses flow; emission control; trip response; required outputs: abatement functionality and environmental compliance	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0008	EO abatement / scrubber	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for EO abatement / scrubber	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0009	EO abatement / scrubber	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for flow; emission control; trip response; evaluate abatement functionality and environmental compliance	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0010	EO abatement / scrubber	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0011	EO abatement / scrubber	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering abatement functionality and environmental compliance	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0012	EO abatement / scrubber	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend flow; emission control; trip response; define risk-based requalification triggers affecting abatement functionality and environmental compliance	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0013	Laser enclosure interlock	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses access-door status; beam dump; trip recovery; required outputs: safe laser operation	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0014	Laser enclosure interlock	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Laser enclosure interlock	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0015	Laser enclosure interlock	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for access-door status; beam dump; trip recovery; evaluate safe laser operation	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0016	Laser enclosure interlock	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0017	Laser enclosure interlock	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe laser operation	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0018	Laser enclosure interlock	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend access-door status; beam dump; trip recovery; define risk-based requalification triggers affecting safe laser operation	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0019	UV curing radiation shielding	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses UV irradiance; exposure risk; enclosure; required outputs: operator protection against ultraviolet radiation	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0020	UV curing radiation shielding	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for UV curing radiation shielding	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0021	UV curing radiation shielding	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for UV irradiance; exposure risk; enclosure; evaluate operator protection against ultraviolet radiation	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0022	UV curing radiation shielding	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0023	UV curing radiation shielding	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering operator protection against ultraviolet radiation	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0024	UV curing radiation shielding	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend UV irradiance; exposure risk; enclosure; define risk-based requalification triggers affecting operator protection against ultraviolet radiation	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0025	Solvent vapor extraction booth	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses capture velocity; flammable atmosphere response; required outputs: occupational exposure control	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0026	Solvent vapor extraction booth	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Solvent vapor extraction booth	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0027	Solvent vapor extraction booth	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for capture velocity; flammable atmosphere response; evaluate occupational exposure control	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0028	Solvent vapor extraction booth	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0029	Solvent vapor extraction booth	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering occupational exposure control	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0030	Solvent vapor extraction booth	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend capture velocity; flammable atmosphere response; define risk-based requalification triggers affecting occupational exposure control	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0031	Chemical storage ventilation cabinet	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses airflow; fire detection; spill sump; required outputs: controlled chemical hazards	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0032	Chemical storage ventilation cabinet	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Chemical storage ventilation cabinet	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0033	Chemical storage ventilation cabinet	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for airflow; fire detection; spill sump; evaluate controlled chemical hazards	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0034	Chemical storage ventilation cabinet	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0035	Chemical storage ventilation cabinet	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled chemical hazards	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0036	Chemical storage ventilation cabinet	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend airflow; fire detection; spill sump; define risk-based requalification triggers affecting controlled chemical hazards	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0037	Flammable liquid transfer earthing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses bonding; interlock; flow; required outputs: electrostatic ignition prevention	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0038	Flammable liquid transfer earthing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Flammable liquid transfer earthing	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0039	Flammable liquid transfer earthing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for bonding; interlock; flow; evaluate electrostatic ignition prevention	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0040	Flammable liquid transfer earthing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0041	Flammable liquid transfer earthing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering electrostatic ignition prevention	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0042	Flammable liquid transfer earthing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend bonding; interlock; flow; define risk-based requalification triggers affecting electrostatic ignition prevention	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0043	Biohazard waste decontamination autoclave	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses load penetration; biological challenge; required outputs: effective disinfection of infectious waste	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0044	Biohazard waste decontamination autoclave	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Biohazard waste decontamination autoclave	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0045	Biohazard waste decontamination autoclave	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for load penetration; biological challenge; evaluate effective disinfection of infectious waste	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0046	Biohazard waste decontamination autoclave	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0047	Biohazard waste decontamination autoclave	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering effective disinfection of infectious waste	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0048	Biohazard waste decontamination autoclave	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend load penetration; biological challenge; define risk-based requalification triggers affecting effective disinfection of infectious waste	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0049	Wastewater neutralization system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses pH cutoffs; chemical feed; sampling; required outputs: controlled wastewater release	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0050	Wastewater neutralization system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wastewater neutralization system	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0051	Wastewater neutralization system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for pH cutoffs; chemical feed; sampling; evaluate controlled wastewater release	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0052	Wastewater neutralization system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0053	Wastewater neutralization system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled wastewater release	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0054	Wastewater neutralization system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend pH cutoffs; chemical feed; sampling; define risk-based requalification triggers affecting controlled wastewater release	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0055	Dust extraction for textile/polymers	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses capture; filter integrity; explosion protections; required outputs: low particulate exposure and contamination	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0056	Dust extraction for textile/polymers	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dust extraction for textile/polymers	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0057	Dust extraction for textile/polymers	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for capture; filter integrity; explosion protections; evaluate low particulate exposure and contamination	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0058	Dust extraction for textile/polymers	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0059	Dust extraction for textile/polymers	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering low particulate exposure and contamination	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0060	Dust extraction for textile/polymers	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend capture; filter integrity; explosion protections; define risk-based requalification triggers affecting low particulate exposure and contamination	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0061	Emergency shower / eyewash	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses delivery rate; access; response; required outputs: emergency decontamination readiness	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0062	Emergency shower / eyewash	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Emergency shower / eyewash	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0063	Emergency shower / eyewash	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for delivery rate; access; response; evaluate emergency decontamination readiness	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0064	Emergency shower / eyewash	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0065	Emergency shower / eyewash	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering emergency decontamination readiness	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0066	Emergency shower / eyewash	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend delivery rate; access; response; define risk-based requalification triggers affecting emergency decontamination readiness	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0067	Fire alarm / suppression system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses detector challenge; alarm distribution; power loss; required outputs: emergency response function	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0068	Fire alarm / suppression system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Fire alarm / suppression system	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0069	Fire alarm / suppression system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for detector challenge; alarm distribution; power loss; evaluate emergency response function	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0070	Fire alarm / suppression system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0071	Fire alarm / suppression system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering emergency response function	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0072	Fire alarm / suppression system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend detector challenge; alarm distribution; power loss; define risk-based requalification triggers affecting emergency response function	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0073	Chemical spill containment berm	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses spill volume; leak path; recovery; required outputs: prevent environmental spread	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0074	Chemical spill containment berm	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Chemical spill containment berm	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0075	Chemical spill containment berm	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for spill volume; leak path; recovery; evaluate prevent environmental spread	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0076	Chemical spill containment berm	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0077	Chemical spill containment berm	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering prevent environmental spread	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0078	Chemical spill containment berm	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend spill volume; leak path; recovery; define risk-based requalification triggers affecting prevent environmental spread	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0079	Medical gas oxygen deficiency monitor	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses setpoint; display; power backup; required outputs: oxygen-depletion detection	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0080	Medical gas oxygen deficiency monitor	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical gas oxygen deficiency monitor	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0081	Medical gas oxygen deficiency monitor	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for setpoint; display; power backup; evaluate oxygen-depletion detection	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0082	Medical gas oxygen deficiency monitor	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0083	Medical gas oxygen deficiency monitor	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering oxygen-depletion detection	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0084	Medical gas oxygen deficiency monitor	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend setpoint; display; power backup; define risk-based requalification triggers affecting oxygen-depletion detection	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0085	HEPA-filtered powder containment booth	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses face velocity; filter leak; differential pressure; required outputs: worker exposure / cross contamination control	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0086	HEPA-filtered powder containment booth	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for HEPA-filtered powder containment booth	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0087	HEPA-filtered powder containment booth	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for face velocity; filter leak; differential pressure; evaluate worker exposure / cross contamination control	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0088	HEPA-filtered powder containment booth	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0089	HEPA-filtered powder containment booth	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering worker exposure / cross contamination control	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0090	HEPA-filtered powder containment booth	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend face velocity; filter leak; differential pressure; define risk-based requalification triggers affecting worker exposure / cross contamination control	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0091	Microbiology waste transfer system	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses containment integrity; disinfectant; required outputs: controlled biohazard movement	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0092	Microbiology waste transfer system	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microbiology waste transfer system	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0093	Microbiology waste transfer system	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for containment integrity; disinfectant; evaluate controlled biohazard movement	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0094	Microbiology waste transfer system	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0095	Microbiology waste transfer system	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering controlled biohazard movement	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0096	Microbiology waste transfer system	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend containment integrity; disinfectant; define risk-based requalification triggers affecting controlled biohazard movement	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0097	Metal polishing slurry containment	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses capture; filtrate; hazardous waste trace; required outputs: safe waste treatment and disposal	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0098	Metal polishing slurry containment	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Metal polishing slurry containment	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0099	Metal polishing slurry containment	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for capture; filtrate; hazardous waste trace; evaluate safe waste treatment and disposal	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0100	Metal polishing slurry containment	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0101	Metal polishing slurry containment	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe waste treatment and disposal	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0102	Metal polishing slurry containment	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend capture; filtrate; hazardous waste trace; define risk-based requalification triggers affecting safe waste treatment and disposal	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0103	Implant passivation acid bath exhaust	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses capture; material compatibility; required outputs: acid vapor protection	URS / DQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0104	Implant passivation acid bath exhaust	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Implant passivation acid bath exhaust	IQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0105	Implant passivation acid bath exhaust	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for capture; material compatibility; evaluate acid vapor protection	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0106	Implant passivation acid bath exhaust	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-32-0107	Implant passivation acid bath exhaust	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering acid vapor protection	PQ	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0108	Implant passivation acid bath exhaust	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend capture; material compatibility; define risk-based requalification triggers affecting acid vapor protection	Routine / Change	Medical device manufacturing, EO, chemical, lasers, biohazard	M02 M05 M07	Medium
MDV-32-0109	Chemical exposure monitoring	Validate sampling approach and action limits	Calibrated monitors and representative exposure measurements	Lifecycle	All medical device production	M02 M05 M07	Medium
MDV-32-0110	EO gas emergency drill	Exercise alarm, evacuation, incident classification and recovery	Documented response adequacy and improvements	Lifecycle	All medical device production	M02 M05 M07	Medium
MDV-32-0111	Cleanroom fire response	Verify safe evacuation and product segregation after incident	Continuity and contamination response plan	Lifecycle	All medical device production	M02 M05 M07	Medium
MDV-32-0112	Emergency power loss	Challenge safe-stop of validated equipment and restart	Defined scrap/rework and device quality status	Lifecycle	All medical device production	M02 M05 M07	Medium
MDV-32-0113	Occupational PPE qualification	Assess glove/respirator suit suitability for chemicals	Hazard-specific equipment selection and training	Lifecycle	All medical device production	M02 M05 M07	Medium
MDV-32-0114	Supplier hazardous material controls	Verify MSDS/SDS and spill control for new chemicals	Documented EHS assessment before use	Lifecycle	All medical device production	M02 M05 M07	Medium

33 R&D, ADL, PROCESS DEVELOPMENT & TRANSFER

19 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-33-0001	Design of experiments	Define interactions and critical variables affecting function	DOE conclusions and process window	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0002	Scale-up study	Compare pilot to production machine geometry/speeds	Bridging plan and product CQA data	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0003	Process characterization	Identify parameter sensitivity and interactions	Evidence of critical process variable classification	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0004	Incoming material equivalence	Bridge polymers/elastomers/coatings/metal grades	Comparable chemical, mechanical and biological behavior	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0005	Prototype vs production tooling	Evaluate mold-cavity effect and manufacturing tolerance	Representative final equipment testing	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0006	ADL test-method transfer	Compare accuracy, precision and bias across labs	Preapproved transfer acceptance criteria	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0007	Reference material establishment	Qualify in-house reference artifacts or test materials	Traceability, uncertainty and stability	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0008	Firmware/software transfer	Verify build/configuration and defect closure	Controlled release and version baseline	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0009	Supplier-to-site process transfer	Verify transferred process windows and equipment equivalence	IQ/OQ/PQ scale-out rationale	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0010	Multi-site transfer	Requalify site-specific utilities, operators and inspection	Comparability and site release evidence	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0011	Packaging transfer	Bridge new sterilizer/film/pack dimension	Packaging OQ/PQ and stability impact	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0012	New sterilizer transfer	Justify EO/radiation/steam cycle equivalence or new cycle	Process PQ and load grouping	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0013	Risk assessment update	Evaluate failures observed during development	Revised product/process risk management file	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0014	Engineering change order	Classify changes by affected CQA and validation evidence	V&V requirement matrix	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0015	Pilot production lots	Determine representative lot size and number for PQ	Statistical justification, not automatic fixed batch count	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0016	Customer-specific device configuration	Check variant family coverage and design outputs	Approved matrix and verification for each variant	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0017	Process capability study	Assess Cpk/Ppk only with stable, suitable process data	Capability decision and mitigation if inadequate	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0018	Legacy product validation remediation	Assess historical data and retrospective gaps prospectively	Gap assessment with targeted supplementary validation	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High
MDV-33-0019	Manufacturing test software development	Validate test script versioning and seeded fault coverage	GxP system control and evidence	Lifecycle	All device families; technology transfer	M01 M02 M03 M04 M07	High

34 FIELD INSTALLATION, SERVICING & REUSE VALIDATION

15 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-34-0001	Installation qualification at customer site	Verify utilities, environmental limits, grounding and site configuration	Site installation checklist for intended use	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0002	Site acceptance test	Demonstrate field essential performance and alarms	Approved functional test results before clinical use	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0003	Clinical user training	Verify competency in critical safe use	Training records and handover acknowledgement	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0004	Preventive maintenance procedure	Establish test tolerances after service	Post-service acceptance benchmarks	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0005	Software patch field validation	Test upgrade/rollback and configuration data preservation	No loss of critical functions or patient data	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0006	Remote field service	Challenge secure connection and audit trail	Approved sessions and access logging	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0007	Reusable device cleaning IFU	Validate worst-case soil, lumen and user technique	Validated cleaning instructions and end-of-life assessment	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0008	Reusable device disinfection IFU	Demonstrate required disinfection level under worst-case	Material compatible process and micro challenge	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0009	Reusable device sterilization IFU	Validate recommended sterilization cycle/reprocessing count	Function and sterile barrier after repeated cycles	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0010	Maximum reuse count	Test wear/degradation and cumulative residues	Safe device performance through labeled cycles	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0011	Complaint returned device handling	Validate containment, decontamination and testing	Secure traceable handling and root-cause evidence	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0012	Refurbishment/remanufacturing screening	Decide if design/function materially changed	Risk and regulatory pathway assessment	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0013	Field calibration	Validate equipment standards and site methods	Traceable calibration data and uncertainty	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0014	Remote monitoring sensors	Verify telemetry reliability and dropout	Data integrity and alarms	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High
MDV-34-0015	Spare part equivalence	Bridge replacements to released design	Approved component compatibility and revalidation need	Lifecycle	Active, reusable and installed devices	M01 M02 M03 M07 M16 M18	High

35 POSTMARKET, COMPLAINTS, CAPA & LIFECYCLE REVIEW

15 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-35-0001	Complaint intake workflow	Validate severity, reportability, traceability and response times	System test cases with documented disposition	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0002	Vigilance/incident data	Link reportable adverse events to manufacturing risk controls	Traceable PMS and trend assessment	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0003	CAPA effectiveness	Demonstrate process change corrects root cause	Predefined objective effectiveness tests	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0004	Recall execution	Conduct lot/UDI trace simulation across markets	Reconciliation and field communication accuracy	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0005	Field safety corrective action	Verify corrective action deployment and affected unit counts	Closed-loop traceability and effectiveness	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0006	Postmarket performance trend	Monitor failure rates, drift and adverse signals	Statistically justifiable triggers	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0007	Risk management feedback	Incorporate post-production data into risk file	Hazard reassessment and changed validation plan	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0008	Periodic validation review	Review OQ/PQ, deviation, repairs and SPC	Rationalized requalification/revalidation scope	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0009	Design trend escalation	Define threshold for design modification	V&V regression and regulatory notifications	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0010	Sterilization load change notification	Track product/pack/sterilizer changes affecting validation	Approved change-specific cycle impact report	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0011	Supplier CAPA follow up	Reassess verification after supplier manufacturing change	Evidence of sustained correction	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0012	Control of nonconforming products	Validate segregation and disposition authorization	Prevention of unintended release	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0013	PMS / PMCF or PMPF data interface	Where relevant, use clinical performance feedback for validation	Evidence-linked performance monitoring	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0014	Records retention/archiving	Validate retrieval, migration and tamper protection	Retention appropriate to market/device class and service life	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High
MDV-35-0015	Process change effect on UDI	Confirm UDI obligations following meaningful device change	Regulatory decision and data accuracy	Lifecycle	All medical devices and IVD	M01 M02 M03 M04 M05 M06 M07	High

36 SPECIALTY, COMBINATION AND ADVANCED MANUFACTURING

108 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0001	Drug-eluting implant coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses drug concentration; coating mass; release kinetics; required outputs: dose uniformity and release profile	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0002	Drug-eluting implant coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Drug-eluting implant coating	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0003	Drug-eluting implant coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for drug concentration; coating mass; release kinetics; evaluate dose uniformity and release profile	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0004	Drug-eluting implant coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0005	Drug-eluting implant coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering dose uniformity and release profile	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0006	Drug-eluting implant coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend drug concentration; coating mass; release kinetics; define risk-based requalification triggers affecting dose uniformity and release profile	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0007	Biodegradable polymer implant extrusion	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses molecular mass; moisture; orientation; required outputs: degradation and mechanical retention	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0008	Biodegradable polymer implant extrusion	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Biodegradable polymer implant extrusion	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0009	Biodegradable polymer implant extrusion	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for molecular mass; moisture; orientation; evaluate degradation and mechanical retention	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0010	Biodegradable polymer implant extrusion	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0011	Biodegradable polymer implant extrusion	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering degradation and mechanical retention	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0012	Biodegradable polymer implant extrusion	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend molecular mass; moisture; orientation; define risk-based requalification triggers affecting degradation and mechanical retention	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0013	Tissue-derived / animal-derived device processing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses source trace; decellularization; viral/TSE risk; required outputs: biological safety and process consistency	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0014	Tissue-derived / animal-derived device processing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Tissue-derived / animal-derived device processing	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0015	Tissue-derived / animal-derived device processing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for source trace; decellularization; viral/TSE risk; evaluate biological safety and process consistency	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0016	Tissue-derived / animal-derived device processing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0017	Tissue-derived / animal-derived device processing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biological safety and process consistency	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0018	Tissue-derived / animal-derived device processing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend source trace; decellularization; viral/TSE risk; define risk-based requalification triggers affecting biological safety and process consistency	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0019	Additively manufactured patient-matched implant	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses file controls; build orientation; powder reuse; required outputs: geometry, porosity and mechanical strength	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0020	Additively manufactured patient-matched implant	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Additively manufactured patient-matched implant	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0021	Additively manufactured patient-matched implant	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for file controls; build orientation; powder reuse; evaluate geometry, porosity and mechanical strength	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0022	Additively manufactured patient-matched implant	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0023	Additively manufactured patient-matched implant	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering geometry, porosity and mechanical strength	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0024	Additively manufactured patient-matched implant	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend file controls; build orientation; powder reuse; define risk-based requalification triggers affecting geometry, porosity and mechanical strength	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0025	3D-printed polymer patient-specific guide	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses resin cure; postprocessing; fit; required outputs: biocompatibility and surgical fit	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0026	3D-printed polymer patient-specific guide	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for 3D-printed polymer patient-specific guide	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0027	3D-printed polymer patient-specific guide	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for resin cure; postprocessing; fit; evaluate biocompatibility and surgical fit	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0028	3D-printed polymer patient-specific guide	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0029	3D-printed polymer patient-specific guide	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering biocompatibility and surgical fit	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0030	3D-printed polymer patient-specific guide	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend resin cure; postprocessing; fit; define risk-based requalification triggers affecting biocompatibility and surgical fit	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0031	Dental CAD/CAM milling software	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses STL/DICOM intake; toolpath; scale; required outputs: correct patient-matched geometry	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0032	Dental CAD/CAM milling software	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Dental CAD/CAM milling software	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0033	Dental CAD/CAM milling software	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for STL/DICOM intake; toolpath; scale; evaluate correct patient-matched geometry	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0034	Dental CAD/CAM milling software	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0035	Dental CAD/CAM milling software	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering correct patient-matched geometry	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0036	Dental CAD/CAM milling software	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend STL/DICOM intake; toolpath; scale; define risk-based requalification triggers affecting correct patient-matched geometry	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0037	Closed-loop implantable controller	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses sensor control; fault injection; watchdog; required outputs: safe therapy in failures	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0038	Closed-loop implantable controller	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Closed-loop implantable controller	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0039	Closed-loop implantable controller	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for sensor control; fault injection; watchdog; evaluate safe therapy in failures	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0040	Closed-loop implantable controller	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0041	Closed-loop implantable controller	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering safe therapy in failures	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0042	Closed-loop implantable controller	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend sensor control; fault injection; watchdog; define risk-based requalification triggers affecting safe therapy in failures	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0043	Wearable sensor skin adhesive application	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses coat weight; cure; placement; required outputs: skin adhesion and signal quality	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0044	Wearable sensor skin adhesive application	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wearable sensor skin adhesive application	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0045	Wearable sensor skin adhesive application	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for coat weight; cure; placement; evaluate skin adhesion and signal quality	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0046	Wearable sensor skin adhesive application	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0047	Wearable sensor skin adhesive application	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering skin adhesion and signal quality	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0048	Wearable sensor skin adhesive application	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend coat weight; cure; placement; define risk-based requalification triggers affecting skin adhesion and signal quality	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0049	Wearable telemetry module	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses RF power; packet loss; battery; required outputs: reliable measurement transmission	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0050	Wearable telemetry module	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Wearable telemetry module	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0051	Wearable telemetry module	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for RF power; packet loss; battery; evaluate reliable measurement transmission	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0052	Wearable telemetry module	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0053	Wearable telemetry module	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reliable measurement transmission	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0054	Wearable telemetry module	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend RF power; packet loss; battery; define risk-based requalification triggers affecting reliable measurement transmission	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0055	Microfluidic lab-on-chip manufacture	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses channel size; bond; sample flow; required outputs: reliable analyte transport and results	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0056	Microfluidic lab-on-chip manufacture	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Microfluidic lab-on-chip manufacture	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0057	Microfluidic lab-on-chip manufacture	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for channel size; bond; sample flow; evaluate reliable analyte transport and results	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0058	Microfluidic lab-on-chip manufacture	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0059	Microfluidic lab-on-chip manufacture	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering reliable analyte transport and results	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0060	Microfluidic lab-on-chip manufacture	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend channel size; bond; sample flow; define risk-based requalification triggers affecting reliable analyte transport and results	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0061	Combination product filled device assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses interface compatibility; fill; closure integrity; required outputs: combined delivery performance	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0062	Combination product filled device assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Combination product filled device assembly	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0063	Combination product filled device assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for interface compatibility; fill; closure integrity; evaluate combined delivery performance	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0064	Combination product filled device assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0065	Combination product filled device assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering combined delivery performance	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0066	Combination product filled device assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend interface compatibility; fill; closure integrity; define risk-based requalification triggers affecting combined delivery performance	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0067	IVF/assisted reproduction single-use device	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses cleanliness; endotoxin; embryo-contact biological risk; required outputs: specialized contact safety and function	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0068	IVF/assisted reproduction single-use device	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for IVF/assisted reproduction single-use device	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0069	IVF/assisted reproduction single-use device	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for cleanliness; endotoxin; embryo-contact biological risk; evaluate specialized contact safety and function	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0070	IVF/assisted reproduction single-use device	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0071	IVF/assisted reproduction single-use device	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering specialized contact safety and function	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0072	IVF/assisted reproduction single-use device	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend cleanliness; endotoxin; embryo-contact biological risk; define risk-based requalification triggers affecting specialized contact safety and function	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0073	Ophthalmic viscoelastic filled syringe	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses fill; endotoxin; closure; extrusion; required outputs: sterile delivery function	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0074	Ophthalmic viscoelastic filled syringe	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Ophthalmic viscoelastic filled syringe	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0075	Ophthalmic viscoelastic filled syringe	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for fill; endotoxin; closure; extrusion; evaluate sterile delivery function	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0076	Ophthalmic viscoelastic filled syringe	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0077	Ophthalmic viscoelastic filled syringe	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering sterile delivery function	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0078	Ophthalmic viscoelastic filled syringe	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend fill; endotoxin; closure; extrusion; define risk-based requalification triggers affecting sterile delivery function	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0079	Medical device with antimicrobial coating	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses agent distribution; antimicrobial performance; durability; required outputs: claimed antimicrobial effectiveness and material safety	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0080	Medical device with antimicrobial coating	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Medical device with antimicrobial coating	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0081	Medical device with antimicrobial coating	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for agent distribution; antimicrobial performance; durability; evaluate claimed antimicrobial effectiveness and material safety	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0082	Medical device with antimicrobial coating	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0083	Medical device with antimicrobial coating	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering claimed antimicrobial effectiveness and material safety	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0084	Medical device with antimicrobial coating	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend agent distribution; antimicrobial performance; durability; define risk-based requalification triggers affecting claimed antimicrobial effectiveness and material safety	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0085	Absorbable surgical mesh processing	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses hydrolysis; fiber strength; pore geometry; required outputs: strength retention and degradation profile	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0086	Absorbable surgical mesh processing	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Absorbable surgical mesh processing	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0087	Absorbable surgical mesh processing	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for hydrolysis; fiber strength; pore geometry; evaluate strength retention and degradation profile	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0088	Absorbable surgical mesh processing	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

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MDV-36-0089	Absorbable surgical mesh processing	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering strength retention and degradation profile	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0090	Absorbable surgical mesh processing	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend hydrolysis; fiber strength; pore geometry; define risk-based requalification triggers affecting strength retention and degradation profile	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0091	Respiratory breathing circuit assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses connections; leak; gas emissions; required outputs: ISO 18562 and gas pathway performance	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0092	Respiratory breathing circuit assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Respiratory breathing circuit assembly	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0093	Respiratory breathing circuit assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for connections; leak; gas emissions; evaluate ISO 18562 and gas pathway performance	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0094	Respiratory breathing circuit assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0095	Respiratory breathing circuit assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering ISO 18562 and gas pathway performance	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0096	Respiratory breathing circuit assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend connections; leak; gas emissions; define risk-based requalification triggers affecting ISO 18562 and gas pathway performance	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0097	Sterile surgical instrument kit assembly	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses kit completeness; traceability; pack fit; required outputs: integral validated barrier and correct content	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0098	Sterile surgical instrument kit assembly	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Sterile surgical instrument kit assembly	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0099	Sterile surgical instrument kit assembly	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for kit completeness; traceability; pack fit; evaluate integral validated barrier and correct content	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0100	Sterile surgical instrument kit assembly	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0101	Sterile surgical instrument kit assembly	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering integral validated barrier and correct content	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0102	Sterile surgical instrument kit assembly	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend kit completeness; traceability; pack fit; define risk-based requalification triggers affecting integral validated barrier and correct content	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium
MDV-36-0103	Cryogenic biological sample cartridge	URS/DQ: trace intended use, CQA, safety and process limits to controlled design	Approved URS/design review addresses thermal compatibility; seals; sample retention; required outputs: no leakage / degradation under cryogenic conditions	URS / DQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0104	Cryogenic biological sample cartridge	IQ: verify installation, asset tag, materials, tools, utilities and calibrated sensors	As-built installation, drawings, metrology and critical service connections verified for Cryogenic biological sample cartridge	IQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0105	Cryogenic biological sample cartridge	OQ: challenge low, nominal and high parameter setpoints using justified settings	Approved ranges and parameter-response evidence for thermal compatibility; seals; sample retention; evaluate no leakage / degradation under cryogenic conditions	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0106	Cryogenic biological sample cartridge	OQ: verify interlocks, alarm recovery, recipe security and fault handling	Challenge applicable safety/scrap/reject alarms and document recovery under normal and worst-case device configuration	OQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-36-0107	Cryogenic biological sample cartridge	PQ: confirm reproducible output under routine personnel, tools, materials and conditions	Statistically justified production sampling (representative approved product-family lots) covering no leakage / degradation under cryogenic conditions	PQ	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	High
MDV-36-0108	Cryogenic biological sample cartridge	Continued verification: monitor drift, wear, changeovers, repairs and change control	Trend thermal compatibility; seals; sample retention; define risk-based requalification triggers affecting no leakage / degradation under cryogenic conditions	Routine / Change	Specialized devices / innovative technology; conditional	M01 M02 M03 M04 M07 M14 M16	Medium

37 PRODUCT FAMILY SPECIFIC VERIFICATION MATRIX

30 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-37-0001	Infusion pump	Verify occlusion and air-in-line detection	Detection performance throughout specified operating range	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0002	Infusion pump	Verify flow rate at low/high backpressure	Dose delivery accuracy under intended use	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0003	Ventilator	Verify delivered tidal volume and PEEP at extremes	Accuracy and alarm safety	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0004	Defibrillator	Verify output energy and synchronized shock timing	Electrical therapy safe function	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0005	Electrosurgical device	Verify HF leakage and insulation failure modes	Applicable IEC 60601 essential performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0006	ECG/EEG monitor	Verify measurement accuracy and artifact rejection	Signal clinical accuracy and alarm reliability	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0007	Pulse oximeter	Validate oxygen saturation across intended populations	Bias and precision against suitable reference	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0008	Orthopedic implant	Verify fatigue and endurance to worst-case service loads	Mechanical safety factor and test reports	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0009	Dental implant	Verify fatigue and torque resistance	Representative fixture and interface qualification	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0010	Catheter	Verify torque, tensile and bending performance	Defined product performance acceptance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0011	Balloon catheter	Verify repeated inflation / deflation cycles	No material failure at maximum cycles	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0012	Vascular stent	Verify crimp recovery, expansion and radial force	Dimensional, fatigue and particulate controls	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0013	Syringe	Verify leakage, plunger glide and dose volume accuracy	Applicable ISO product standards / device specification	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0014	Hypodermic needle	Verify needle sharpness, hub retention and lumen patency	Fit for intended use and safe penetration	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0015	IV administration set	Verify flow, connector leaks and clamp action	Functional/physical integrity	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0016	Blood bag	Verify seal/burst and chemical compatibility	Storage/safety as claimed	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0017	Surgical suture	Verify tensile and needle attachment	Suture lot performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0018	Surgical glove	Verify pinhole and mechanical barrier performance	Lot AQL and product performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0019	Respirator	Verify fit, filtration and pressure drop	Claimed use conditions / relevant conformity route	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0020	Surgical mask	Verify bacterial filtration, breathability and splash where claimed	Intended protective performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0021	IOL	Verify optic power, haptic strength and injector delivery	Refractive and surgical delivery performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0022	Contact lens	Verify optical power, base curve and solution compatibility	Wear safety and optical effect	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-37-0023	IVD glucose kit	Validate hematocrit, interfering agents, near-cutoff bias	Clinically appropriate accuracy	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0024	IVD lateral flow kit	Validate specificity, sensitivity and cross-reactivity	Clinical performance and false result controls	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0025	IVD molecular assay	Validate contamination, LoD, primers/probes and variant inclusivity	Robust detection with control of false positives	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0026	IVD immunoassay	Validate high-dose hook effect and lot consistency	Cutoff classification and analytical performance	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0027	Reusable surgical device	Verify function after maximum reprocessing cycles	Mechanical and biological safety over service life	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0028	Combination product	Validate drug-device interfaces separately and combined	Integrated performance, stability and compatibility	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0029	Software as a medical device	Validate intended use including real-world user workflows	Clinical safety/performance with controlled algorithms	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High
MDV-37-0030	Connected device	Verify outage safe state, cyber protection and recovery	No unacceptable patient risk on network fault	Lifecycle	Conditional product-specific requirements	M02 M03 M04 M07 M14 M18 M29	High

38 CROSS-FUNCTIONAL WORST-CASE AND REVALIDATION MATRIX

35 controlled validation/qualification checkpoints | Each row requires site risk screening, approved protocol, evidence and QA disposition.

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-38-0001	Multicavity molding	Demonstrate cavity-to-cavity comparability during PQ	Sampling plan spans all cavities / shifts	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0002	Multiple production lines	Justify line grouping or perform separate PQ	Equipment equivalence and product family rationale	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0003	Operator variation	Evaluate between-operator process output variation	Documented statistical/engineering comparison	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0004	Raw material grade change	Challenge process window and device biological effects	Bridging and risk file update	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0005	Product size family	Test geometric extremes that affect process output	Worst-case selection evidence	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0006	Longest lumen / most complex geometry	Validate cleanability and sterilization access	Representative test geometry	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0007	Thickest packaging laminate	Challenge heat seal penetration and cooling	Worst-case sealing range	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0008	Largest and smallest sterile package	Challenge sterilant/dose access and seal geometry	Sterile packaging equivalence	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0009	Maximum irradiation loading	Challenge dose distribution and product degradation	Dmin/Dmax validated loading	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0010	Maximum EO pallet density	Challenge humidity and EO penetration	Relevant worst-case study	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0011	Longest hold time	Verify bioburden/chemical stability through hold	Risk-based study/monitoring	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0012	Maximum storage age	Verify critical materials at end of qualified life	Incoming/staged material performance	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0013	Worst-case rework count	Validate cumulative heating, mechanical and chemical impact	Final device safety/function maintained	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0014	Power failure during critical step	Assess scrap decisions and restart/recovery	Approved safe-state and line-clearance criteria	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0015	New software release	Assess regression tests and cybersecurity controls	Software lifecycle release package	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0016	Vendor relocation	Establish new equipment/site equivalence or requalification	QA-approved change and test plan	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0017	Cleanroom major shutdown	Justify reclassification and HEPA verification scope	Environmental qualification after change	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0018	Sterilizer chamber service	Assess mapping, sensors, vacuum and PQ re-execution	Defined requalification tests and release	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0019	New device claim or intended use	Assess need for new design validation and clinical evidence	Approved regulatory/technical impact	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0020	New package artwork	Assess content, UDI and label durability	Verification, not unnecessary full equipment PQ	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0021	New IVD calibration algorithm	Perform reference panel regression and cutoff analysis	Version and analytical performance report	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0022	Sensor calibration interval change	Analyze drift history and uncertainty	Scientific recalibration / interval basis	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High

CHECK ID	ASSET / PROCESS	MICRO-LEVEL CHECKPOINT	EVIDENCE / ACCEPTANCE FOCUS	STAGE	SCOPE	STANDARDS	RISK
MDV-38-0023	Product contamination complaint	Trigger cleaning/bioburden/packaging investigations	CAPA, validation impact and protective release controls	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0024	Clinical use incident	Trace failure to design, process and validation plan	Risk file and targeted revalidation decisions	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0025	Test laboratory relocation	Requalify equipment and transfer applicable test methods	Comparable measurement results	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0026	Critical tooling replacement	Check tool design equivalence and cavity PQ	Inspection and process reproducibility	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0027	Change to EO aeration duration	Validate new residual limits and product compatibility	ISO 10993-7 supported release controls	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0028	Changing from EO to radiation	Perform full sterilization and material/packaging compatibility reassessment	New validated process and sterility assurance	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0029	Switching packaging film grade	Challenge seal process and aging/distribution	Package revalidation impact	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0030	Adding alternate power adaptor	Electrical safety and EMC verification	Essential performance maintained	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0031	Increasing device service life	Demonstrate reliability/aging and reusable cycles	Design validation against extended claim	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0032	Adding new language to IFU	Check translation and critical warning comprehension	Market-specific user information verification	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0033	Device software hosting region migration	Assess data integrity, availability, access control	Cloud CSV and privacy risk controls	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0034	Supplier material deviation	Risk-based incoming hold, engineering evaluation and test	Disposition supported by quantified evidence	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High
MDV-38-0035	Change in critical dimension tolerance	Verify measurement method capability and process capability	Design requirements and OQ/PQ controls	Lifecycle	Across device families	M01 M02 M03 M04 M05 M07 M08	High

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