GLOBAL MEDICAL DEVICE QUALITY MANAGEMENT • STERILE + NON-STERILE • IVD • SOFTWARE • IMPLANTS

COMPREHENSIVE MEDICAL DEVICE SOP MASTER LIST

Worldwide regulatory crosswalk | Product-family-specific manufacturing | Department-wise controlled SOP index

Coverage includes Class A/B/C/D (India) and relevant global device classifications; sterile and non-sterile disposables; implants; orthopedic and dental devices; surgical instruments; catheters and infusion sets; wound care; electronic and active medical devices; IVD/POCT; SaMD/AI; sterile barrier packaging; servicing and reprocessing.

SOP TITLES	FUNCTIONAL GROUPS	DOCUMENT	DATE / ISSUE
1,518	28	MASTER INDEX	04 NOV 2026 • 00

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DOCUMENT NOTE: 1,518 proposed SOP titles, not 1,518 fully authored, approved or implemented procedures. Applicability and procedural requirements must be determined against actual devices, processes, legal entities, manufacturing licences, intended markets and risk profiles.

01 DOCUMENT CONTROL, SCOPE & IMPLEMENTATION RULES

Objective

Provide a micro-level, department-wise proposed SOP inventory to perform a medical device manufacturing QMS gap assessment, assign procedure authors, schedule controlled issuance, and manage readiness for applicable medical-device regulatory expectations.

Key regulatory distinction

For US-regulated device manufacturers, 21 CFR Part 820 QMSR took effect 2 February 2026 and incorporates ISO 13485:2016 by reference. It replaces the earlier QS regulation approach and QSIT inspection paradigm. The register uses QMSR, not superseded terms, for the current US crosswalk.

Core global framework

ISO 13485:2016 (QMS), ISO 14971:2019 (risk management), Regulation (EU) 2017/745 MDR, Regulation (EU) 2017/746 IVDR, India MDR 2017 Fifth Schedule, UK MHRA requirements and Australia TGA Essential Principles. Device-type-specific ISO/IEC standards apply only when relevant.

Device classification

Indian device classes A/B/C/D are different from EU MDR class I, IIa, IIb, III and IVDR A/B/C/D, and from US classifications. Classification, intended use and target markets determine which regulatory and QMS obligations apply.

Facility coverage

Device R&D/design, physical/chemical inspection, cleanrooms, sterile and non-sterile assembly, polymer extrusion/molding, catheters, metals/implants, textiles/disposables, electronics, diagnostics/IVD, software/AI, additive manufacturing and installation/service.

Sterile vs aseptic

Not all sterile devices are aseptically manufactured. Sterile device manufacturers often use validated terminal sterilization and ISO 11607 packaging. Aseptic assembly/simulation procedures are conditional; EU GMP Annex 1 for medicinal products must not automatically be imposed on every medical-device manufacturer.

Priority definitions

P1 = site baseline or critical process control to review first; P2 = specialized, risk-based, conditional technology or lifecycle SOP. Neither P1 nor P2 establishes whether a specific SOP is legally mandatory for every device.

Documents, records and owners

Each title is a candidate SOP. The author shall establish procedure purpose, scope, responsibilities, detailed steps, acceptance criteria, forms/logs, risk controls, references, training and QA approval. The Excel tracker supplies ownership/status fields.

Official standards access

Several ISO/IEC standards are copyrighted and not reproduced here. The reference list points to official regulator/standards pages. Check currently adopted editions, national amendments, regulatory transition rules and applicable product-specific standards before issuing SOPs.

02 RISK-BASED IMPLEMENTATION & OWNERSHIP WORKFLOW

PHASE	ACTIVITY	KEY DELIVERABLE
01	Define device portfolio and sites	Approve intended use, risk class by country, device materials, production steps, sterilization and outsourcing
02	Select regulatory requirements	Approve target markets, licence/certification scope, specific standards and QMS exclusions
03	Map risks and critical processes	Link ISO 14971 risk controls to design input, production/verification, acceptance, PMS and field processes
04	Activate SOPs in the tracker	Use P1 first, evaluate P2 conditional processes and mark N/A with justification and QA approval
05	Write / review / approve	Create individual SOP procedures and supporting forms, DMR/medical device files, DHR and traceability
06	Qualify / validate / train	Qualify equipment, validate special processes, train operators and establish record review requirements
07	Verify implementation	Internal audit, mock regulatory inspection, risk based sampling and CAPA closure
08	Maintain throughout lifecycle	Revisit change controls, design transfer, vigilance, PMS, complaints, supplier controls and regulatory updates

03 DEPARTMENT-WISE SOP DISTRIBUTION

FUNCTIONAL GROUP	SOP TITLES	NUMBERING SERIES
Quality Assurance & QMS	152	IGC-MD-QA-
Regulatory Affairs & Market Access	61	IGC-MD-RA-
Risk, Clinical & Post-market Surveillance	66	IGC-MD-PMS-
Design & Development / R&D	56	IGC-MD-RND-
Design Verification / Reliability Testing	40	IGC-MD-DVT-
Quality Control - Physical & Chemical	49	IGC-MD-QCP-
Microbiology, Biocompatibility & Cleanliness	90	IGC-MD-MIC-
General Device Production & Assembly	53	IGC-MD-PRD-
Plastics, Tubing & Catheter Manufacturing	64	IGC-MD-PLS-
Metal, Orthopedic & Instrument Manufacturing	57	IGC-MD-MET-
Textile, Wound Care & Disposable Devices	36	IGC-MD-TEX-
Electronics & Active Device Manufacturing	50	IGC-MD-ELC-
IVD Reagents, Kits & Point-of-Care Devices	54	IGC-MD-IVD-
Software, SaMD, AI & Cybersecurity	60	IGC-MD-SWE-
Cleanroom & Controlled / Aseptic Operations	37	IGC-MD-CLN-
Sterilization, Reprocessing & Sterility Assurance	60	IGC-MD-STL-
Packaging, Labelling & UDI	73	IGC-MD-PKG-
Validation & Process Qualification	107	IGC-MD-VAL-
Engineering, Maintenance & Calibration	60	IGC-MD-ENG-
Utilities, HVAC & Environmental Monitoring	44	IGC-MD-UTL-

FUNCTIONAL GROUP	SOP TITLES	NUMBERING SERIES
Warehouse, Distribution & Traceability	44	IGC-MD-WH-
Procurement & Supplier Quality	24	IGC-MD-SUP-
HR, Training & Administration	39	IGC-MD-HRA-
Computerized Systems / IT / Data Integrity	35	IGC-MD-IT-
Environment, Health & Safety	44	IGC-MD-EHS-
Installation, Servicing & Field Support	25	IGC-MD-SVC-
Additive Manufacturing, Dental & Customized Devices	28	IGC-MD-AM-
Management Review & Quality Strategy	10	IGC-MD-MGT-
TOTAL	**1518**	**28 department / function groups**

04 DEVICE FAMILY APPLICABILITY GUIDE

DEVICE / FACILITY FAMILY	FILTER PHRASE	TYPICAL CONTROLS
General non-sterile device assembly	ALL HARDWARE	Device family risk, material compatibility, controlled records, tool/process validation and QC
Sterile disposable devices	STERILE DEVICES	Sterility assurance, biological controls, packaging validation and traceability
Implants / orthopedic / dental	ORTHOPEDIC / IMPLANT / INSTRUMENT	High traceability, biological evaluation, cleaning, mechanical strength, material and surface control
Syringes / needles / IV sets / catheters	CATHETERS / INFUSION / SYRINGES	Polymer processing, fluid path controls, leakage, bonding and device-specific acceptance
Medical textiles / surgical disposables	DISPOSABLES / WOUND / SURGICAL TEXTILES	Fabric, coating, barrier performance, cutting/conversion, particulate control
IVD assays, kits, POCT and readers	IVD / LFA / PCR / POCT	Performance evaluation, reagent lot controls, cross-reactivity, false result risks and stability
Medical electronics and active devices	ACTIVE / ELECTRONIC DEVICES	IEC 60601 where appropriate, electronics, firmware, alarms and service
Software as a medical device / AI	SaMD / SOFTWARE-CONTAINING DEVICES	Software lifecycle, cybersecurity, SOUP, model validation, field patches
Sterile barrier and packaging	STERILE PACKAGED DEVICES	ISO 11607, seal validation, transport/aging, integrity and labeling
Contract sterilization / EO / gamma / steam	EO STERILIZATION / GAMMA / EBEAM / STEAM / OTHER	Product-specific sterilization validation, batch evidence and contracted process oversight
Reusable medical devices	REUSABLE DEVICES	Validated cleaning/disinfection/sterilization instructions, use cycle life and service
3D printed / custom made devices	AM / CUSTOMIZED / DENTAL	Patient-specific data, build parameters, powder control and custom-made obligations
Installation and servicing	ACTIVE / REUSABLE / SERVICED DEVICES	Service controls and device installation and complaint interface

05 PRIMARY REGULATORY REFERENCE LEGEND

Source codes in the Excel tracker are high-level alignment anchors, not proof of clause-by-clause regulatory compliance. Verify each standard and exact clauses for the regulated device and jurisdiction.

CODE	FRAMEWORK	APPLICATION
ISO13485	ISO 13485:2016 (reviewed/confirmed 2025)	Manufacturer QMS and product realization
ISO14971	ISO 14971:2019	Product lifecycle risk activities

CODE	FRAMEWORK	APPLICATION
FDA-QMSR	FDA 21 CFR Part 820 - QMSR (effective 2026-02-02)	Finished device manufacturers subject to US jurisdiction
FDA-MDR	FDA 21 CFR Part 803 / 806	US market vigilance and field actions
FDA-UDI	FDA 21 CFR Parts 801 and 830	US UDI/GUDID where applicable
FDA-CSA	FDA Computer Software Assurance, February 2026	US-regulated production or QMS software
FDA-CYBER	FDA Cybersecurity in Medical Devices Guidance, February 2026	Connected and cyber devices, where applicable
EU-MDR	Regulation (EU) 2017/745 - MDR	Medical devices marketed in EU
EU-IVDR	Regulation (EU) 2017/746 - IVDR	In vitro diagnostics marketed in EU
UK-PMS	GB UK Medical Devices Regulations 2002 and PMS amendments effective 2025	UK GB only; Northern Ireland follows EU regime for relevant devices
IND-MDR5	India Medical Devices Rules 2017 - Fifth Schedule	CDSCO/SLA medical device licence scope
TGA	Australia TGA Medical Devices Regulations 2002 Essential Principles	Australia marketed products
ISO11607	ISO 11607 (Parts 1 & 2)	Terminally sterilized devices
ISO11135	ISO 11135 - Ethylene oxide sterilization	EO-sterilized devices
ISO11137	ISO 11137 series - Radiation sterilization	Gamma/e-beam/X-ray sterilized devices
ISO17665	ISO 17665 - Moist heat sterilization	Steam sterilized devices
ISO11737	ISO 11737 - Bioburden and sterility testing	Sterility assurance tests
ISO10993	ISO 10993 series - Biological evaluation	Patient-contact devices
ISO14644	ISO 14644 series - Cleanrooms	Controlled facilities
IEC62304	IEC 62304 - Medical device software life cycle	Medical device software
IEC62366	IEC 62366-1 - Usability engineering	Devices with human interaction
IEC60601	IEC 60601 series - Medical electrical equipment	Medical electrical equipment
ISO15223	ISO 15223-1 - Device labeling symbols	Labeling for applicable devices
ISO20417	ISO 20417 - Information supplied by manufacturer	Device information to users
ISO14155	ISO 14155 - Clinical investigation	Medical device clinical investigations
ISO20916	ISO 20916 - IVD clinical performance studies	IVD clinical performance
ISO23640	ISO 23640 - Stability evaluation of IVD reagents	IVD reagents and kits
LOCAL-EHS	Local legal EHS/occupational/radiation/chemical/waste requirements	All sites, process-specific

06 COMPLETE SOP MASTER INDEX • DEPARTMENT BY DEPARTMENT

1,518 individual proposed titles follow. The Excel tracker contains additional fields for process owner, reviewers, market applicability, priority, status, issue dates, document links and required records.

QUALITY ASSURANCE & QMS | 152 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-001	Quality policy, objectives and site quality plan	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-002	Organization chart and GMP responsibility matrix	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-003	Quality unit independence and decision authority	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-004	Site Master File preparation and periodic update	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-005	Quality agreements between legal entities and sites	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-006	Quality governance meeting and escalation management	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-007	Quality risk management (QRM) program	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-008	Risk register creation, scoring, review and archival	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-009	Annual GMP compliance review and improvement plan	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-010	Quality culture and employee reporting channels	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-011	GMP document hierarchy and numbering convention	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-012	Standard operating procedure life-cycle management	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-013	Master document register issuance and reconciliation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-014	Controlled document drafting, verification and approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-015	Document effective-date control and deployment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-016	Document periodic review and obsolescence	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-017	Distribution, retrieval and destruction of obsolete copies	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-018	Good documentation practices / ALCOA+ controls	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-019	Controlled forms, logbooks and registers management	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-020	Blank form issue, reconciliation and destruction	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-021	GMP record retention and secure archival	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-022	GMP record retrieval and authorized access	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-023	Electronic record versus paper record equivalence review	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-024	Data integrity governance and gap assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-025	Electronic data audit-trail review governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-026	Planned deviation approval and risk assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-027	Unplanned deviation initiation and classification	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-028	Critical deviation immediate escalation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-029	Event chronology and evidence preservation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-030	Deviation impact assessment for affected batches	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-031	Root cause analysis using 5-Why / fishbone	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-032	Human error investigation and system factors review	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-033	CAPA initiation and action assignment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-034	CAPA risk-based due-date extension	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-035	CAPA implementation evidence verification	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-036	CAPA effectiveness check and closure	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-037	Recurring deviation and CAPA trend analysis	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-038	Non-conforming material identification and disposition	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-039	Manufacturing incident investigation and batch linkage	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-040	Laboratory OOS notification to QA and decision pathway	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-041	OOT trend investigation governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-042	Sterility-test failure escalation and investigation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-043	Environmental monitoring excursion impact assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-044	Microbial contamination investigation governance	Sterile devices / controlled areas, as applicable	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-045	Mix-up / cross-contamination investigation procedure	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-046	Data-integrity event investigation and remediation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-047	GMP change control request, categorization and approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-048	Change impact evaluation for validation and filings	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-049	Temporary change approval and expiry controls	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-050	Emergency GMP change governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-051	Change implementation, training and effectiveness	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-052	Post-change review and formal closure	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-053	Batch record issue, reconciliation and retrieval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-054	Laboratory raw data review and release recommendation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-055	Batch disposition: release, reject, reprocess or hold	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-056	Conditional release / exceptional disposition governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-057	Batch rejection and destruction authorization	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-058	Product quality review / annual product review	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-059	Management review of product quality trends	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-060	Ongoing process verification and statistical review	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-061	GMP batch-to-batch traceability and genealogy	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-062	Retest-date and expiry-date assignment governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-063	Shelf-life extension assessment and approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-064	Product transfer and technical change governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-065	Commercial batch certification market-specific workflow	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-066	Internal GMP audit master schedule	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-067	Process audit conduct and report issue	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-068	Unannounced / for-cause GMP audit procedure	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-069	Audit finding classification and CAPA tracking	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-070	Regulatory inspection preparedness and response room	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-071	Regulatory inspection conduct and evidence provision	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-072	Regulatory observation response and commitment tracking	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-073	Inspection readiness mock-audit program	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-074	Qualified person / authorized person oversight (where applicable)	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-075	Contract manufacturer quality oversight and audit	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-076	Contract laboratory qualification and quality agreement	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-077	Outsourced GMP service provider risk assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-078	Supplier corrective action request (SCAR)	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-079	Quality complaints receipt, triage and classification	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-080	Complaint sample evaluation and investigation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-081	Product recall initiation, strategy and execution	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-082	Mock recall challenge and reconciliation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-083	Field alert / expedited quality defect notification by market	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-084	Quality defect risk assessment for patient impact	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-085	Returned goods quality evaluation and disposition	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-086	Product discontinuation and residual stock control	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-087	Site contamination control strategy (CCS) governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-088	Sterile manufacturing CCS periodic assessment	Sterile devices / controlled areas, as applicable	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-089	Cross-contamination control and segregation strategy	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-090	Cleaning validation limit and worst-case rationale approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-091	Highly potent / sensitizing substance control strategy	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-092	Dedicated facilities assessment for special risk products	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-093	Bioburden / endotoxin control strategy	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-094	Aseptic process deviation risk escalation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-095	Environmental monitoring program approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-096	Sterilization cycle failure batch impact assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-097	Lyophilization process interruption impact assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-098	Container closure integrity failure escalation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-099	Sterility assurance level (SAL) strategy oversight	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-100	Contamination control effectiveness metrics	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-101	Microbial identification / objectionable organism risk review	Sterile devices / controlled areas, as applicable	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-102	Extractables / leachables control strategy (where applicable)	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-103	Genotoxic / mutagenic impurity risk assessment governance	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-104	Line clearance verification and independent check	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-105	Area status labeling and visual control verification	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-106	Dispensing / weighing verification by QA	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-107	Yield and reconciliation investigation criteria	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-108	In-process quality inspection and approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-109	Rejected / printed packaging component reconciliation	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-110	Batch sampling plan approval and oversight	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-111	Market-specific label and artwork change approval	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-112	Reconciliation of tamper-evidence and serialization records	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-113	QA oversight of outsourced sterilization	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-114	Real-time temperature excursion quality disposition	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-115	Cold chain excursion investigation and release decision	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-116	Customer notification of quality-related changes	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-117	Data integrity oversight of laboratory computerized systems	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-118	Quality oversight of calibration and maintenance overdue equipment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-119	Equipment breakdown product impact assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-120	Hold-time excursion product impact assessment	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-121	Cleaning validation failure and re-clean authorization	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-122	Regulatory commitment tracking and compliance closure	All device sites	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-123	ISO 13485 QMS scope and justified nonapplicability determination	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-124	Medical device quality manual and documented-process map	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-125	Medical device file (MDF) / product family index governance	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-126	Device master record (DMR) structure and approval	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-127	Device history record (DHR) content, traceability and review	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-128	Quality system interfaces between design, manufacturing and servicing	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-129	Device-specific process validation status matrix governance	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-130	Regulatory-required documented procedures register maintenance	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-131	Risk management file and QMS process integration	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-132	Product acceptance authority and device release governance	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-133	UDI/label control responsibility and approval	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-134	EU PRRC qualification, appointment and escalation (EU market)	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-135	Regulatory requirements flow-down to manufacturing sites	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-136	Device risk classification change impact to QMS controls	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-137	Complaint/MDR vigilance interface for device quality unit	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-138	Control of reusable devices and reprocessing claims	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-139	Preservation of sterile barrier integrity across lifecycle	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-140	Post-distribution nonconforming device evaluation and disposition	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QA-141	QMS requirements for contract sterilization service providers	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-142	GMP applicability for Class A/B/C/D and device category by country	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-143	Design-transfer gate and first article production release	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-144	Process family QMS audit against device risk criticality	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-145	Device batch/serial nonconformance and suspect unit segregation	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-146	Customer-specific quality agreement and device supply controls	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-147	Use of risk management in supplier and outsourced processes	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-148	Device acceptance sampling plans and statistical rationale approval	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-149	ISO 13485 certificate and external audit scope maintenance	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-150	Product release under conditions of approved technical file	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-151	Control of implants and high-risk device traceability	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR
IGC-MD-QA-152	Device family periodic product quality and trending review	ALL DEVICES	P1	ISO13485;FDA-QMSR;IND-MDR5;EU-MDR

End of Quality Assurance & QMS • 152 titles

REGULATORY AFFAIRS & MARKET ACCESS | 61 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RA-001	Regulatory pathway determination and device classification by market	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-002	Intended purpose / indications for use approval and control	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-003	Device accessory versus component regulatory status determination	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-004	Medical device/IVD borderline-product assessment and records	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-005	India Class A/B/C/D medical device classification workflow	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-006	India CDSCO and State Licensing Authority responsibility matrix	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-007	India manufacturing licence application preparation and review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-008	India loan licence / contract manufacture licence assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-009	India import licence and authorized agent appointment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RA-010	India Device Master File and Plant Master File review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-011	India Fifth Schedule QMS compliance evidence maintenance	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-012	India licence renewal/change endorsement and post-approval variation	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-013	Indian medical device registration / notification applicability monitoring	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-014	US product code and FDA classification determination	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-015	US establishment registration and device listing workflow	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-016	US 510(k), De Novo or PMA submission management, as relevant	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-017	US QMSR regulatory requirements gap review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-018	US UDI/GUDID, labelling and applicable product-specific obligations	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-019	EU MDR classification under Annex VIII and rule justification	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-020	EU IVDR classification under Annex VIII and rule justification	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-021	EU declaration of conformity issue and change control	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-022	EU technical documentation Annex II / Annex III completeness review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-023	EU GSPR checklist / standards evidence matrix maintenance	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-024	EU notified body selection and certification application management	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-025	EU QMS conformity assessment Annex IX pathway management	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-026	EU authorised representative / importer / distributor interfaces	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-027	EU registration, SRN, EUDAMED and UDI obligations assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-028	EU implant card and information supplied to patient, when applicable	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-029	EU product / clinical evaluation and PMCF/PMFP regulatory evidence	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-030	UK MHRA registration and UK Responsible Person assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-031	GB UKCA/CE conformity route and transitional arrangement assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-032	UK medical device vigilance and post-market obligations review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-033	Northern Ireland separate EU MDR/IVDR obligations review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RA-034	Australia ARTG inclusion and sponsor/manufacturer evidence handling	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-035	Australia TGA Essential Principles compliance matrix	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-036	Australia conformity assessment certification pathway review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-037	Australia adverse event reporting and post-market responsibilities	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-038	Canada medical device licence / MDSAP / CMDCAS applicability review	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-039	Japan PMDA/MHLW QMS and licence pathway assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-040	Brazil ANVISA / Saudi SFDA / international submission applicability	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-041	Country-specific approved label, symbol and language matrix control	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-042	Regulatory change monitoring and standards transition assessment	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-043	Regulator / notified body audit finding response and correspondence	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-044	Product change significance assessment and regulatory notification decision	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-045	Regulatory certificate, licence and expiry tracking	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-046	Regulatory authority safety communication and field action approval	ALL MARKETS	P1	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-047	EU technical documentation lifecycle update and release	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-048	Basic UDI-DI assignment and regulatory device grouping assessment	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-049	EU notified body certificate limitations and scope review	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-050	IVD performance evaluation documentation and review	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-051	EU IVDR scientific validity / analytical / clinical performance evidence review	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-052	Software medical device regulatory qualification and classification	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-053	Custom-made device regulatory statement management	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-054	System/procedure pack requirements and documentation	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-055	Clinical investigation application and ethics document control	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-056	Clinical evaluation report / PMCF plan filing workflow	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-057	Regulatory submission response to deficiency questions	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RA-058	MDR/IVDR transition and legacy device transition controls	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-059	Device change record linkage to regulatory submissions	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-060	Product claims substantiation and promotional compliance review	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR
IGC-MD-RA-061	Regulatory intelligence and country-specific surveillance program	MARKET / DEVICE SPECIFIC	P2	EU-MDR;EU-IVDR;IND-MDR5;FDA-QMSR

End of Regulatory Affairs & Market Access • 61 titles

RISK, CLINICAL & POST-MARKET SURVEILLANCE | 66 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PMS-001	Medical device risk management policy and plan	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-002	Risk management responsibilities and acceptability criteria approval	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-003	Intended use, reasonably foreseeable misuse and user profile analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-004	Device characteristics related to safety identification	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-005	Hazard identification for physical, biological and mechanical risks	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-006	Hazard identification for software, cybersecurity and usability risks	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-007	Hazardous situation / sequence of events analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-008	Harm severity and probability estimation methodology	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-009	Risk evaluation against pre-established criteria	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-010	Fault tree analysis for system-level critical failures	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-011	Product design FMEA and risk control action management	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-012	Process FMEA and manufacturing risk control management	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-013	Use-related risk analysis and use error reduction	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-014	Risk reduction by inherent safety / protective measures / information	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-015	Verification of risk-control implementation	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-016	Verification of risk-control effectiveness	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-017	Risk introduced by risk controls and unintended consequences	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-018	Residual risk assessment and acceptance	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-019	Benefit-risk analysis where individual residual risks are unacceptable	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-020	Overall residual risk evaluation and benefit-risk conclusion	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-021	Risk management report and pre-release approval	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-022	Production and post-production information collection into risk file	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-023	Risk management file periodic update and traceability	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-024	Risk acceptability criteria change management	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-025	Risk management integration with CAPA / complaints / PMS	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-026	Risk management review after field safety corrective action	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PMS-027	Risks related to cleaning, disinfection and reuse claims	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-028	Biological hazards and contact categorization risk analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-029	Electrical, electromagnetic and thermal hazard analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-030	Software of unknown provenance (SOUP) risk analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-031	IVD incorrect-result and clinical decision risk analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-032	Environmental, transport and storage-related risk analysis	ALL DEVICES	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-033	Clinical evaluation plan and clinical evidence appraisal	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-034	Clinical data literature search protocol and review	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-035	State-of-the-art clinical comparator evaluation	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-036	Clinical investigation feasibility and protocol review	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-037	Clinical investigation product accountability and traceability	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-038	Clinical performance / clinical investigation report controls	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-039	Clinical evaluation report periodic update	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-040	Post-market clinical follow-up (PMCF) plan and evaluation	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-041	Post-market performance follow-up (PMPF) for IVDs	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-042	Post-market surveillance system and plan governance	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-043	Proactive PMS data acquisition and signal monitoring	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-044	Device complaint intake, event chronology and triage	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-045	Complaint handling for suspected reportable serious incident	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-046	Service report and literature vigilance signal extraction	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-047	Trend reporting threshold and escalation management	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-048	Vigilance serious incident reportability and timelines by market	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-049	Field safety corrective action (FSCA) and recall procedure	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-050	Field safety notice preparation and dissemination	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-051	US MDR reportability decision tree and 21 CFR 803 submission	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-052	US corrections/removals assessment and 21 CFR 806 reporting	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-053	EU MDR/IVDR vigilance reporting and authority notification	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-054	UK MHRA vigilance report and PMSR / PSUR governance	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-055	Australia TGA adverse event reporting workflow	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-056	Device traceability-based recall / mock recall and effectiveness check	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-057	Complaint file / returned samples forensic investigation	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-058	Implant recipient traceability and escalation support where lawful	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-059	PMS report / PSUR preparation and approval according to class	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-060	Post-market information review into labeling and risk file	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-061	Product safety signal handling / trend statistical review	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-062	Device cybersecurity vulnerability postmarket intake and triage	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PMS-063	Adverse event / usability issue root cause and CAPA link	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-064	False positive / false negative IVD report investigation	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-065	Postmarket benefit-risk reassessment and design-change trigger	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS
IGC-MD-PMS-066	Clinical claims alignment with approved labeling	MARKET / RISK-CLASS SPECIFIC	P1	ISO14971;EU-MDR;EU-IVDR;UK-PMS

End of Risk, Clinical & Post-market Surveillance • 66 titles

DESIGN & DEVELOPMENT / R&D | 56 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RND-001	New device concept screening and design feasibility	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-002	Design and development planning with phase gate criteria	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-003	Design history / development record compilation	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-004	Design responsibility and cross-functional review matrix	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-005	Customer / user / patient needs elicitation and translation	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-006	Intended purpose, clinical workflow and environment specification	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-007	Design input requirements definition and approval	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-008	Design input completeness, ambiguity and conflict review	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-009	System requirement decomposition and traceability	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-010	Design output / engineering drawings / specifications control	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-011	Design reviews: agenda, independence, actions and closure	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-012	Design verification strategy and plan	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-013	Design validation strategy including representative users	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-014	Design-to-risk traceability matrix maintenance	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-015	Design change impact assessment and revision management	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-016	Design transfer readiness review and manufacturing handover	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-017	First article acceptance and pilot build planning	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-018	Device material selection and biocompatibility planning	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-019	Design for manufacturing and assembly assessment	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-020	Design for reliability and field-serviceability review	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-021	Design for cleaning / disinfection / sterilization assessment	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-022	Design for safe disposal / end-of-life assessment	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-023	Design for packaging and transport robustness	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-024	Design freeze, baseline and controlled design release	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-025	Component obsolescence and alternative part approval	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-026	Critical supplier design input and change notification	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-027	Design for installation/service and maintenance strategy	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-028	Human factors / usability engineering plan	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-RND-029	Device lifecycle requirements engineering change tracking	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-030	New product introduction phase gate and risk review	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-031	Prototype identification and nonclinical-use labelling control	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-032	Prototype bench test deviations and disposition	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-033	Pilot production / process capability study coordination	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-034	Design equivalence assessment for product line extensions	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-035	Verification versus validation decision and documentation	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-036	Post-design transfer modifications and retraining	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-037	Implant device geometry, fixation and load-case requirements	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-038	Wearable device power, skin-contact and environmental requirements	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-039	Electrical medical device system architecture requirements	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-040	Medical electrical system essential performance allocation	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-041	IVD assay analytical performance and clinical needs definition	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-042	POCT device-user environment and operator variability specification	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-043	Catheter fluid path, kink resistance and biocompatibility requirements	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-044	Drug-device combination product responsibility assessment	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-045	Sterile single-use device design for sterilization compatibility	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-046	Reusable instrument reprocessing-cycle design durability	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-047	Dental patient-matched device design input control	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-048	Custom implant patient CT data conversion control	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-049	Additive manufactured part build orientation design review	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-050	Software as a medical device (SaMD) clinical workflow design	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-051	Interoperable device interface and data integrity design	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-052	AI/ML dataset provenance, bias and intended population assessment	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-053	Critical alarm design and clinical risk justification	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-054	Labelling and IFU usability verification in design control	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-055	Design control for pediatric or vulnerable-user populations	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-RND-056	Environmental sustainability and material restriction assessment	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR

End of Design & Development / R&D • 56 titles

DESIGN VERIFICATION / RELIABILITY TESTING | 40 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-DVT-001	Design verification master plan and traceability review	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-002	Bench test protocol creation with acceptance criteria	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-003	Test fixture design, calibration and suitability	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-004	Sample size determination for verification testing	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-DVT-005	Test specimen conditioning and pre-test inspection	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-006	Dimensional and tolerance stack-up verification	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-007	Mechanical strength / torque / load testing method	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-008	Tensile, compression, bend and fatigue test execution	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-009	Leak tightness, burst pressure and flow resistance testing	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-010	Catheter pushability, trackability and kink test method	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-011	Connector / Luer connection dimensional and leak assessment	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-012	Needle sharpness, penetration force and bevel test method	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-013	Syringe plunger force and delivery accuracy verification	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-014	Infusion delivery accuracy and occlusion alarm test method	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-015	Implant wear and corrosion resistance verification	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-016	Transport / vibration / shock environmental test control	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-017	Temperature, humidity, IP ingress and salt mist testing	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-018	Drop / impact test execution and acceptance	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-019	Device cleaning and reprocessing durability validation tests	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-020	Accelerated life / reliability demonstration test planning	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-021	Reliability prediction, confidence and statistical assessment	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-022	Risk-control effectiveness testing and evidence integration	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-023	Verification anomaly / engineering nonconformity investigation	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-024	Verification report review and independent acceptance	ALL DEVELOPED DEVICES	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-025	Electrical safety type testing and certification evidence management	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-026	Essential performance and single-fault condition testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-027	EMC immunity and emissions test coordination	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-028	Battery safety, charging and power failure testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-029	Alarm accuracy, priority and audibility testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-030	Software system test procedure and requirements coverage	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-031	Network disconnection, latency and recovery test execution	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-032	Cybersecurity penetration test and remediation workflow	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-033	IVD precision, repeatability and reproducibility testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-034	IVD analytical sensitivity and limit-of-detection determination	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-035	IVD analytical specificity, interference and cross-reactivity	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-036	IVD measuring range, linearity and hook-effect testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-037	IVD lot-to-lot method comparison study	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-038	IVD clinical performance and diagnostic concordance testing	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-039	Wearable sensor drift and calibration verification	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-DVT-040	Human factors summative validation test coordination	SPECIALIZED DEVICES	P2	ISO13485;ISO14971;EU-MDR

End of Design Verification / Reliability Testing • 40 titles

QUALITY CONTROL - PHYSICAL & CHEMICAL | 49 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QCP-001	Incoming device component inspection and release	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-002	Sampling plan selection using statistically valid basis	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-003	First article inspection and drawing conformance verification	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-004	In-process inspection and acceptance criteria verification	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-005	Final inspection / final acceptance documentation	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-006	Identification, segregation and control of rejected items	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-007	Vernier, micrometer and gauge measurement methods	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-008	Optical comparator / vision measurement system operation	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-009	Coordinate measuring machine (CMM) operational qualification	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-010	Surface roughness measurement and reporting	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-011	Coating thickness and uniformity testing	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-012	Mechanical tensile/compression test execution	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-013	Flexural, torsional and fatigue test method	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-014	Hardness test / material certificate verification	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-015	Dimensional inspection for injection molded features	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-016	Plastic tubing inner/outer diameter and wall thickness testing	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-017	Leak and burst test for fluid path device components	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-018	Connector gauge and fitting dimensional assessment	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-019	Weight, density and mass balance measurements	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-020	Metal alloy certificate, grade and traceability verification	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-021	XRF / elemental alloy identification screening	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-022	Polymer identity testing using FTIR where applicable	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-023	Residual chemical process agent testing and acceptance	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-024	Weld joint strength / integrity assessment	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-025	Surface contamination / cleanliness test method	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-026	Water extractable/ionic contamination testing, where applicable	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-027	Colour, transparency, visual appearance and cosmetic defects	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-028	Visual inspection under magnification and defect grading	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-029	Sample retention and laboratory chain of custody	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-030	Independent review of raw test results and release recommendation	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-031	Test method change control and cross-lab transfer	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-032	Quality control investigation, retest and result invalidation rules	ALL HARDWARE	P1	ISO13485;IND-MDR5
IGC-MD-QCP-033	Medical adhesive bond peel strength and cure verification	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-034	Silicone elastomer durometer and compression set test	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-035	Device lubricity and coating durability assessment	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-QCP-036	Suture tensile, knot strength and needle attachment testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-037	Dressing absorbency and fluid retention testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-038	Barrier textile fabric tensile / lint / particulate testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-039	Electronic printed circuit board inspection and test	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-040	Sensor accuracy, signal stability and calibration verification	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-041	Battery charging / discharging QC acceptance	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-042	Electromagnetic screening product acceptance	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-043	IVD liquid reagent pH and osmolality testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-044	IVD reagent concentration and potency test method	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-045	IVD reference calibrator / control acceptance testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-046	IVD cartridge fluidic leak and movement verification	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-047	IVD functional challenge panel testing	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-048	Device shelf-life chemical compatibility acceptance	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5
IGC-MD-QCP-049	Extractables and leachables analytical test coordination	IVD / IMPLANTS / ACTIVE	P2	ISO13485;IND-MDR5

End of Quality Control - Physical & Chemical • 49 titles

MICROBIOLOGY, BIOCOMPATIBILITY & CLEANLINESS | 90 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MIC-001	Microbiology laboratory zoning and aseptic conduct	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-002	Microbiology analyst gowning and qualification	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-003	Aseptic microbiological sampling technique	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-004	Microbiology equipment cleaning and sanitization	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-005	Microbial culture inventory and traceability	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-006	Culture media purchase and receipt control	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-007	Microbiological media preparation, sterilization and labeling	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-008	Growth promotion test for prepared culture media	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-009	Media storage, shelf life and reconciliation	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-010	Reference microorganism receipt and passage control	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-011	Incubators operation, monitoring and mapping	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-012	Autoclave operation for microbiology sterilization	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-013	Biological indicator usage and result interpretation	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-014	Sterility testing isolator / LAF use and checks	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-015	Microbiology laboratory waste decontamination	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-016	Microbiological result data integrity and review	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-017	Environmental monitoring sample chain of custody	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-018	Raw material bioburden / microbial limits testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MIC-019	Purified water total microbial count testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-020	Water for injection microbial monitoring	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-021	Bacterial endotoxins test (LAL / recombinant reagent where justified)	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-022	Sterility test method suitability and execution	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-023	Sterility test invalidation criteria and investigation	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-024	Microbial enumeration test for nonsterile products	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-025	Tests for specified / objectionable microorganisms	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-026	Preservative efficacy / antimicrobial effectiveness testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-027	Bioburden testing of pre-sterilization bulk solution	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-028	Bioburden testing of sterile filter feed	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-029	Microbial identification to appropriate taxonomic level	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-030	Gram stain, biochemical and confirmatory ID	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-031	Endotoxin method inhibition/enhancement suitability	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-032	Microbial cleaning verification / swab recovery	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-033	Compressed gas microbiological testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-034	Filter / wet component microbiological testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-035	Packaging component microbiological quality testing	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-036	Environmental monitoring program risk-based locations	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-037	Settle plate environmental monitoring	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-038	Active viable air sampling	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-039	Surface contact plate monitoring	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-040	Glove and personnel monitoring	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-041	Non-viable particle monitoring in classified areas	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-042	Alert/action limits setting and periodic review	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-043	EM data trending, identification and escalation	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-044	Environmental excursion investigation support	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-045	Aseptic process simulation microbiological assessment	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-046	Disinfectant efficacy and rotation study	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-047	Disinfectant expiry / in-use hold time	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-048	Cleanroom microbiological qualification study	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-049	Isolator / RABS glove integrity microbiological support	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-050	Water system biofilm trend / action response	All device sites	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-051	Microbiological QC laboratory zoning and sample workflow	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-052	Microbial culture media preparation and release verification	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-053	Culture media growth promotion and sterility verification	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-054	Microbiological sample receipt, quarantine and identification	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MIC-055	Product bioburden test method selection and validation	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-056	Method suitability / inhibition / neutralization assessment	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-057	Bioburden routine testing and trend assessment	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-058	Microbial species identification for product and environment	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-059	Sterility testing applicability and test method control	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-060	Sterility test positive event investigation and report	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-061	Bacterial endotoxin test applicability and method suitability	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-062	Endotoxin testing of implant / fluid path products	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-063	Product cleanliness / particulate test selection	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-064	Microbiological test method transfer and change control	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-065	Microbiology laboratory contamination control and cleaning	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-066	Incubator temperature monitoring and excursion response	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-067	Controlled microbial reference strain management	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-068	Microbiological OOS/deviation / invalid test investigation	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-069	Test sample representativeness and batch size linkage	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-070	Biological indicator management and performance verification	STERILE / BIOLOGICAL-CONTACT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-071	Patient-contact material categorization and contact duration assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-072	Biological evaluation plan per applicable ISO 10993 requirements	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-073	Chemical characterization and analytical evaluation plan	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-074	Extractables and leachables test design and toxicological review	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-075	Cytotoxicity test commissioning and review	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-076	Sensitization and irritation endpoint assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-077	Systemic toxicity and implantation endpoint assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-078	Hemocompatibility assessment for blood-contacting devices	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-079	Material-mediated pyrogenicity assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-080	Animal testing avoidance / justification and ethics review	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-081	Biological evaluation report preparation and expert review	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-082	Biological safety impact assessment after material change	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-083	Cleaning agent residue toxicological acceptance assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-084	Sterilant residuals EO/ECH compliance and release controls	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-085	ISO 10993-7 residual test sampling and trending	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-086	Water quality microbiological control for cleaning operations	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-087	Reusable-device cleaning efficacy testing and acceptance	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-088	Endotoxin monitoring for sterile implant processes	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-089	Pyrogenic risk of process contaminants assessment	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993
IGC-MD-MIC-090	Surface cleanliness verification for implants and catheters	PATIENT-CONTACT / IMPLANT	P1	ISO13485;ISO14971;ISO10993

End of Microbiology, Biocompatibility & Cleanliness • 90 titles

GENERAL DEVICE PRODUCTION & ASSEMBLY | 53 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PRD-001	Production order / work order issuance and authorization	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-002	Device master record to production traveler linkage	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-003	Manufacturing line startup and readiness checks	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-004	Tool and fixture verification before production	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-005	Production equipment status identification and changeover	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-006	Material dispensing / kitting against approved bill of materials	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-007	Controlled component issue by lot/serial identification	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-008	Assembly workstation preparation and line clearance	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-009	Production personnel line entry and hygiene checks	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-010	Critical process parameter setup and verification	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-011	Validated parameter recipe download and authorization	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-012	Production operations sampling and in-process inspection	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-013	Independent verification of safety-critical assembly steps	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-014	Rework authorization and approved rework instruction issue	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-015	Scrap identification / segregation / recording and analysis	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-016	Product configuration control and version identification	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-017	Handling damage, foreign object and particulate prevention	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-018	Mix-up prevention across product variants and sizes	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-019	Tooling life limits and changeout decision control	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-020	Component orientation / correct-side-up verification	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-021	Adhesive and lubricant dispensing / mix preparation	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-022	Glue cure time / temperature / humidity monitoring	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-023	Press fit / snap fit assembly controls	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-024	Thread fastener torque and verification control	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-025	Ultrasonic welding machine setup and cycle logging	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-026	Laser / thermal bonding operation control	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-027	Adhesive bonding process setup and curing records	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-028	Soldering / joining and operator workmanship criteria	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-029	In-process dimensional measurement and challenge samples	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-030	Subassembly labeling and hold-point controls	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-031	Device batch / unit numbering and genealogy creation	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-032	Device production traveler completeness and closure	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-033	Work-in-progress preservation and contamination prevention	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-034	Product transfer to final QC / approved storage	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-035	Production deviations and escalation before continuation	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PRD-036	Device build record reconciliation and QA review	ALL HARDWARE	P1	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-037	Operator certification for critical manual assembly	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-038	Poka-yoke / error-proofing challenge and effectiveness test	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-039	Line balance / takt time and manufacturing process change review	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-040	Manufacturing process capability study and trend review	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-041	Visual defect standard library development and control	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-042	Reference sample / golden unit issuance and expiry	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-043	Automated assembly reject bin and re-verification controls	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-044	In-line sensor alarm / reject challenge and escalation	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-045	Automated vision inspection setup and false reject control	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-046	Manufacturing cell software recipe / tool revision control	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-047	Critical component installation orientation verification	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-048	Device accessories and kit completeness reconciliation	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-049	Production hold-time between operations justification	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-050	In-process shelf-life controls for adhesives and chemicals	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-051	Return to operation following power or compressed-air failure	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-052	Contamination risk review for shared equipment or room	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5
IGC-MD-PRD-053	Lot splitting / lot merging and device genealogy rules	ALL HARDWARE	P2	ISO13485;FDA-QMSR;IND-MDR5

End of General Device Production & Assembly • 53 titles

PLASTICS, TUBING & CATHETER MANUFACTURING | 64 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PLS-001	Polymer resin incoming qualification and grade confirmation	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-002	Polymer batch identity and melt-flow index verification	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-003	Resin drying and moisture target control	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-004	Resin mixing / masterbatch addition and traceability	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-005	Injection mold setup, clamping and first-shot approval	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-006	Mold temperature and water cooling monitoring	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-007	Injection pressure, hold pressure and cycle-time controls	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-008	Injection molded part visual inspection and flash trimming	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-009	Injection molding process validation and control charts	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-010	Mold cleaning, change and preventive care	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-011	Thermoplastic extrusion equipment setup and verification	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-012	Extrusion barrel profile and screw speed management	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-013	Extruded tubing laser measurement and wall thickness control	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-014	Tubing puller, cutter and winding line control	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PLS-015	Co-extrusion / multilayer tube process monitoring	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-016	Tube surface lubrication / coating control	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-017	Medical-grade thermoplastic welding and heat sealing	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-018	Tubing annealing / stress-relief process controls	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-019	Die tooling wear, cleaning and release assessment	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-020	Polymer batch changeover and purging verification	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-021	Polymer regrind/reuse prohibition or control justification	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-022	Polymer ageing, discoloration and degradation monitoring	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-023	Material lot-to-finished tube traceability	POLYMER / SINGLE USE	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-024	Catheter shaft and lumen inspection / sizing	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-025	Catheter tip forming and taper specification control	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-026	Catheter hydrophilic coating application and cure	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-027	Catheter marker band assembly and retention verification	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-028	Guidewire core assembly and tip bonding	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-029	Guidewire coating thickness and lubricity checks	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-030	Tubing-to-hub adhesive bond strength verification	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-031	Luer fitting / connector assembly verification	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-032	Stopcock and valve assembly process control	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-033	IV fluid administration set tube cutting and bonding	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-034	IV drip chamber / Y-port component assembly	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-035	IV roller clamp and flow regulator assembly	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-036	Blood collection tubing and needle holder assembly	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-037	Medical syringe barrel molding and cosmetic inspection	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-038	Syringe plunger, gasket and lubricant assembly	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-039	Needle cannula cutting, grinding and deburring	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-040	Needle siliconization and drying controls	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-041	Needle hub attachment / pull-off force checks	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-042	Needle guard / safety shield deployment verification	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-043	Microbore tubing coil memory and kink prevention	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-044	Hemostasis valve assembly and leakage testing	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-045	Catheter inflation balloon forming and bond verification	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-046	Balloon burst, compliance and leak production testing	CATHETERS / INFUSION / SYRINGES	P1	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-047	Disposable syringes: barrel transparent inspection standardization	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-048	Disposable syringes: plunger seal insertion force control	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-049	Disposable syringes: hub dimensional mismatch rejection	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-050	Disposable syringes: needle dead-space / residual volume measurement	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PLS-051	Disposable syringes: graduation mark printing and legibility	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-052	Disposable syringes: sterile unit pack visual inspection	POLYMER / SINGLE USE	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-053	IV administration sets: flow regulator functional challenge	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-054	IV administration sets: drip chamber integrity check	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-055	IV administration sets: air vent filter seal verification	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-056	IV administration sets: roller clamp occlusion test	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-057	IV administration sets: tube bond pull force check	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-058	IV administration sets: final leakage pressure acceptance	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-059	Catheters: distal tip profile inspection	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-060	Catheters: guidewire compatibility acceptance	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-061	Catheters: hydrophilic coat friction verification	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-062	Catheters: radiopaque marker retention test	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-063	Catheters: catheter lumen patency challenge	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR
IGC-MD-PLS-064	Catheters: catheter kink resistance in-process verification	CATHETERS / INFUSION / SYRINGES	P2	ISO13485;FDA-QMSR;EU-MDR

End of Plastics, Tubing & Catheter Manufacturing • 64 titles

METAL, ORTHOPEDIC & INSTRUMENT MANUFACTURING | 57 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MET-001	Medical-grade alloy / bar stock identity verification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-002	Metal forging / casting incoming acceptance	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-003	CNC machining program approval and revision control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-004	CNC setup and first piece dimensional inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-005	Tool path / fixture / cutting tool life control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-006	Cutting fluid concentration, quality and replacement	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-007	Precision drilling / tapping / reaming controls	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-008	Metal part burr removal and deburring verification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-009	Laser cutting / engraving machine qualification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-010	Laser weld process parameter setting and inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-011	Mechanical polishing / buffing process control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-012	Surface passivation / electropolishing process control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-013	Surface anodizing / conversion coating controls	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-014	Implant blasting / grit blasting media condition controls	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-015	Implant surface roughness and texture specification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-016	Metal particulate removal and wash process control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-017	Ultrasonic cleaning bath operation and monitoring	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-018	Implant final cleaning and residue acceptance	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MET-019	Medical implant surface coating / plasma spray control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-020	Porous coating bond strength and thickness checks	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-021	Implant screw thread gauge and fit verification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-022	Bone plate dimensional and mechanical checks	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-023	Joint implant mating surface fit and inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-024	Surgical blade sharpness / edge condition verification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-025	Surgical instrument assembly and alignment checks	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-026	Instrument jaw, hinge and ratchet functional inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-027	Instrument hardness and corrosion resistance checks	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-028	Orthopedic implant serialized / lot traceability control	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-029	Implant segregation and foreign-body prevention	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-030	Heat treatment furnace operation and cycle review	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-031	Heat treatment hardness / microstructure acceptance	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-032	Metal machining scrap and alloy grade segregation	ORTHOPEDIC / IMPLANT / INSTRUMENT	P1	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-033	Stent laser cutting / strut dimensional inspection	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-034	Stent electropolishing and surface finishing validation	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-035	Stent crimping onto delivery system control	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-036	Implantable mesh dimensional and burst test verification	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-037	Dental implant thread and connection interface acceptance	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-038	Dental abutment polishing and particle control	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-039	Tissue-contact implant surface cleanliness release	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-040	Anodized orthopedic screw color coding / material verification	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-041	Porous implant 3D lattice and powder evacuation verification	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-042	Implant retrieval / explant investigation traceability	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-043	Surgical instrument repair / remanufacturing classification	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-044	Implant sterility barrier / packaging compatibility approval	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-045	Bone drill cutting performance and endurance testing	ORTHOPEDIC / CARDIOVASCULAR / DENTAL	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-046	Orthopedic screws and plates: implant lot laser etch verification	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-047	Orthopedic screws and plates: screw torque / pull-out test sampling	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-048	Orthopedic screws and plates: bone plate bend angle inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-049	Orthopedic screws and plates: machining coolant residue screening	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-050	Orthopedic screws and plates: implant final ultrasonic clean acceptance	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-051	Orthopedic screws and plates: screw surface burr optical inspection	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-052	Surgical instruments: instrument hinge smooth movement check	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-053	Surgical instruments: instrument locking ratchet load check	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-054	Surgical instruments: instrument scissor cutting performance	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MET-055	Surgical instruments: instrument cleaning residual test	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-056	Surgical instruments: passivation appearance and free iron check	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993
IGC-MD-MET-057	Surgical instruments: instrument marking / identity confirmation	ORTHOPEDIC / IMPLANT / INSTRUMENT	P2	ISO13485;EU-MDR;ISO10993

End of Metal, Orthopedic & Instrument Manufacturing • 57 titles

TEXTILE, WOUND CARE & DISPOSABLE DEVICES | 36 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-TEX-001	Medical textile fibre/yarn grade receipt and storage	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-002	Gauze fabric weaving / knitting process controls	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-003	Gauze cutting, folding and ply count verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-004	Absorbent cotton de-fattening / scouring process checks	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-005	Absorbent cotton bleaching, washing and neutralization control	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-006	Medical dressing adhesive coating and coat-weight monitoring	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-007	Wound dressing lamination and layer bonding inspection	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-008	Dressing pad die cutting and dimension verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-009	Bandage elasticity, compression and stretch testing	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-010	Surgical drape cutting, fold and packaging operations	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-011	Surgical gown seam construction and barrier test controls	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-012	Medical mask pleating, nose bridge and strap attachment	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-013	Medical face mask filtration and breathability acceptance	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-014	Medical gloves dipping / curing and powder-free processing	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-015	Medical glove pinhole integrity and barrier inspection	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-016	Suture filament extrusion or braiding control	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-017	Suture needle swaging and pull-off force verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-018	Suture knot performance and strength checks	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-019	Surgical mesh knitting and pore size verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-020	Nonwoven meltblown or spunbond conversion control	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-021	Disposable device kit component count and segregation	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-022	Wound dressing absorbency and retention QC	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-023	Sterile dressing packaging line controls	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-024	Disposable surgical set bill-of-material reconciliation	DISPOSABLES / WOUND / SURGICAL TEXTILES	P1	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-025	Medical gloves: glove wall thickness sampling	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-026	Medical gloves: glove tensile / elongation verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-027	Medical gloves: glove leak integrity water test	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-028	Medical gloves: glove size and donning verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-029	Medical gloves: glove powder residue limit control	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-TEX-030	Medical gloves: glove batch packaging reconciliation	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-031	Surgical masks and gowns: mask ear loop bond strength test	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-032	Surgical masks and gowns: mask particle filtration study coordination	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-033	Surgical masks and gowns: mask nose piece retention verification	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-034	Surgical masks and gowns: gown barrier material hydrostatic test	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-035	Surgical masks and gowns: gown critical seam integrity check	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607
IGC-MD-TEX-036	Surgical masks and gowns: gown lint generation / particulate control	DISPOSABLES / WOUND / SURGICAL TEXTILES	P2	ISO13485;EU-MDR;ISO11607

End of Textile, Wound Care & Disposable Devices • 36 titles

ELECTRONICS & ACTIVE DEVICE MANUFACTURING | 50 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-ELC-001	PCB supplier and design revision verification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-002	Printed circuit board incoming visual inspection	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-003	Electrostatic discharge controlled area procedure	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-004	SMD component traceability and kitting	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-005	Solder paste receipt, storage and shelf-life control	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-006	Stencil printing and solder paste deposition inspection	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-007	Surface mount pick-and-place program verification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-008	Reflow soldering profile approval and monitoring	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-009	Through-hole soldering and workmanship inspection	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-010	Automated optical inspection and defect classification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-011	BGA X-ray inspection or equivalent acceptance	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-012	PCB functional board-level test and serialization	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-013	Conformal coating application, cure and visual check	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-014	Sensor mounting / bonding and calibration controls	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-015	Embedded firmware loading and version identification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-016	Device bootloader security and production programming	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-017	Device communication interface test controls	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-018	Battery assembly, polarity and pack inspection	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-019	Power supply and electrical insulation verification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-020	Protective earth / leakage current routine test	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-021	Cable harness crimping and pull force verification	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-022	Connector pin-out / continuity and insulation checks	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-023	Display / touch screen assembly and calibration	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-024	Alarm volume, prioritization and functional challenge	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-025	Software version, hardware revision and device configuration release	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-ELC-026	Active device final functional test and burn-in	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-027	Environmental stress screening process validation	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-028	Field-replaceable unit identification and traceability	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-029	Packaging shipment vibration protection for active devices	ACTIVE / ELECTRONIC DEVICES	P1	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-030	Infusion pump drive motor assembly and setting	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-031	Infusion pump flow rate and occlusion pressure test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-032	Infusion pump door interlock / free flow protection test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-033	Patient monitor sensor accuracy and alarm limit verification	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-034	ECG signal simulation and lead integrity test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-035	Pulse oximeter sensor pairing and accuracy test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-036	Medical weighing balance load and repeatability verification	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-037	Medical thermometer / probe accuracy and response test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-038	Mechanical ventilator pneumatic circuit and valve test	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-039	Ventilator flow/pressure and alarm safety challenge	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-040	Physiotherapy electrical stimulation output verification	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-041	Diagnostic imaging accessory electrical and EMC testing	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-042	Portable device battery endurance and charge retention	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-043	Wireless connectivity / pairing and interference checks	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-044	Device power cycling and data persistence verification	INFUSION / MONITORING / MEASURING	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-045	Medical electronic monitors: sensor zero point calibration	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-046	Medical electronic monitors: alarm indicator visual and sound test	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-047	Medical electronic monitors: power cycle memory retention test	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-048	Medical electronic monitors: display and controls usability line check	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-049	Medical electronic monitors: electrical insulation final test	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971
IGC-MD-ELC-050	Medical electronic monitors: firmware/hardware revision mismatch prevention	ACTIVE / ELECTRONIC DEVICES	P2	ISO13485;IEC60601;ISO14971

End of Electronics & Active Device Manufacturing • 50 titles

IVD REAGENTS, KITS & POINT-OF-CARE DEVICES | 54 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-IVD-001	IVD master formulation / assay recipe creation and approval	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-002	IVD biological reagent vendor qualification and acceptance	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-003	IVD buffer preparation and pH adjustment controls	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-004	IVD reagent weighing, dispensing and traceability	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-005	IVD protein / antibody reagent dilution and formulation	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-006	Antibody conjugation process parameters and acceptance	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-007	Latex particle coating / bead coupling operation	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-IVD-008	Reagent mixing, homogenization and filtration controls	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-009	IVD reagent aliquot filling volume setup and monitoring	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-010	IVD liquid reagent dispensing and capping	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-011	IVD dry reagent deposition and controlled drying	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-012	Lyophilization cycle controls for IVD reagents, when used	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-013	Enzyme activity retention and stabilization operations	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-014	IVD reagent lot-to-lot bridge testing	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-015	IVD master calibration curve / cutoff assignment	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-016	IVD calibrator assignment and reference method traceability	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-017	IVD positive/negative control panel selection	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-018	IVD reagent stability sample selection and storage	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-019	IVD real-time / accelerated stability study process	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-020	IVD open-vial / onboard / in-use stability assessment	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-021	IVD packaging desiccant insertion and moisture control	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-022	IVD cold chain storage and temperature excursion handling	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-023	IVD release by sensitivity/specificity and QC panel review	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-024	IVD biohazardous reagent containment and decontamination	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-025	IVD final kit bill-of-material and lot reconciliation	IVD REAGENTS / KITS / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-026	Lateral flow conjugate pad reagent deposition	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-027	Lateral flow nitrocellulose membrane test/control line striping	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-028	Lateral flow membrane drying / humidity control	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-029	Lateral flow strip slitting and cutting tolerance controls	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-030	Lateral flow cassette insertion and assembly	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-031	Lateral flow cassette seal and pouching line controls	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-032	Lateral flow assay visual intensity / reader assessment	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-033	Lateral flow positive / negative sample panel release testing	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-034	IVD PCR reagent master mix preparation	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-035	PCR oligo / primer / probe material identity verification	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-036	PCR reagent RNase/DNase contamination prevention	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-037	PCR tube / cartridge assembly and sealing	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-038	Nucleic acid extraction kit component dispensing	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-039	Microfluidic cartridge chip bonding and leak testing	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-040	Point-of-care reader mechanical and electronic assembly	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-041	POCT reader assay calibration curve firmware release	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-042	IVD false positive / false negative investigation	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-043	IVD limit of detection and assay sensitivity lot review	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-IVD-044	IVD interferences / cross-reactivity routine monitoring	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-045	IVD test kit IFU / intended user / sample types verification	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-046	IVD contamination carryover / amplicon segregation controls	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-047	IVD clinical performance sample chain of custody	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-048	IVD lot field complaint investigation and re-test strategy	IVD / LFA / PCR / POCT	P1	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-049	Lateral flow IVD kits: membrane capillary flow-time inspection	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-050	Lateral flow IVD kits: test line dispense volume verification	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-051	Lateral flow IVD kits: conjugate pad humidity exposure control	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-052	Lateral flow IVD kits: strip placement tolerance check	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-053	Lateral flow IVD kits: reader threshold verification	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5
IGC-MD-IVD-054	Lateral flow IVD kits: kit stability time-point release study	IVD / LFA / PCR / POCT	P2	EU-IVDR;ISO13485;IND-MDR5

End of IVD Reagents, Kits & Point-of-Care Devices • 54 titles

SOFTWARE, SAMD, AI & CYBERSECURITY | 60 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SWE-001	Medical device software lifecycle plan and classification	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-002	Software safety classification and intended use review	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-003	Software development and configuration management plan	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-004	Software requirements and architecture definition	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-005	Software system / subsystem interface specification	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-006	SOUP evaluation, version and known-anomaly assessment	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-007	Software item and unit design review	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-008	Source code version control / branching and release tags	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-009	Software coding standard and peer code review	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-010	Software unit verification and static analysis	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-011	Software integration verification and regression test	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-012	Software system verification against software requirements	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-013	Software anomaly / bug classification, triage and closure	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-014	Software change request and risk impact analysis	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-015	Software traceability matrix and risk controls linkage	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-016	Software build reproducibility and release authorization	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-017	Software installation package checksum and integrity check	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-018	Firmware over-the-air update validation and rollback	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-019	Device interoperability and interface risk testing	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-020	Software usability and workflow error prevention	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-021	Cloud-connected device service availability and continuity	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SWE-022	Software backup, disaster recovery and data restoration	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-023	Safety-related alarm logic software verification	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-024	Embedded software hardware-in-the-loop test procedure	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-025	Software release notes and known-residual anomalies	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-026	Production firmware loading and post-flash verification	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-027	Software maintenance, end-of-support and retirement process	SaMD / SOFTWARE-CONTAINING DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-028	Medical device cybersecurity management plan	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-029	Cybersecurity threat modeling and attack surface analysis	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-030	Security risk assessment linked to device safety risk file	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-031	Secure development lifecycle (secure SDLC) design controls	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-032	Software bill of materials (SBOM) creation and maintenance	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-033	Third-party software vulnerability tracking and provenance	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-034	Static/dynamic software security testing process	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-035	Penetration test planning, execution and issue closure	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-036	Authentication / authorization and role separation verification	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-037	Secure boot, signature verification and firmware integrity	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-038	Encryption at rest / in transit design verification	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-039	Secure network communication and hardening	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-040	Remote service access approval and session logging	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-041	Vulnerability intake, triage, disclosure and remediation	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-042	Cybersecurity security-update / patch release and regression tests	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-043	Coordinated vulnerability disclosure and customer notification	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-044	Cybersecurity field action and incident escalation	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-045	Security log retention and privacy data handling	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-046	Cybersecurity support period and end-of-life disclosures	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-047	Software/AI operational monitoring for performance deterioration	CONNECTED DEVICES / CYBER DEVICES	P1	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-048	AI model dataset provenance and consent authorization review	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-049	Training / validation / test cohort separation and leakage controls	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-050	Data de-identification, annotation and label quality controls	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-051	Representativeness and bias assessment for intended population	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-052	AI model version identification and configuration control	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-053	AI model performance acceptance across clinical subgroups	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-054	AI/ML model drift monitoring and postmarket triggers	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-055	Human oversight / fallback and out-of-distribution detection	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-056	AI-enabled medical device change impact and regulatory assessment	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-057	AI model deployment verification and rollback	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SWE-058	Model transparency / clinical instructions / limitations review	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-059	Model cybersecurity, data poisoning and adversarial test assessment	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER
IGC-MD-SWE-060	AI software performance signal investigation and CAPA	AI/ML DEVICES ONLY	P2	IEC62304;ISO14971;FDA-CYBER

End of Software, SaMD, AI & Cybersecurity • 60 titles

CLEANROOM & CONTROLLED / ASEPTIC OPERATIONS | 37 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-CLN-001	Controlled-area access management and entry authorization	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-002	Personnel hygiene and cleanroom training / qualification	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-003	Cleanroom gowning / degowning and observation	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-004	Cleanroom garment laundering, sterilization and inspection	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-005	Material movement into controlled / sterile barrier areas	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-006	Room line clearance, cleaning and sanitation	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-007	Disinfectant selection and efficacy / contact time verification	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-008	Disinfectant preparation, label and expiry management	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-009	Surface and equipment cleaning verification	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-010	Cleanroom environmental monitoring location rationale	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-011	Viable air monitoring / settle plate sampling	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-012	Surface sampling by contact plate / swab method	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-013	Non-viable particle monitoring and excursion response	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-014	Temperature and relative humidity monitoring and excursion	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-015	Differential pressure / airflow alarm response	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-016	Airlock / pass box material transfer control	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-017	HEPA filter integrity testing and periodic classification	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-018	Personnel microbiological monitoring and retraining	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-019	Cleanroom contamination investigation and impact assessment	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-020	Controlled-area room recovery after maintenance	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-021	Manufacturing in an ISO classified environment verification	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-022	Sterile device primary packaging exposure time limitations	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-023	Microbial monitoring program data review and trend analysis	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-024	Environmental monitoring limits and action response	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-025	Cleanroom cleaning equipment segregation and storage	STERILE / CLEAN PRODUCTION	P1	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-026	Aseptic assembly process contamination risk analysis	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-027	Aseptic process personnel qualification and intervention controls	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-028	Aseptic transfer of components through protected environment	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-029	Aseptic material hold time and container exposure control	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-CLN-030	Aseptic processing simulation applicability assessment	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-031	Aseptic process simulation execution and batch impact response	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-032	Aseptic filtration where relevant to device-associated solutions	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-033	Closed-process connection integrity and leak test	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-034	Aseptic work surface cleaning and disinfection	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-035	Laminar airflow / unidirectional zone verification	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-036	Aseptic device assembly glove breach response	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607
IGC-MD-CLN-037	Aseptic product disposition after environmental excursion	ASEPTIC PROCESSES / SPECIALIZED	P2	ISO13485;ISO14644;ISO11607

End of Cleanroom & Controlled / Aseptic Operations • 37 titles

STERILIZATION, REPROCESSING & STERILITY ASSURANCE | 60 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-STL-001	Sterilization method selection and compatibility risk assessment	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-002	Sterilization validation master plan and requalification	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-003	Sterility assurance level (SAL) justification and claims	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-004	Product bioburden baseline and routine monitoring linkage	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-005	Sterile load configuration and worst-case family determination	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-006	Sterile product family grouping and process challenge device	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-007	Sterilization process deviation / hold / batch impact investigation	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-008	Sterile product release decision and batch record review	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-009	Outsourced sterilization quality agreement and vendor monitoring	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-010	Sterilization batch traceability to device lots and serial numbers	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-011	Sterilization cycle change control and revalidation	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-012	Parametric release assessment where permitted	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-013	Sterilization equipment calibration / preventive maintenance	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-014	Biological indicator lot qualification / incubation / result release	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-015	Chemical indicator suitability and acceptance controls	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-016	Sterile barrier integrity investigation after sterilization	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-017	Residual shelf life and sterilization reprocessing limits control	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-018	Sterilization validation independent quality approval	STERILE DEVICES	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-019	Ethylene oxide sterilizer operation and cycle setup	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-020	Ethylene oxide preconditioning temperature / humidity control	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-021	EO concentration / exposure duration / humidity monitoring	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-022	EO load preparation and chamber loading checks	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-023	EO biological indicator placement / PCD retrieval	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-024	EO sterilization cycle printout and electronic record review	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-STL-025	EO post-cycle aeration and residual release	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-026	EO/ECH residual testing and toxicological acceptance	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-027	EO sterilization process validation and half-cycle rationale	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-028	EO sterilization routine process challenge and monitoring	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-029	EO chamber leak integrity / interlock challenge	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-030	EO sterilization process excursion and release hold	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-031	EO gas cylinder receipt, storage and inventory control	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-032	EO occupational exposure / leak response and alarms	EO STERILIZATION	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-033	Gamma irradiation process validation and dose mapping	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-034	Gamma irradiation routine dosimetry / batch release	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-035	Radiation sterilization dose establishment and substantiation	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-036	Radiation bioburden audit and dose audit review	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-037	Radiation product density / loading configuration change control	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-038	E-beam irradiation conveyor speed and dose verification	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-039	Radiation sterilization contract service batch certificate approval	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-040	Moist heat steam sterilization cycle development and qualification	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-041	Steam sterilizer physical parameters and load monitoring	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-042	Steam sterilization steam quality / noncondensable gases testing	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-043	Autoclave air removal / Bowie-Dick / leak test assessment	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-044	Steam sterilization worst-case load / thermometric mapping	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-045	Steam sterilization biological indicator challenge and release	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-046	Dry heat sterilization / depyrogenation qualification where applicable	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-047	Vaporized hydrogen peroxide process validation when appropriate	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-048	Sterilization methods compatibility requalification after device change	GAMMA / EBEAM / STEAM / OTHER	P1	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-049	Reprocessing IFU cleaning instructions validation	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-050	Manual cleaning method and soil challenge validation	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-051	Automated washer/disinfector cycle compatibility verification	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-052	Disinfection efficacy and high-level disinfection claims	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-053	Reusable surgical instrument cleaning residue testing	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-054	Reusable device inspection for wear, corrosion and damage	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-055	Repeated reprocessing cycle durability and performance study	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-056	Reusable device sterilization compatibility testing	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-057	Reprocessing IFU user comprehension and reproducibility	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-058	Reusable device maximum cycle life and retirement criteria	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-059	Reusable-device packaging for reprocessing / transport	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665
IGC-MD-STL-060	Service return biohazard decontamination verification	REUSABLE DEVICES	P2	ISO13485;ISO11135;ISO11137;ISO17665

End of Sterilization, Reprocessing & Sterility Assurance • 60 titles

PACKAGING, LABELLING & UDI | 73 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PKG-001	Packaging material receipt-to-line issuance traceability	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-002	Packaging master record issue and approval	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-003	Primary packaging line clearance	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-004	Secondary packaging line clearance	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-005	Printed material identity check before line start	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-006	Foil / PVC / PVDC roll issuance and reconciliation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-007	Blister packaging machine setup and operation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-008	Blister seal temperature / pressure / dwell controls	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-009	Blister leak testing and online IPC	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-010	Strip packaging machine setup and operation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-011	Bottle counting / filling for tablets and capsules	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-012	Bottle cap application and induction seal checks	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-013	Bottle labeling and label inspection	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-014	Sachet / stick pack line setup and operation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-015	Topical tube / carton packaging linkage	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-016	Sterile serialization / aggregation label reconciliation	Sterile devices / controlled areas, as applicable	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-017	Batch coding / expiry printing verification	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-018	Packaging vision system / barcode challenge check	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-019	Cartoner operation and leaflet insertion verification	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-020	Tamper-evident packaging inspection	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-021	Line rejects, reworks and scrap segregation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-022	Printed component reconciliation and controlled destruction	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-023	Finished pack shipper packing and sealing	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-024	Online checkweigher challenge and IPC	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-025	Packaging final yield and reconciliation	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-026	Artwork proof control and regulatory labeling check	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-027	Market-specific leaflet / caution label verification	All device sites	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-028	Primary packaging specification and controlled BOM	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-029	Packaging material supplier/lot release	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-030	Sterile barrier system design and qualification planning	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-031	Packaging process sealer set-point and start-up verification	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-032	Heat seal temperature / pressure / dwell monitoring	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-033	Form-fill-seal machine operation and lot recording	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-034	Pouch / tray loading and device orientation verification	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-035	Seal integrity visual inspection and defect standardization	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PKG-036	Seal strength / peel force method and release acceptance	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-037	Package bubble / dye / microbial barrier test method	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-038	Blister tray thermoforming and dimensional inspection	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-039	Pouch / blister sealer validation and requalification	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-040	Package shelf-life / accelerated aging justification	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-041	Real-time aging study and sterile barrier integrity	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-042	Transit / distribution simulation and post-transport packaging test	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-043	Sterilization-process compatibility with sterile barrier	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-044	Packaging area line clearance / mix-up prevention	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-045	Packaging reconciliation and device count verification	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-046	Tamper evident seal acceptance and tamper investigation	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-047	Packaging change risk assessment and retest decision	ALL PACKAGED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-048	Device label master approval and artwork change management	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-049	Device IFU preparation and controlled translation review	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-050	Medical device symbols selection and ISO 15223-1 evaluation	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-051	Label content review against intended purpose and market	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-052	Market-specific language, import and manufacturer identification	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-053	UDI-DI and UDI-PI issuance, update and retirement	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-054	Basic UDI-DI and EU database registration controls	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-055	Barcode printing / vision readability acceptance	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-056	GUDID / EUDAMED device record governance where applicable	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-057	Software version and electronic labelling controls	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-058	Expiry date / manufacture date / sterilization lot label accuracy	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-059	Sterile and single-use claims verification	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-060	Implant label / implant card package content verification	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-061	IVD kit label / performance claim consistency verification	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-062	Labelling line clearance and print reconciliation	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-063	Wrong label / mislabelled product hold and recall escalation	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-064	Packaging insert and instruction version reconciliation	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-065	Device traceability label verification and printer challenge	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-066	UDI direct marking feasibility and process verification	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-067	Device label electronic record archival and retrieval	ALL MARKETED DEVICES	P1	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-068	Sterile pouch packaging: seal jaw temperature recorder review	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-069	Sterile pouch packaging: seal width and continuity acceptance	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-070	Sterile pouch packaging: pouch material lot identity reconciliation	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-071	Sterile pouch packaging: pouch peel strength sampling frequency	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-PKG-072	Sterile pouch packaging: sealer setup before lot change	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI
IGC-MD-PKG-073	Sterile pouch packaging: seal defect failure escalation	STERILE PACKAGED DEVICES	P2	ISO11607;EU-MDR;FDA-UDI

End of Packaging, Labelling & UDI • 73 titles

VALIDATION & PROCESS QUALIFICATION | 107 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-VAL-001	Site Validation Master Plan preparation and maintenance	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-002	User requirement specification (URS) control	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-003	Design qualification and traceability matrix	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-004	Risk assessment for validation and qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-005	Factory acceptance test (FAT) execution	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-006	Site acceptance test (SAT) execution	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-007	Commissioning-to-qualification turnover	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-008	Installation qualification (IQ) protocol execution	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-009	Operational qualification (OQ) protocol execution	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-010	Performance qualification (PQ) protocol execution	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-011	Validation protocol preparation, review and approval	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-012	Validation execution incident and deviation management	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-013	Validation summary report generation and closure	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-014	Periodic review of validated state	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-015	Requalification / revalidation trigger assessment	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-016	Validation change and lifecycle documentation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-017	Critical manufacturing equipment qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-018	Manufacturing process validation lifecycle management	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-019	Process design / PPQ / continued process verification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-020	Reaction and crystallization process validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-021	Topical bulk mixing and filling process validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-022	Dry powder blending and filling PPQ	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-023	Sterile compounding and filling process validation	Sterile devices / controlled areas, as applicable	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-024	Sterilization process validation / lethality studies	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-025	Depyrogenation cycle validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-026	Sterilizing-grade filtration validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-027	Lyophilizer equipment qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-028	Lyophilization cycle development, PPQ and verification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-029	Automatic inspection machine qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-030	Computerized vision inspection challenge testing	All device sites	P1	ISO13485;FDA-QMSR;ISO14971

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-VAL-031	Critical cleaning process validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-032	Cleaning validation swab/rinse recovery studies	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-033	Equipment dirty/clean hold time validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-034	Bulk intermediate and formulated product hold-time study	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-035	Blend uniformity and mixing validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-036	Container closure integrity method validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-037	Primary packaging seal integrity validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-038	Transportation / cold chain qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-039	Cleanroom classification and qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-040	Cleanroom airflow visualization / smoke studies	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-041	HVAC system IQ/OQ/PQ	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-042	Airflow, differential pressure and recovery-time studies	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-043	HEPA filter integrity testing and certification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-044	Air change rate and recovery study	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-045	Temperature and relative humidity mapping	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-046	Warehouse / cold-room temperature mapping	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-047	Purified water system validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-048	Water-for-injection system qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-049	Clean steam system qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-050	Compressed air and process gas validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-051	Sterile gas filtration qualification	Sterile devices / controlled areas, as applicable	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-052	Clean-in-place (CIP) cycle validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-053	Steam-in-place (SIP) cycle validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-054	Autoclave thermal mapping and load pattern qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-055	Dry-heat oven / tunnel depyrogenation validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-056	Wash equipment cleaning-cycle validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-057	Aseptic isolator / RABS decontamination validation	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-058	VHP cycle development and biological challenge	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-059	Lyophilizer sterilization / SIP qualification	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-060	BMS/EMS system qualification and alarm challenge	All device sites	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-061	Medical device process validation master plan and policy	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-062	Process validation need assessment (100% verification not feasible)	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-063	Production software process assurance risk screening	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-064	Critical process parameter / critical quality attribute identification	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-065	Device assembly process IQ/OQ/PQ methodology	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-066	Worst-case device / material / tooling selection	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-VAL-067	Validation run plan / statistical confidence selection	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-068	Product family / bracketing validation justification	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-069	IQ installation verification and utility readiness	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-070	OQ operating range and limit challenge testing	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-071	PQ repeatability / reproducibility and production coverage	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-072	Validation deviations, acceptance and approval	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-073	Process change revalidation trigger and review	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-074	Annual validation and continued process monitoring review	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-075	Installation / operational qualification handover controls	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-076	Process monitoring, control charts and out-of-control response	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-077	Automated inspection system validation and false accept study	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-078	Measurement system analysis / gauge R&R qualification	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-079	Manufacturing fixture and automated tester verification	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-080	Critical manual operation operator requalification study	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-081	Equipment relocation and requalification assessment	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-082	Device production line process transfer validation	ALL DEVICE SITES	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-083	Plastic injection molding process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-084	Extrusion / tubing line process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-085	Laser welding / ultrasonic welding process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-086	Medical adhesive bonding and cure process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-087	Metal passivation / coating process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-088	Catheter balloon bonding process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-089	Device cleaning process effectiveness validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-090	Metal implant final wash / particulate cleaning validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-091	Medical device packaging heat sealer validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-092	Sterile barrier performance validation ISO 11607	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-093	EO sterilization validation / half-cycle evidence	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-094	Radiation sterilization validation / dose establishment	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-095	Steam sterilization cycle validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-096	IVD reagent formulation / mixing validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-097	IVD filling and dispense accuracy validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-098	IVD stability and shipping condition validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-099	PCB assembly reflow soldering process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-100	Active device firmware loading / configuration validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-101	Automated device functional test system validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-102	Medical device software release validation and acceptance	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-VAL-103	Reusable device reprocessing validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-104	Additive manufacture 3D printing process validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-105	Process validation for coating thickness and cure	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-106	Critical machining surface finish and burr removal validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971
IGC-MD-VAL-107	Medical device bioburden test method suitability validation	DEVICE TYPE SPECIFIC	P1	ISO13485;FDA-QMSR;ISO14971

End of Validation & Process Qualification • 107 titles

ENGINEERING, MAINTENANCE & CALIBRATION | 60 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-ENG-001	Engineering organization, work request and responsibilities	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-002	Asset numbering, equipment identification and history files	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-003	Equipment user requirement specification (URS) preparation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-004	Engineering drawing control: P&ID, GA and as-built files	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-005	Plant equipment installation and commissioning handover	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-006	Equipment preventive maintenance master plan	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-007	Maintenance job card issuance and closure	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-008	Breakdown maintenance response and restoration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-009	Maintenance deviation / quality impact escalation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-010	Risk-based maintenance of product contact equipment	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-011	Maintenance after-hours and emergency callout	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-012	Equipment lubrication plan and food/pharma grade lubricant control	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-013	GMP workshop and tools segregation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-014	Engineering spare part identification and inventory	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-015	Critical spare parts min/max controls	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-016	Engineering contractor entry, permit and GMP oversight	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-017	Technical change / modification assessment	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-018	Equipment obsolescence and replacement planning	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-019	Equipment history card and breakdown trend review	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-020	Maintenance effectiveness and MTBF/MTTR trend review	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-021	Pest-proofing and facility fabric maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-022	Equipment decommissioning and asset disposal	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-023	Reactors and pressure vessel inspection maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-024	Mechanical seals and agitator maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-025	Centrifuge / ANFD preventive maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-026	Vacuum dryer preventive maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-027	Solvent transfer pumps and mechanical seal checks	All device sites	P1	ISO13485;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-ENG-028	Fluid bed processor and granulator maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-029	Compression machine preventive maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-030	Punch / die tooling wear and punch cup inspection	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-031	Topical homogenizer and filling machine maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-032	Autoclave preventive maintenance and safety interlocks	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-033	Sterile filling machine preventive maintenance	Sterile devices / controlled areas, as applicable	P1	ISO13485;IND-MDR5
IGC-MD-ENG-034	Lyophilizer condenser, vacuum and shelf maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-035	Lyo chamber stopper mechanism maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-036	Aseptic isolator / RABS maintenance access control	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-037	Sterile filter housing inspection and gasket control	Sterile devices / controlled areas, as applicable	P1	ISO13485;IND-MDR5
IGC-MD-ENG-038	Labeling / packing machine preventive maintenance	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-039	Metal detector preventive maintenance and challenge support	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-040	Equipment guard, interlock and emergency-stop verification	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-041	Calibration master list and classification	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-042	Critical measurement system calibration frequency	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-043	Calibration traceability to recognized standards	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-044	Calibration contract laboratory qualification	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-045	Calibration standard certificate review	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-046	Balance and load cell calibration support	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-047	Temperature sensor / RTD / thermocouple calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-048	Differential pressure transmitter calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-049	Pressure gauge / vacuum gauge calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-050	Flow meter and totalizer calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-051	pH / conductivity online probe calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-052	Humidity sensor calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-053	PLC / SCADA data point verification	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-054	Calibration sticker issuance and tamper controls	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-055	Out-of-calibration investigation and product impact	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-056	Calibration overdue equipment lockout	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-057	Measuring instrument storage and handling	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-058	Environmental data logger calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-059	Sterilizer temperature mapping instrument calibration	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-ENG-060	Lyophilizer pressure and temperature sensor calibration	All device sites	P1	ISO13485;IND-MDR5

End of Engineering, Maintenance & Calibration • 60 titles

UTILITIES, HVAC & ENVIRONMENTAL MONITORING | 44 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-UTL-001	Utility system operation and shift logbook	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-002	Purified water system operation and distribution	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-003	Purified water pretreatment filtration maintenance	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-004	Reverse osmosis / EDI operation and sanitization	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-005	Purified water loop sanitization and monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-006	Water sampling point disinfection and flushing	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-007	Purified water online conductivity and TOC monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-008	Purified water microbial alert / action response	Sterile devices / controlled areas, as applicable	P1	ISO13485;ISO14644
IGC-MD-UTL-009	Water system change and requalification impact assessment	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-010	Water for injection generation and distribution	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-011	WFI storage and hot loop temperature control	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-012	WFI sanitization and endotoxin control	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-013	Clean steam generator operation and quality control	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-014	Plant steam boiler operation and safety checks	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-015	Compressed air generation, drying and filtration	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-016	Compressed air dew point / oil / particle monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-017	Nitrogen generator / supply operation and quality monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-018	Process gas point-of-use filtration and filter checks	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-019	Vacuum plant operation and vacuum quality monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-020	CIP skids operation, chemical dosing and documentation	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-021	SIP plant operation and cycle control	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-022	Heat exchanger inspection and utility cross-leak controls	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-023	HVAC air handling unit operation and monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-024	AHU differential pressure / airflow alarm response	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-025	HEPA / pre-filter change and certification	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-026	AHU filter differential pressure monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-027	Room differential pressure cascade monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-028	Cleanroom temperature and RH monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-029	Cleanroom recovery after power / HVAC failure	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-030	HVAC planned shutdown and restart authorization	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-031	Unidirectional airflow unit / LAF operation	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-032	Airlock / interlock operation and alarm management	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-033	Dust extraction / dedusting system operation	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-034	HVAC requalification and trending schedule	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-035	Building management system (BMS) alarm review	All device sites	P1	ISO13485;ISO14644

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-UTL-036	Environmental monitoring system (EMS) trending and alarm review	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-037	Chilled water plant operation and monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-038	Cooling tower operation and biocide control	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-039	Heating hot water and process heat utility monitoring	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-040	Diesel generator operation and changeover	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-041	UPS system operation, battery maintenance and alarm	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-042	Emergency power for aseptic and cold-chain processes	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-043	Electrical preventive maintenance / thermography	All device sites	P1	ISO13485;ISO14644
IGC-MD-UTL-044	Energy management / utility consumption trend	All device sites	P1	ISO13485;ISO14644

End of Utilities, HVAC & Environmental Monitoring • 44 titles

WAREHOUSE, DISTRIBUTION & TRACEABILITY | 44 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-WH-001	Material receiving and delivery document verification	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-002	Incoming vehicle inspection and unloading control	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-003	Goods inward note / goods receipt entry	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-004	Excipient receipt and contamination prevention	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-005	Primary packaging materials receipt and quarantine	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-006	Printed packaging materials secured receipt	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-007	Temperature-sensitive material acceptance and logging	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-008	Cold-chain receipt temperature excursion handling	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-009	Materials sampling booth issue and status control	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-010	Raw material quarantine identification	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-011	QC sampling request and sampling logistics	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-012	Material status: quarantine / released / rejected	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-013	Controlled material location / bin address allocation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-014	Material identification and label traceability	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-015	Warehouse temperature and humidity recording	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-016	Cold-room / freezer monitoring and alarm escalation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-017	Controlled substances / narcotic security (where applicable)	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-018	Flammable chemicals and solvents warehouse control	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-019	Hazardous substances storage compatibility segregation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-020	Highly potent / allergenic material storage segregation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-021	Returned / recalled product segregated storage	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-022	Rejected material cage and locked access	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-023	Stock rotation FEFO / FIFO and expiry surveillance	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-WH-024	Material retest date monitoring and requalification	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-025	Raw material dispensing and issue authorization	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-026	Independent weight verification and dispensing reconciliation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-027	Weighing balance pre-use check and cleaning	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-028	Dispensing booth line clearance and containment	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-029	Sampling tool cleaning and traceable storage	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-030	Staging of materials to production	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-031	Intra-site and inter-site material movement	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-032	Inventory cycle counts and stock adjustments	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-033	Inventory discrepancies and investigation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-034	Finished goods receipt from packaging	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-035	Finished goods quarantine before QA release	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-036	Finished goods pick, pack and dispatch	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-037	Temperature-controlled finished product dispatch	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-038	Shipment vehicle qualification / inspection	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-039	Transport lane qualification / route risk assessment	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-040	Dispatch batch traceability to consignee	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-041	Material shortage / damaged package investigation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-042	Obsolete / scrap material disposition and destruction	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-043	Inventory data system access and transaction review	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5
IGC-MD-WH-044	Customer returned goods receiving and isolation	All device sites	P1	ISO13485;FDA-UDI;IND-MDR5

End of Warehouse, Distribution & Traceability • 44 titles

PROCUREMENT & SUPPLIER QUALITY | 24 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SUP-001	Procurement request approval and specification verification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-002	Approved vendor list management	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-003	Vendor prequalification questionnaire review	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-004	Critical raw material supplier audit coordination	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-005	Supplier criticality and quality risk ranking	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-006	Excipient vendor qualification and supply chain risk	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-007	Primary packaging supplier qualification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-008	Sterile component supplier qualification	Sterile devices / controlled areas, as applicable	P1	ISO13485;EU-MDR
IGC-MD-SUP-009	Single-source critical supplier continuity planning	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-010	Procurement purchase order technical review	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-011	Quality agreement requirements for critical suppliers	All device sites	P1	ISO13485;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SUP-012	Contract manufacturing organization selection support	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-013	Contract laboratory due-diligence evaluation	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-014	Third-party calibration service qualification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-015	Third-party sterilization service qualification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-016	Incoming supplier COA reliability and periodic verification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-017	Supplier performance scorecard and on-time quality	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-018	Supplier nonconformance / rejection escalation	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-019	Supplier change notification tracking	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-020	Supply chain authenticity / anti-counterfeit verification	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-021	Broker / distributor traceability due diligence	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-022	Purchased equipment FAT/qualification deliverable control	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-023	Maintenance services / spare parts procurement control	All device sites	P1	ISO13485;EU-MDR
IGC-MD-SUP-024	Outsourced IT/cloud service vendor qualification	All device sites	P1	ISO13485;EU-MDR

End of Procurement & Supplier Quality • 24 titles

HR, TRAINING & ADMINISTRATION | 39 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-HRA-001	GMP organization structure and job description control	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-002	Recruitment and qualification of GMP personnel	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-003	New employee joining and initial GMP induction	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-004	GMP annual training needs assessment	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-005	Training matrix and role-based curriculum creation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-006	GMP SOP training assignment and effectiveness	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-007	Training records, attendance and qualification tracking	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-008	Periodic refresher training and training overdue escalation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-009	Qualified trainer assessment and authorization	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-010	Department-specific on-the-job training (OJT)	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-011	Operator competency qualification and requalification	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-012	Aseptic personnel qualification tracking	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-013	Employee hygiene and sickness reporting	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-014	Personnel entry / access and gowning orientation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-015	Medical fitness assessment as permitted by law	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-016	Contractual worker GMP induction and supervision	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-017	Visitor GMP induction and escort rules	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-018	External auditor / regulator access and escort	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-019	Personnel transfer / role change retraining	All device sites	P1	ISO13485;IND-MDR5

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-HRA-020	GMP disciplinary and conduct escalation	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-021	Personnel exit, document recovery and access removal	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-022	Occupational exposure surveillance referral process	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-023	Employee shift rostering and fatigue risk controls	All device sites	P1	ISO13485;IND-MDR5
IGC-MD-HRA-024	Staff / visitor access badge administration	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-025	Security gate material movement and gate pass	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-026	Site housekeeping and waste segregation oversight	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-027	GMP gown / uniform issuance and laundering	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-028	Cafeteria and personnel welfare area hygiene	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-029	Pest management contract and monitoring review	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-030	Facility maintenance work permit coordination	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-031	Security incident reporting and escalation	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-032	Emergency communication and evacuation coordination	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-033	Contractor attendance and site movement register	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-034	Vehicle parking / loading dock administrative control	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-035	Documented business continuity contact tree	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-036	IT asset allocation and return at exit	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-037	GMP training venue and assessment logistics	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-038	Records room restricted access coordination	All device sites	P2	ISO13485;IND-MDR5
IGC-MD-HRA-039	GMP signage and room identification maintenance	All device sites	P2	ISO13485;IND-MDR5

End of HR, Training & Administration • 39 titles

COMPUTERIZED SYSTEMS / IT / DATA INTEGRITY | 35 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-IT-001	GxP computerized system inventory and risk ranking	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-002	Computer system validation master plan	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-003	Computerized system URS and supplier assessment	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-004	Computerized system functional / design specification	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-005	Computer system configuration baseline control	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-006	Computerized system IQ / OQ / PQ	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-007	Computer software validation and acceptance testing	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-008	Risk-based GxP system periodic review	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-009	User access provisioning / role approval	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-010	Privileged administrator access control	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-011	User deactivation and periodic access review	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-012	Password, lockout and authentication controls	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-IT-013	Electronic records / signature compliance assessment	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-014	Electronic signature accountability and linking	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-015	Time synchronization and electronic timestamps	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-016	Audit trail activation / configuration and review	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-017	GMP data backup, restoration and recovery test	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-018	Disaster recovery and business continuity tests	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-019	Cybersecurity patch / antivirus risk assessment	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-020	GxP change control for software and configuration	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-021	Infrastructure / network qualification boundary	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-022	ERP / warehouse system GxP validation	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-023	LIMS system validation and sample traceability	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-024	CDS / HPLC chromatography system validation	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-025	BMS / EMS / SCADA validation and audit trails	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-026	Manufacturing execution system (MES) validation	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-027	Electronic batch record (EBR) validation and review	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-028	Electronic document management system (eDMS) validation	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-029	Data migration and legacy data verification	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-030	Cloud-hosted GxP system supplier oversight	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-031	Electronic data archiving and retention	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-032	Incident / downtime management and paper fallback	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-033	Spreadsheet validation / controlled calculations	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-034	Printer, label software and serialization system controls	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR
IGC-MD-IT-035	Electronic instrument interfaces and data transfer verification	All device sites	P1	ISO13485;FDA-CSA;FDA-QMSR

End of Computerized Systems / IT / Data Integrity • 35 titles

ENVIRONMENT, HEALTH & SAFETY | 44 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-EHS-001	Environmental, health and safety management program	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-002	Legal register for EHS permits and statutory consents	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-003	Job safety analysis (JSA) and risk assessment	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-004	Process safety management / HAZOP program	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-005	Chemical risk assessment and SDS control	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-006	Chemical compatibility and storage segregation	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-007	Flammable solvent dispensing and explosion prevention	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-008	Static electricity / bonding / grounding controls	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-009	ATEX / hazardous area equipment selection interface	All device sites	P1	ISO13485;LOCAL-EHS

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-EHS-010	Reactor thermal runaway and pressure relief response	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-011	Confined space entry permit and gas testing	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-012	Hot work permit and fire watch	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-013	Work at height permit and fall protection	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-014	Electrical isolation / lock-out tag-out (LOTO)	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-015	Pressure vessel / boiler inspection and certification	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-016	Forklift / material handling equipment safety	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-017	Compressed gas cylinder storage and handling	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-018	Cryogenic liquid / liquid nitrogen handling where applicable	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-019	Respiratory protective equipment selection and fit testing	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-020	Chemical PPE selection, issue and maintenance	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-021	Personnel exposure incident / spill first aid	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-022	Solvent spill containment and emergency cleanup	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-023	Hydrogenation / pyrophoric chemical risk controls (where applicable)	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-024	Hazardous waste segregation, labeling and manifest	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-025	Solvent waste storage, transporter and disposal review	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-026	Effluent treatment plant operation and monitoring	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-027	ETP sampling, analysis and compliance review	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-028	Air emission / scrubber monitoring and maintenance	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-029	Wastewater / drain contamination prevention	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-030	Fire alarm, extinguisher and hydrant inspection	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-031	Emergency response plan and incident command	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-032	Mock fire / evacuation drill and effectiveness	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-033	Chemical release / toxic gas emergency response	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-034	Medical emergency / occupational injury reporting	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-035	Environmental incident notification and root cause analysis	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-036	Accident / near-miss reporting and CAPA	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-037	Safety training and contractor safety induction	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-038	Energy isolation and equipment maintenance coordination	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-039	Noise, heat stress and ergonomics monitoring	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-040	EHS preventive inspection and safety walkdown	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-041	Emergency shower / eyewash inspection	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-042	Sustainability and solvent reduction initiative review	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-043	Biological waste decontamination and disposal (where applicable)	All device sites	P1	ISO13485;LOCAL-EHS
IGC-MD-EHS-044	Radiation source and laser safety (if installed)	All device sites	P1	ISO13485;LOCAL-EHS

End of Environment, Health & Safety • 44 titles

INSTALLATION, SERVICING & FIELD SUPPORT | 25 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-SVC-001	Medical device installation planning and customer site readiness	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-002	Customer equipment installation qualification protocol	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-003	Field service technician competency authorization	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-004	Installation / commissioning / initial calibration verification	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-005	Device configuration and serial number handover checks	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-006	User acceptance test and initial training documentation	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-007	Service work order initiation and device traceability	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-008	Preventive maintenance schedule by device model	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-009	Field service troubleshooting and fault isolation	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-010	Device repair part identification and approved replacement	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-011	Post-service electrical and functional safety testing	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-012	Device repair vs remanufacturing regulatory assessment	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-013	Service record review for reportable events and complaints	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-014	Field service software update and version traceability	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-015	Field-service spare part incoming acceptance	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-016	Field complaint / on-site adverse incident escalation	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-017	Service warranty / out-of-warranty segregation of records	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-018	Service device return, receipt and decontamination	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-019	Calibration of customer instruments and certificates	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-020	Remote device monitoring consent and data protection control	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-021	Field upgrade / retrofit / product change traceability	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-022	Customer incident containment / loaner device control	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-023	Installation and servicing external contractor qualification	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-024	Service trending and failure mode CAPA feedback	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR
IGC-MD-SVC-025	End-of-life disposal and device decommissioning protocol	ACTIVE / REUSABLE / SERVICED DEVICES	P1	ISO13485;EU-MDR;FDA-QMSR

End of Installation, Servicing & Field Support • 25 titles

ADDITIVE MANUFACTURING, DENTAL & CUSTOMIZED DEVICES | 28 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-AM-001	Patient image / DICOM data receipt and authorization	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-002	Patient-matched design request and anatomical fit verification	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-003	3D segmentation and dimensional reconstruction quality review	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-004	Custom-made device prescription and legal eligibility review	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-005	Custom-made technical file / manufacturer statement issuance	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-006	CAD print orientation, support design and build preparation	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-AM-007	Additive build file revision and digital release	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-008	Metal additive manufacturing powder receipt and reuse limits	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-009	Polymer additive manufacturing resin / material lot controls	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-010	Additive laser parameter / build chamber atmosphere monitoring	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-011	3D print in-process layer inspection / failure response	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-012	Build plate preparation and traceability	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-013	3D printed part support removal and post-processing	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-014	Powder evacuation / trapped-powder inspection for implants	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-015	Metal 3D print heat treatment / hot isostatic pressing control	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-016	Dental resin postcure exposure and washing procedure	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-017	Patient-specific surgical guide fit and feature verification	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-018	3D printed product porosity / mechanical property testing	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-019	3D print orientation worst-case process validation	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-020	3D printed part final cleaning and biocompatibility review	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-021	Dentistry impression scan / digital model accuracy check	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-022	Dental aligner thermoforming and trimming procedure	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-023	Dental restoration milling / sintering acceptance	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-024	Dental implant custom abutment inspection and packaging	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-025	Orthopedic patient-matched implant identification & release	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-026	3D print printer qualification and calibration control	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-027	Additive device manufacturing software version management	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR
IGC-MD-AM-028	3D print job archive / build history and audit trail controls	AM / CUSTOMIZED / DENTAL	P2	ISO13485;ISO14971;EU-MDR

End of Additive Manufacturing, Dental & Customized Devices • 28 titles

MANAGEMENT REVIEW & QUALITY STRATEGY | 10 PROPOSED SOPs

SOP ID	SOP / CONTROLLED PROCEDURE TITLE	DEVICE / FACILITY APPLICABILITY	P	REGULATORY MAP
IGC-MD-MGT-001	Senior management annual PQS review and resource commitment	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-002	GMP management review agenda and action tracking	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-003	Quality metric KPI definition, ownership and escalation	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-004	Quality performance scorecard and critical trend review	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-005	Site capacity and GMP resource adequacy assessment	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-006	Regulatory inspection escalation to corporate leadership	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-007	Management of material product shortages and quality impact	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-008	Supplier and outsourced activity governance escalation	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-009	Capital investment and critical remediation prioritization	All device sites	P1	ISO13485;ISO14971;EU-MDR
IGC-MD-MGT-010	Business continuity and supply interruption risk review	All device sites	P1	ISO13485;ISO14971;EU-MDR

End of Management Review & Quality Strategy • 10 titles

07 STANDARD CONTROLLED SOP AUTHORING BLUEPRINT

Use this blueprint to turn each selected master-index item into an executable, signed and approved site SOP. Forms, validation protocols, device master records, and risk files are separate controlled documents as applicable.

NO.	SOP ELEMENT	EXPECTED CONTENT / EVIDENCE
01	Document title and control	SOP number, version, effective date, pagination, approved master / supersession
02	Purpose and scope	Device family, facility, risk class, intended operation, exclusions
03	Regulatory applicability	ISO 13485 process / US QMSR / EU / India / UK / Australia obligations as selected
04	Definitions and responsibilities	Operators, QA/QC, process owner, regulatory, engineering, independent reviewer
05	Prerequisites	Training and authorization, approved equipment/materials, DMR/technical file and risk controls
06	Risk and EHS precautions	Relevant harm, human factors, contamination, ESD, chemical and electrical controls
07	Stepwise execution	Specific sequence, time, tolerances, tools, checks, independent hold points
08	Critical control parameters	Operational ranges, alarms, challenge and acceptance criteria
09	Accept/reject criteria	Clear measurable specifications linked to DMR and design outputs
10	Data recording	Attributable contemporaneous original records, corrections and review
11	Nonconformance escalation	Containment, QA approval, CAPA / regulatory reporting / batch impact
12	Traceability	Lot/serial, UDI, device DHR, material and sterilization load links
13	Records and forms	Templates, equipment logs, DHR, evidence, approved labels and traceability
14	Related documents	Documented risk file, DMR, control plan, change, CAPA, deviation and procedures
15	Training and implementation	Competency matrix, effective before use, requalification and evidence
16	Review and revision	Periodic and triggered review, document owner, QA approval, obsolete copy handling

08 OFFICIAL REGULATORY SOURCES & SAFETY NOTES

This selected list is provided as a traceable starting point; the Excel Regulatory References sheet lists all links.

ISO13485 ISO 13485:2016 (reviewed/confirmed 2025): https://www.iso.org/standard/59752.html

ISO14971 ISO 14971:2019: https://www.iso.org/standard/72704.html

FDA-QMSR FDA 21 CFR Part 820 - QMSR (effective 2026-02-02): https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr

FDA-CSA FDA Computer Software Assurance, February 2026: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software

FDA-CYBER FDA Cybersecurity in Medical Devices Guidance, February 2026: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket

EU-MDR Regulation (EU) 2017/745 - MDR: https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

EU-IVDR Regulation (EU) 2017/746 - IVDR: https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng

UK-PMS GB UK Medical Devices Regulations 2002 and PMS amendments effective 2025: https://www.gov.uk/government/publications/medical-devices-post-market-surveillance-requirements

IND-MDR5 India Medical Devices Rules 2017 - Fifth Schedule: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules%2C%202017.pdf

TGA Australia TGA Medical Devices Regulations 2002 Essential Principles: https://www.tga.gov.au/products/medical-devices/manufacturing

ISO11607 ISO 11607 (Parts 1 & 2): https://www.iso.org/search.html?query=ISO%2011607

ISO11135 ISO 11135 - Ethylene oxide sterilization: https://www.iso.org/search.html?query=ISO%2011135

ISO11137 ISO 11137 series - Radiation sterilization: https://www.iso.org/search.html?query=ISO%2011137

ISO17665 ISO 17665 - Moist heat sterilization: https://www.iso.org/search.html?query=ISO%2017665

ISO10993 ISO 10993 series - Biological evaluation: https://www.iso.org/search.html?query=ISO%2010993

IEC62304 IEC 62304 - Medical device software life cycle: https://webstore.iec.ch/en/search?query=62304

Limitations and compliance controls

A generic global SOP master index cannot literally enumerate every future device technology, specialty device standard or country-specific licence condition. Confirm facility and product applicability through a documented gap assessment, design/risk file review, licence/technical documentation crosswalk and independent QA/regulatory approval. Product release requires an effective QMS and complete actual validation, verification and acceptance evidence.

Several inherited generic GMP procedural titles address universal quality controls; they must be rewritten in device-appropriate terminology before adoption. Specialized systems (sterile filling, aseptic manufacture, EO/radiation sterilization, software, devices incorporating drugs or biologics, implants and IVD reagents) each require technical and legal review.

YOUR GLOBAL PARTNER IN MEDICAL DEVICE QMS & REGULATORY COMPLIANCE

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