SCOPE QMS STARTER PACKAGE

The following table lists the standard operating procedures required by EN ISO 13485:2021 and MDR, including associated document templates.

Process name	Applicable document templates
QM Manual	• QM manual with quality policy • Process overview • Process instruction in general (with flow chart)
Document control	• Meeting minutes • Report (general) • Guide (general) • Directories of process instructions, forms, standards, laws and regulations
Signature regulation	• Process instruction incl. proposal for electronic signature
Order acquisition	• Invoice • Non-disclosure agreement
Project management	• Project manual • Milestone release
Medical device development	• Checklist Contents Technical Documentation • Purpose • Classification • Product description • Instructions for use • Requirement specifications • Checklist of safety and performance requirements according to Annex I of the MDR • Design Transfer Checklist
Risk management	• Risk management files • Risk management plan • Risk table
Usability management	• Usability file • Use Scenarios • Observation and confidentiality agreement
Procurement	• Order • Order list • Inventory list • Order confirmation
Incoming goods	• Goods receipt book • Incoming goods inspection • Delivery note • Marking customer property
Acceptance of services	• Acceptance protocol
Supplier management	• Supplier master sheet • Supplier list • Quality assurance agreement

Change, Improvement & Error Management	• Error, improvement or change message • Activity list
Identification & Traceability	• Identification labels • Nameplate design
Measuring equipment	• Measuring device list • Checklist Measuring Equipment Calibration
Human Resources Management	• Checklist staff entry • Job profile • Application for further training • Staff appraisal • Checklist for staff leaving
Training & Further Education	• Training participant feedback • Training participation • Competence & Training Matrix
Working environment & infrastructure	• Maintenance plan • Maintenance list • Cleaning and hygiene plan
Information management	(no templates, must be regulated individually)
Customer feedback	• Confirmation of service provision
Data analysis (process key figures)	• Quality targets • Overview of key figures
Internal audit	• Audit programme • Audit plan • Audit checklist according to EN ISO 13485:2021 • Audit report
Management review	• Management review report
Software LifeCycle	• Software Development Plan • Software design specifications • Software Configuration Management • Software Problem Report • Software Risk List • Unit Test Plan • Integration Test Plan • Software release • Software Maintenance Plan
Process validation	• Validation plan • Validation report
Change Control	• List of changes • Notification of change • Amendment • Change order
Handling contaminated products	• Decontamination certificate
Computer System Validation (CSV)	• CSV list • CSV validation plan • CSV validation report • CSV Rating
Verification & Validation	• Verification and validation plan

	• Test protocol • Test report
Installation	• Work instruction - must be regulated individually
Maintenance	• Work instruction - must be regulated individually
Notification to regulatory authority	• Reporting incidents and recalls • Product release

The following process instructions are currently out-of-scope and therefore not included:

- sterile medical devices
- Implantable medical devices