SCOPE QMS STARTER PACKAGE

The following table lists the processes required by EN ISO 13485:2016 and MDR, including associated document templates.

Process name	Applicable document templates
QM Manual	• QM manual with the quality policy • Process overview • Process instruction general (with flowchart)
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 • Confidentiality agreement
Project management	• Project Manual • Milestone release
Development medical device	• Checklist Contents Technical Documentation • Purpose • Classification • Product description • Instruction manual • Requirements specifications • Checklist of safety and performance requirements according to Annex II of the MDR • Design Transfer Checklist
Risk Management	• Risk Management File • Risk Management Plan • Risk table
Usability Management	• Usability file • Use Scenarios • Observation and confidentiality agreement
Procurement	• Order • Order list • Inventory list • Order confirmation
Goods receipt	• Goods receipt book • Incoming goods inspection • Delivery bill • Marking customer property
Acceptances of services	• Acceptance protocol
Supplier Management	• Supplier master sheet • Supplier list • Quality assurance agreement

Change, improvement & error management	• Message error, improvement, or change • Operation 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 education • Employee review • Checklist personnel departure
Training & 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 objectives • Key figures overview
Internal audit	• Audit program • Audit plan • Audit checklist according to EN ISO 13485:2016 • 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	• Change list • Change notice • Change request • 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 the 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