ISO 13485:2003

Medical Device Standard

Documented Requirements by Section

(1:20:37)

Clause	Description	Document Type
4.2.2	Quality manual	Manual
4.2.3	Control of documents	Procedure
4.2.4	Control of records	Procedure
7.3.1	Design & development planning	Procedure
7.4.1	Purchasing process	Procedure
7.5.1.2.3	Servicing activities	Procedure
7.5.2.1	Validation of computer software	Procedure
7.5.2.2	Validation of sterile processes	Procedure
7.5.3.1	Product identification	Procedure
7.5.3.1	Returned product identification	Procedure
7.5.3.2.1	Product traceability	Procedure
7.5.5	Preservation of product (processing)	Procedure
7.5.5	Preservation of product (shelf-life)	Procedure
7.6	Control of monitoring & measuring devices	Procedure
8.2.1	Feedback system	Procedure
8.2.2	Internal audits	Procedure
8.3	Control of nonconforming product	Procedure
8.4	Analysis of data	Procedure
8.5.1	Issue & implementation of advisory notices	Procedure
8.5.2	Corrective action	Procedure
8.5.3	Preventive action	Procedure

Legend: M **= manual** / P **= procedure** / R **= record**

ISO 13485:2003

Medical Device Standard

Documented Requirements by Section

(1:20:37)

Clause	Description	Document Type
5.6.1	Management review	Record
6.2.2 (e)	Competence, awareness & training	Record
6.3	Maintenance	Record
7.1 (d)	Planning of product realization	Record
7.1	Risk management	Record
7.2.2	Review of requirements related to product	Record
7.3.2	Design & development inputs	Record
7.3.3	Design & development outputs	Record
7.3.4	Design & development review	Record
7.3.5	Design & development verification	Record
7.3.6	Design & development validation	Record
7.3.7	Control of design & development changes	Record
7.4.1	Supplier evaluations	Record
7.4.2	Purchasing information	Record
7.4.3	Verification of purchased product	Record
7.5.1.1	Batch records	Record
7.5.1.2.2	Installation activities	Record
7.5.1.2.3	Servicing activities	Record
7.5.1.3	Sterilization parameters	Record
7.5.2.1	Validation (process)	Record
7.5.2.2	Validation (sterilization)	Record
7.5.3.2.1	Product traceability	Record
7.5.3.2.2	Consignee name & address	Record
7.5.4	Customer property	Record
7.5.5	Preservation of product	Record
7.6	Calibration (as found)	Record
7.6	Calibration (corrected)	Record
8.2.2	Internal audits	Record
8.2.4.1	Product release	Record
8.2.4.2	Product inspection & testing	Record
8.3	Nonconformances (authorization)	Record
8.3	Nonconformances (nature)	Record
8.4	Analysis of data	Record
8.5.1	Customer complaints (investigations)	Record
8.5.1	Customer complaints (no action)	Record
8.5.2	Corrective action	Record
8.5.3	Preventive action	Record

Legend: M **= manual** / P **= procedure** / R **= record**