



Reading sample / Table of contents



DIN EN ISO 13485:2021 – Production & Services

Contents

Chapters 1 and 2 Scope & Normative References
Chapter 3 Terms Abbreviations
Chapter 4 Quality Management System
Chapter 5 Management Responsibility
Chapter 6 Resource Management
Chapter 7 Production and service provision
Chapter 8 Measurement, Analysis & Improvement

Process instructions (61)

4.1.6 Validation Software	7.1.0 Production Risk Management
4.2.4 Control of external documents	7.2.3 Quotation preparation
4.2.4 Document control	7.2.3 Order processing
4.2.5 Control of quality records	7.2.3 Order change
4.2.5 Confidential Information	7.2.3 Sales
5.3.0 Quality policy	7.4.1 Selection of suppliers
5.4.1 Quality objectives	7.4.1 Procurement
5.5.3 Internal communication	7.4.1 Supplier audit
5.6.0 Management review	7.4.1 Supplier evaluation
6.1.0 Provision of resources	7.4.1 Supplier communication
6.1.0 Planning of production resources	7.4.1 Framework agreements
6.2.0 Introduction of new employees	7.4.3 Goods receipt
6.2.0 Setting	7.5.1 Service
6.2.0 Required training	7.5.1 Production
6.2.0 Training	7.5.3 / 7.5.4 Installation Maintenance
6.2.0 Further training	7.5.5 Sterilization
6.3.0 External maintenance	7.5.6 Process validation
6.3.0 Internal maintenance	7.5.8 Delivery
7.1.0 Work preparation	7.5.8 Identification

7.5.8 Returns
7.5.9 Traceability
7.5.10 Customer property
7.5.11 Storage
7.5.11 Packaging
7.5.11 Shipping
7.6.0 Monitoring measuring equipment
8.2.1 Customer satisfaction
8.2.1 Feedback
8.2.2 Complaint processing
8.2.4 Internal Audit
8.2.6 Special tests
8.2.6 External tests / laboratory

Work instructions (8)

4.2.4 Creating documents
7.2.3 Quotation preparation
7.4.1 Selection of suppliers
7.4.1 Procurement rules

Forms / forms of proof (35)

4.0.0 Documentation levels (included in Chapter 4)
4.1.5 QAA critical processes
4.1.6 Software validation
4.2.2 Interactions of the processes
4.2.4 List of documents (this file)
4.2.5 List of records
5.1.0 / 5.3.0 Management Commitment / Quality Policy
5.1.0 Declaration no other certifier
5.4.1 Quality objectives
5.5.1 Organizational chart
5.5.1 Responsibilities and authorities
5.5.2 Letter of appointment BDL
5.5.3 List of communication channels
5.5.3 QM Calendar
5.6.0 Management review
6.2.0 Training and authorization matrix
6.2.0 Job description
6.2.0 Proof of instruction
6.2.0 Confidentiality
6.3.0 Infrastructure
6.3.0 List of machines
6.3.0 Maintenance measures
6.3.0 Maintenance record

8.2.6 Planning tests
8.2.6 Series tests
8.2.6 Verification Production
8.3.1 Control of non-conforming products
8.3.1 Callback
8.3.3 Recommendations and measures after delivery
8.3.4 Rework
8.4.0 Data analysis
8.5.1 Planning Improvement
8.5.2 Corrective actions
8.5.3 Preventive measures

7.4.3 Goods receipt
7.5.9 Traceability
7.5.11 Product preservation
7.6.0 Handling of test equipment

6.4.0 Waste plan
6.4.0 Prevention concept
6.4.0 Cleanliness concept
7.1.0 Process chain / quality plan
7.1.0 Risks Measures
7.4.1 Outsourced processes
7.4.1 Supplier Checklist
7.4.1 Supplier evaluation
7.5.1 Batch report
7.5.4 Installation activities
7.5.4 Product Maintenance
7.5.6 Process changes
7.5.6 Process validation
7.5.8 Product status accompanying sheet
7.6.0 Test equipment file
8.2.1 Customer satisfaction complaints
8.2.1 Feedback
8.2.4 Audit deviation
8.2.4 Audit report
8.2.4 Audit checklist 13485:2021
8.2.4 Supplier Audit Checklist
8.2.4 Audit plan
8.2.4 Audit program
8.2.6 Test plan
8.3.1 Error list

8.3.1 Control of non-conforming products
8.3.2 Special releases
8.3.3 Recommended measures
8.3.4 Rework / Improvements
8.4.0 Data analysis

8.5.1 Improvements
8.5.2 / 8.5.3 Corrective and preventive actions
8.5.2 Corrective actions

You will find the excerpt on the following pages.