# ISO 13485:2016 Mapping of Requirements to Documents

This table maps all requirements of the ISO 13485:2016 (by section) to the relevant documents.

> Note that the document names in the "Fulfilled in Document" column are based on the OpenRegulatory templates. You'll probably have a different system for assigning document names, so feel free to rename them.

## ISO 13485:2016

| Section | Title | Document |
|---|---|---|
| 4.1 | General QMS Requirements | *Quality Management ManualSOP Management ReviewSOP PurchasingSOP Software Validation* |
| 4.2.1 | General Documentation Requirements | *Quality Management Manual* |
| 4.2.2 | Quality Management Manual | *Quality Management Manual* |
| 4.2.3 | Medical Device File | *SOP Product Certification and RegistrationSOP Integrated Software Development* |
| 4.2.4 | Control of Documents | *SOP Document and Record Control* |
| 4.2.5 | Control of Records | *SOP Document and Record Control* |
| 5.1 | Management Obligations | *Quality Management ManualSOP Management Review* |
| 5.2 | Client Orientation | *SOP Update of Regulations and KPIs* |
| 5.3 | Quality Policies | *Quality Management ManualSOP Management Review* |
| 5.4 | QMS Planning and Quality Goals | *Quality Management Manual and KPIsSOP Management Review* |
| 5.5 | Responsibilities, Competencies and Communication | *Quality Management Manual* |
| 5.6 | Management Review | *SOP Management Review* |
| 6.1 | Allocation of Resources | *SOP Management Review and KPIs* |
| 6.2 | Staff Resources | *SOP Human Resources Administration* |
| 6.3 | Infrastructure | *SOP Software Validation* |
| 6.4 | Work Environment | *- not applicable -* |
| 6.4.2 | Control of Contamination | *- not applicable -* |
| 7.1 | Planning of Product Development | *SOP Integrated Software Development* |

| Section | Title | Document |
|---|---|---|
| 7.2 | Customer-Oriented Processes | *SOP Integrated Software DevelopmentSOP Feedback Management* |
| 7.3 | Development | *SOP Integrated Software DevelopmentSOP Product Certification and RegistrationSOP Change Management* |
| 7.4 | Purchasing | *SOP Purchasing* |
| 7.5 | Production and Service Provision | *SOP Integrated Software Development* |
| 7.5.5 | Special Requirements for Sterile Medical Devices | *- not applicable -* |
| 7.5.9 | Traceability | *SOP Product Certification and Registration* |
| 7.6 | Control of Surveillance and Measurement | *SOP Post-Market SurveillanceSOP Software Validation* |
| 8.1 | General Measurement, Analysis and Improvement | *SOP Integrated Software DevelopmentSOP Internal AuditingSOP Management Review* |
| 8.2.1 | Feedback | *SOP Feedback Management* |
| 8.2.2 | Complaint Processing | *SOP Feedback ManagementSOP Corrective and Preventive Actions* |
| 8.2.3 | Reporting to Authorities | *SOP Incident Reporting* |
| 8.2.4 | Internal Audit | *SOP Internal Auditing* |
| 8.2.5 | Surveillance and Measurement of Processes | *SOP Management Review* |
| 8.2.6 | Surveillance and Measurement of Products | *SOP Post-Market Surveillance* |
| 8.3 | Control of Nonconforming Products | *SOP Corrective and Preventive ActionsSOP Incident Reporting* |
| 8.4 | 8.4 Data Analysis | *SOP Management Review* |
| 8.5 | 8.5 Improvement: Corrective and Preventive Action | *SOP Corrective and Preventive Actions* |