# ISO 13485 Documentation Toolkit

https://advisera.com/13485academy/iso-13485-documentation-toolkit/

Note: The documentation should preferably be implemented in the order in which it is listed here.

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| | **00** | **Document Management** | | |
| 1 | 00 | Procedure for Document and Record Control | 4.2.3; 4.2.4; 4.2.5 | ✓ |
| 2 | 00.1 | Appendix 1 – List of Internal Documents | 4.2.2 | |
| 3 | 00.2 | Appendix 2 – List of External Documents | 4.2.4 | |
| 4 | 00.3 | Appendix 3 – List of Types of Records | 4.2.5 | |
| 5 | 00.4 | Appendix 4 – Registry of Records for Retention/Central Archive | 4.2.5 | |
| | **01** | **Preparations for the Project** | | |
| 6 | 01 | Project Plan | | |
| | **02** | **Quality Policy** | | |
| 7 | 02 | Quality Policy | 5.3 | ✓ |
| 8 | 02.1 | Quality Objectives and Realization Plan | 4.2.1; 5.4.1 | ✓ |
| | **03** | **Quality Manual** | | |
| 9 | 03 | Quality Manual | 4.2.1; 4.2.2 | ✓ |
| | **04** | **Human Resources** | | |
| 10 | 04 | Procedure for Human Resources | 6.2 | ✓ |
| 11 | 04.1 | Appendix 1 – Training Program | 6.2 | |
| 12 | 04.2 | Appendix 2 – Training Record | 6.2 | ✓ |
| 13 | 04.3 | Appendix 3 – Record of Attendance | 6.2 | ✓ |
| | **05** | **Infrastructure and Work Environment** | | |
| 14 | 05 | Procedure for Infrastructure and Work Environment | 6.3; 6.4.1; 6.4.2 | ✓ |

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| 15 | 05.1 | Appendix 1 – Record of Infrastructure Maintenance | 6.3 | ✓ |
| | **06** | **Risk Management** | | |
| 16 | 06 | Procedure for Risk Management | 7.1 | ✓ |
| 17 | 06.1 | Appendix 1 – Risk Management Plan | 7.1 | ✓ |
| 18 | 06.2 | Appendix 2 – Risk Management File | 7.1 | ✓ |
| 19 | 06.3 | Appendix 3 – Risk Assessment Record | 7.1 | ✓ |
| 20 | 06.4 | Appendix 4 – Risk Management Review | 7.1 | ✓ |
| 21 | 06.5 | Appendix 5 – Identification of Hazards and Characteristics Related to Safety | 7.1 | ✓ |
| | **07** | **Sales** | | |
| 22 | 07 | Sales Procedure | 7.2.1, 7.2.2; 7.2.3 | |
| 23 | 07.1 | Appendix 1 – Product Requirement Review Record | 7.2.2 | ✓ |
| | **08** | **Customer Complaints and Feedback** | | |
| 24 | 08 | Procedure for Customer Communication, Feedback and Complaints | 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 | ✓ |
| 25 | 08.1 | Appendix 1 – Customer Feedback Report | 8.2.1 | ✓ |
| 26 | 08.2 | Appendix 2 – Registry of Customer Complaints | 8.2.2 | ✓ |
| 27 | 08.3 | Appendix 3 – Registry of Reports to the Authorities | 8.2.3 | ✓ |
| | **09** | **Design and Development** | | |
| 28 | 09 | Procedure for Design and Development | 7.3 | ✓ |
| 29 | 09.1 | Appendix 1 – Design and Development File | 7.3.10 | ✓* |
| 30 | 09.2 | Appendix 2 – Project Plan and Review | 7.3.4; 7.3.5; 7.3.6; | ✓ |
| 31 | 09.3 | Appendix 3 – Change Review Record | 7.3.9 | ✓ |

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| 32 | 09.4 | Appendix 4 – Design Review Minutes | 7.3.4 | ✓ |
| 33 | 09.5 | Appendix 5 - Design and Development Verification and Validation Plans | 7.3.5, 7.3.6 | ✓ |
| 34 | 09.6 | Appendix 6 – Verification Report | 7.3.6 | ✓ |
| 35 | 09.7 | Appendix 7 – Validation Report | 7.3.7 | ✓ |
| 36 | 09.8 | Appendix 8 – Design and Development Transfer Record | 7.3.8 | ✓ |
| | **10** | **Purchasing and Evaluation of Suppliers** | | |
| 37 | 10 | Procedure for Purchasing and Evaluation of Suppliers | 4.1.5; 7.4 | ✓ |
| 38 | 10.1 | Appendix 1 – Checklist for Evaluation of Suppliers | 7.4.1 | ✓* |
| 39 | 10.2 | Appendix 2 – List of Approved Suppliers | 7.4.1 | |
| 40 | 10.3 | Appendix 3 – Registry of Complaints about Suppliers | 7.4.1 | |
| 41 | 10.4 | Appendix 4 – Request and Order for Purchasing | 7.4.2 | ✓* |
| 42 | 10.5 | Appendix 5 – Purchasing Verification Record | 7.4.3 | ✓ |
| | **11** | **Production and Service Provision** | | |
| 43 | 11 | Procedure for Production and Service Provision | 7.1; 7.5 | ✓* |
| 44 | 11.1 | Appendix 1 – Product Specification | 7.1 a); 7.2.2; 7.5.2 | ✓* |
| 45 | 11.2 | Appendix 2 – Record of Product/Service Conformance | 7.1d); 7.2.2 | ✓ |
| 46 | 11.3 | Appendix 3 – Quality Plan | 7.1 | |
| 47 | 11.4 | Appendix 4 – Notification to a Customer about Changes on Property | 7.5.10 | ✓* |
| 48 | 11.5 | Appendix 5 – Record of Production Process Validation | 7.5.6 | ✓ |
| 49 | 11.6 | Appendix 6 – Record of Medical Device Installation | 7.5.3 | ✓ |

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| 50 | 11.7 | Appendix 7 – Record of Servicing Activities | 7.5.4 | ✓ |
| | **12** | **Identification and Traceability** | | |
| 51 | 12 | Procedure for Identification and Traceability | 7.5.8; 7.5.9 | ✓ |
| | **13** | **Sterilization** | | |
| 52 | 13 | Procedure for Sterile Medical Devices | 6.4.2; 7.5.2; 7.5.5; 7.5.7 | ✓* |
| 53 | 13.1 | Appendix 1 – Record for Sterilization | 7.5.5 | ✓* |
| | **14** | **Validation** | | |
| 54 | 14 | Procedure for Validation | 7.5.6 | ✓ |
| 55 | 14.1 | Appendix – Validation Master Plan | 7.5.6 | ✓ |
| | **15** | **Software Validation** | | |
| 56 | 15 | Procedure for Documentation and Validation of Computer Software | 4.1.6; 7.5.6 | ✓* |
| 57 | 15.1 | Appendix 1 – Record of Software Validation | 7.5.6 | ✓ |
| | **16** | **Warehousing** | | |
| 58 | 16 | Warehousing Procedure | 7.5.11 | ✓* |
| 59 | 16.1 | Appendix 1 – Record for Temperature and Humidity Control | 7.5.11 | ✓** |
| | **17** | **Nonconformities** | | |
| 60 | 17 | Procedure for Control of Nonconforming Products | 8.3 | ✓ |
| 61 | 17.1 | Appendix 1 – Nonconforming Product Record | 8.3.2; 8.3.4 | ✓ |
| 62 | 17.2 | Appendix 2 – Registry of Nonconformities | 8.3.2 | ✓ |
| 63 | 17.3 | Appendix 3 – Registry of Recalled/Withdrawn Products | 8.3.3 | ✓ |
| | **18** | **Adverse Event Investigation** | | |

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| 64 | 18 | Procedure for Vigilance and Adverse Event Investigation and Reporting | 8.2.3; 8.3.3 | ✓ |
| 65 | 18.1 | Appendix 1 – Adverse Event Report | 8.2.3 | ✓ |
| | **19** | **Equipment Maintenance** | | |
| 66 | 19 | Procedure for Equipment Maintenance and Measuring Equipment | 6.3; 7.6 | ✓ |
| 67 | 19.1 | Appendix 1 – List of Equipment | 6.3; 7.6 | |
| 68 | 19.2 | Appendix 2 – Plan for Preventive Maintenance of Equipment | 6.3 | |
| 69 | 19.3 | Appendix 3 – Maintenance and Calibration Record | 7.6 | ✓ |
| | **20** | **Internal Audit** | | |
| 70 | 20 | Procedure for Internal Audit | 8.2.4 | ✓ |
| 71 | 20.1 | Appendix 1 – Internal Audit Checklist | 8.2.4 | |
| 72 | 20.2 | Appendix 2 – Internal Audit Program | 8.2.4 | ✓ |
| 73 | 20.3 | Appendix 3 – Internal Audit Report | 8.2.4 | ✓ |
| 74 | 20.4 | Appendix 4 – Internal Audit Plan | 8.2.4 | |
| | **21** | **Corrective and Preventive Action** | | |
| 75 | 21 | Procedure for Corrective and Preventive Action | 8.5.2; 8.5.3 | ✓ |
| 76 | 21.1 | Appendix 1 – Corrective/Preventive Action Request | 8.5.2; 8.5.3 | ✓ |
| 77 | 21.2 | Appendix 2 – Registry and Status of Corrective and Preventive Actions | 8.5.2; 8.5.3 | ✓ |
| | **22** | **Data Analysis** | | |
| 78 | 22 | Procedure for Data Analysis | 8.4 | ✓ |
| 79 | 22.1 | Appendix 1 – Data Analysis Report | 8.4 | ✓ |
| | **23** | **Management Review** | | |
| 80 | 23 | Procedure for Management Review | 5.6 | ✓ |

| No. | Doc. code | Document name | ISO 13485 clause | Mandatory document |
|---|---|---|---|---|
| 81 | 23.1 | Appendix 1 – Matrix of Key Performance Indicators | 5.6.2e);<br>5.6.2f) | |
| 82 | 23.2 | Appendix 2 – Management Review Minutes | 5.6.1 | ✓ |

* The listed documents are not mandatory if the corresponding processes don't exist in the organization.

** The document is mandatory if special conditions for preservation/warehousing of the medical device(s) are required.