

ISO 13485 Documentation Toolkit

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

No.	Doc. Code	Name of Document	ISO 13485 Clause	Mandatory document
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 Detention/ Central Archive	4.2.5	
6	01	Project Plan		
7	02	Quality Policy	5.3	✓
8	02.1	Quality Objectives	4.2.1; 5.4.1	✓
9	03	Quality Manual	4.2.1; 4.2.2.	✓
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	✓
14	05	Procedure for Infrastructure and Work Environment	6.3; 6.4.1; 6.4.2	✓
15	05.1	Appendix 1 – Record of Infrastructure Maintenance	6.3	✓
16	06	Procedure for Risk Management	7.1	✓
17	06.1	Appendix 1 – Risk Management Record	7.1	✓
18	07	Sales Procedure	7.2.1, 7.2.2; 7.2.3	
19	07.1	Appendix 1 – Product Requirement Review Record	7.2.2	✓
20	08	Procedure for Customer Communication, Feedback and Complaints	7.2.3; 8.2.1; 8.2.2; 8.2.3	✓**
21	08.1	Appendix 1 – Customer Feedback Report	8.2.1	✓
22	08.2	Appendix 2 – Registry of Customer Complaints	8.2.2	✓
23	08.3	Appendix 3 – Registry of Reports to the Authorities	8.2.3	✓
24	09	Procedure for Design and Development	7.3.1; 7.3.8; 7.3.9	✓
25	09.1	Appendix 1 – Design and Development File	7.3.10	✓***
26	09.2	Appendix 2 – Project Plan and Review	7.3.4; 7.3.5; 7.3.6;	✓

27	09.3	Appendix 3 – Change Review Record	7.3.9	✓
28	09.4	Appendix 4 – Design Review Minutes	7.3.4	✓
29	09.5	Appendix 5 - Design and Development Verification and Validation Plans	7.3.6, 7.3.5	✓
30	09.6	Appendix 6 – Verification Report	7.3.6	✓
31	09.7	Appendix 7 – Validation Report	7.3.7	✓
32	09.8	Appendix 8 – Design and Development Transfer Record	7.3.8	✓
33	10	Procedure for Purchasing and Evaluation of Suppliers	7.4, 7.4.1; 7.4.3	✓
34	10.1	Appendix 1 – Checklist for Evaluation of Suppliers	7.4.1	✓ ***
35	10.2	Appendix 2 – List of Approved Suppliers	7.4.1	
36	10.3	Appendix 3 – Registry of Complaints about Suppliers	7.4.1	
37	10.4	Appendix 4 – Request and Order for Purchasing	7.4.2	✓ ***
38	10.5	Appendix 5 – Purchasing Verification Record	7.4.3	✓
39	11	Procedure for Production and Service Provision	7.1; 7.5	✓ ***
40	11.1	Appendix 1 – Product Specification	7.1 a), 7.2.2, 7.5.2	✓ ***
41	11.2	Appendix 2 – Record of Product/Service Conformance	7.1d), 7.2.2, 7.3.3	✓
42	11.3	Appendix 3 – Quality Plan	7.1	
43	11.4	Appendix 4 – Notification to a Customer about Changes on his Property	7.5.10	✓ ***
44	11.5	Appendix 5 – Record of Production Process Validation	7.5.6	✓
45	11.6	Appendix 6 – Record of Traceability	7.5.9	✓ ***
46	11.7	Appendix 7 – Record of Medical Device Installation	7.5.3	✓
47	11.8	Appendix 8 – Record of Servicing Activities	7.5.4	✓
48	12	Procedure for Sterile Medical Devices	6.4.2, 7.5.7, 7.5.5	✓
49	12.1	Appendix 1 – Record for Sterilization	7.5.5	✓ ***
50	13	Procedure for Documentation and Validation of Computer Software	4.1.6, 7.5.6	✓ ***
51	13.1	Appendix 1 – Record of Software Validation	7.5.6	✓
52	14	Warehousing Procedure	7.5.11	✓ ***
53	14.1	Appendix 1 – Record of Warehousing Temperature Control	7.5.11	
54	15	Procedure for Control of Non-Conforming Products	8.3, 8.3.4	✓
55	15.1	Appendix 1 – Non-Conforming Product Record	8.3.2; 8.3.4	✓

56	15.2	Appendix 2 – Registry of Non-Conformities	8.3.2	✓
57	15.3	Appendix 3 – Registry of Recalled / Withdrawn Products	8.3.3	✓
58	16	Procedure for Adverse Event Investigation and Reporting	8.2.3	✓
59	16.1	Appendix 1 – Investigation Report	8.2.3	✓
60	17	Procedure for Equipment Maintenance and Measuring Equipment	6.3; 7.6;	✓
61	17.1	Appendix 1 – List of Equipment	6.3; 7.6	
62	17.2	Appendix 2 – Plan for Preventive Maintenance of Equipment	6.3	
63	17.3	Appendix 3 – Maintenance and Calibration Record	7.6	✓
64	18	Procedure for Internal Audit	8.2.4	✓
65	18.1	Appendix 1 – Internal Audit Checklist	8.2.4	
66	18.2	Appendix 2 – Internal Audit Program	8.2.4	
67	18.3	Appendix 3 – Internal Audit Report	8.2.4	✓
68	18.4	Appendix 4 – Internal Audit Plan	8.2.4	
69	19	Procedure for Corrective and Preventive Action	8.5.2; 8.5.3	✓
70	19.1	Appendix 1 – Corrective/Preventive Action Request	8.5.2; 8.5.3	✓
71	19.2	Appendix 2 – Registry and Status of Corrective and Preventive Actions	8.5.2; 8.5.3	✓
72	20	Procedure for Data Analysis	8.4	✓
73	20.1	Appendix 1 – Data Analysis Report	8.4	✓
74	21	Procedure for Management Review	5.6.1; 5.6.2; 5.6.3;	✓
75	21.1	Appendix 1 – Matrix of Key Performance Indicators	5.6.2e) f)	
76	21.2	Appendix 2 – Management Review Minutes	5.6.1	✓

* National or regional regulations might require the organization to establish documented procedures for identifying training needs.

** National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.

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