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	Name of Document	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	✓
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 Review	7.1	✓

	07	**Sales**		
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	✓
	08	**Customer Complaints and Feedback**		
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	✓
	09	**Design and Development**		
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	✓
	10	**Purchasing and Evaluation of Suppliers**		
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	✓
	11	**Production and Service Provision**		
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 Property	7.5.10	✓*
44	11.5	Appendix 5 – Record of Production Process Validation	7.5.6	✓
45	11.6	Appendix 6 – Record of Medical Device Installation	7.5.3	✓
46	11.7	Appendix 7 – Record of Servicing Activities	7.5.4	✓
	12	**Sterilization**		
47	12	Procedure for Sterile Medical Devices	6.4.2, 7.5.7, 7.5.5	✓
48	12.1	Appendix 1 – Record for Sterilization	7.5.5	✓*
	13	**Software Validation**		
49	13	Procedure for Documentation and Validation of Computer Software	4.1.6, 7.5.6	✓*
50	13.1	Appendix 1 – Record of Software Validation	7.5.6	✓
	14	**Warehousing**		
51	14	Warehousing Procedure	7.5.11	✓*
52	14.1	Appendix 1 – Record for Temperature and Humidity Control	7.5.11	
	15	**Nonconformities**		
53	15	Procedure for Control of Non-Conforming Products	8.3, 8.3.4	✓
54	15.1	Appendix 1 – Non-Conforming Product Record	8.3.2; 8.3.4	✓
55	15.2	Appendix 2 – Registry of Non-Conformities	8.3.2	✓
56	15.3	Appendix 3 – Registry of Recalled / Withdrawn Products	8.3.3	✓
	16	**Adverse Event Investigation**		
57	16	Procedure for Adverse Event Investigation and Reporting	8.2.3	✓
58	16.1	Appendix 1 – Investigation Report	8.2.3	✓
	17	**Equipment Maintenance**		
59	17	Procedure for Equipment Maintenance and Measuring Equipment	6.3; 7.6;	✓
60	17.1	Appendix 1 – List of Equipment	6.3; 7.6	

61	17.2	Appendix 2 – Plan for Preventive Maintenance of Equipment	6.3	
62	17.3	Appendix 3 – Maintenance and Calibration Record	7.6	✓
	18	**Internal Audit**		
63	18	Procedure for Internal Audit	8.2.4	✓
64	18.1	Appendix 1 – Internal Audit Checklist	8.2.4	
65	18.2	Appendix 2 – Internal Audit Program	8.2.4	
66	18.3	Appendix 3 – Internal Audit Report	8.2.4	✓
67	18.4	Appendix 4 – Internal Audit Plan	8.2.4	
	19	**Corrective and Preventive Action**		
68	19	Procedure for Corrective and Preventive Action	8.5.2; 8.5.3	✓
69	19.1	Appendix 1 – Corrective/Preventive Action Request	8.5.2; 8.5.3	✓
70	19.2	Appendix 2 – Registry and Status of Corrective and Preventive Actions	8.5.2; 8.5.3	✓
	20	**Data Analysis**		
71	20	Procedure for Data Analysis	8.4	✓
72	20.1	Appendix 1 – Data Analysis Report	8.4	✓
	21	**Management Review**		
73	21	Procedure for Management Review	5.6.1; 5.6.2; 5.6.3	✓
74	21.1	Appendix 1 – Matrix of Key Performance Indicators	5.6.2e) f)	
75	21.2	Appendix 2 – Management Review Minutes	5.6.1	✓

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