ISO 13485 & MDR Integrated Documentation Toolkit

https://advisera.com/13485academy/iso-13485-eu-mdr-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 / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
	00	**Document Management**			
1	00	Procedure for Document and Record Control	ISO 13485 clauses 4.2.3, 4.2.4, 4.2.5	✓	
2	00.1	Appendix 1 – List of Internal Documents	ISO 13485 clause 4.2.2		
3	00.2	Appendix 2 – List of External Documents	ISO 13485 clause 4.2.4		
4	00.3	Appendix 3 – List of Types of Records	ISO 13485 clause 4.2.5		
5	00.4	Appendix 4 – Registry of Records for Retention/Central Archive	ISO 13485 clause 4.2.5		
	01	**Preparations for the Project**			
6	01	Project Plan			
	02	**Quality Policy**			
7	02	Quality Policy	ISO 13485 clause 5.3	✓	
8	02.1	Quality Objectives and Realization Plan	ISO 13485 clauses 4.2.1, 5.4.1 MDR article 10 (9), Annex IX (Chapter I)	✓	✓
	03	**Quality Manual**			
9	03	Quality Manual	ISO 13485 clauses 4.2.1, 4.2.2	✓	
	04	**Human Resources**			
10	04	Procedure for Human Resources	ISO 13485 clause 6.2	✓	
11	04.1	Appendix 1 – Training Program	ISO 13485 clause 6.2		
12	04.2	Appendix 2 – Training Record	ISO 13485 clause 6.2	✓	
13	04.3	Appendix 3 – Record of Attendance	ISO 13485 clause 6.2	✓	

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	05	**Infrastructure and Work Environment**			
14	05	Procedure for Infrastructure and Work Environment	ISO 13485 clauses 6.3, 6.4.1, 6.4.2	✓	
15	05.1	Appendix 1 – Record of Infrastructure Maintenance	ISO 13485 clause 6.3	✓	
	06	**Risk Management**			
16	06	Procedure for Risk Management	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
17	06.1	Appendix 1 – Risk Management Plan	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
18	06.2	Appendix 2 – Risk Management File	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
19	06.3	Appendix 3 – Procedure for FMEA Risk Assessment	ISO 13485 clause 7.1 MDR Annex I (Chapter I)		
20	06.4	Appendix 4 – FMEA Risk Assessment Record	ISO 13485 clause 7.1 MDR Annex I (Chapter I)		
21	06.5	Appendix 5 – Risk Management Review	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
	07	**Sales**			
22	07	Sales Procedure	ISO 13485 clauses 7.2.1, 7.2.2, 7.2.3		
23	07.1	Appendix 1 – Product Requirement Review Record	ISO 13485 clause 7.2.2	✓	
	08	**Customer Complaints and Feedback**			

No.	Doc. Code	Name of Document	ISO 13485 Clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
24	08	Procedure for Customer Communication, Feedback and Complaints	ISO 13485 clauses 7.2.3, 8.2.1, 8.2.2, 8.2.3	✓	
25	08.1	Appendix 1 – Customer Feedback Report	ISO 13485 clause 8.2.1	✓	
26	08.2	Appendix 2 – Registry of Customer Complaints	ISO 13485 clause 8.2.2	✓	
27	08.3	Appendix 3 – Registry of Reports to the Authorities	ISO 13485 clause 8.2.3	✓	
	09	**Design and Development**			
28	09	Procedure for Design and Development	ISO 13485 clauses 7.3.1, 7.3.8, 7.3.9	✓	
29	09.1	Appendix 1 – Design and Development File	ISO 13485 clause 7.3.10	✓*	
30	09.2	Appendix 2 – Project Plan and Review	ISO 13485 clauses 7.3.4, 7.3.5, 7.3.6	✓	
31	09.3	Appendix 3 – Change Review Record	ISO 13485 clause 7.3.9	✓	
32	09.4	Appendix 4 – Design Review Minutes	ISO 13485 clause 7.3.4	✓	
33	09.5	Appendix 5 - Design and Development Verification and Validation Plans	ISO 13485 clauses 7.3.6, 7.3.5	✓	
34	09.6	Appendix 6 – Verification Report	ISO 13485 clause 7.3.6	✓	
35	09.7	Appendix 7 – Validation Report	ISO 13485 clause 7.3.7	✓	
36	09.8	Appendix 8 – Design and Development Transfer Record	ISO 13485 clause 7.3.8	✓	
	10	**Purchasing and Evaluation of Suppliers**			
37	10	Procedure for Purchasing and Evaluation of Suppliers	ISO 13485 clauses 7.4, 7.4.1, 7.4.3	✓	
38	10.1	Appendix 1 – Checklist for Evaluation of Suppliers	ISO 13485 clause 7.4.1	✓*	
39	10.2	Appendix 2 – List of Approved Suppliers	ISO 13485 clause 7.4.1		
40	10.3	Appendix 3 – Registry of Complaints about Suppliers	ISO 13485 clause 7.4.1		

No.	Doc. Code	Name of Document	ISO 13485 Clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
41	10.4	Appendix 4 – Request and Order for Purchasing	ISO 13485 clause 7.4.2	✓*	
42	10.5	Appendix 5 – Purchasing Verification Record	ISO 13485 clause 7.4.3	✓	
43	10.6	Appendix 6 – Quality Agreement for Critical Supplier	ISO 13485 clause 7.4.2	✓	
44	10.7	Appendix 7 – Quality Agreement for Subcontractor	ISO 13485 clause 4.1.5	✓	
	11	**Production and Service Provision**			
45	11	Procedure for Production and Service Provision	ISO 13485 clauses 7.1, 7.5	✓*	
46	11.1	Appendix 1 – Product Specification	ISO 13485 clauses 7.1 a), 7.2.2, 7.5.2	✓*	
47	11.2	Appendix 2 – Record of Product/Service Conformance	ISO 13485 clauses 7.1d), 7.2.2, 7.3.3	✓	
48	11.3	Appendix 3 – Quality Plan	ISO 13485 clause 7.1		
49	11.4	Appendix 4 – Notification to a Customer about Changes on Property	ISO 13485 clause 7.5.10	✓*	
50	11.5	Appendix 5 – Record of Production Process Validation	ISO 13485 clause 7.5.6	✓	
51	11.6	Appendix 6 – Record of Medical Device Installation	ISO 13485 clause 7.5.3	✓	
52	11.7	Appendix 7 – Record of Servicing Activities	ISO 13485 clause 7.5.4	✓	
	12	**Sterilization**			
53	12.1	Procedure for EtO Sterilization	ISO 13485 clauses 6.4.2, 7.5.7, 7.5.5	✓*	
54	12.2	Procedure for Steam Sterilization	ISO 13485 clauses 6.4.2, 7.5.7, 7.5.5	✓*	
55	12.3	Procedure for Dry Heat Sterilization	ISO 13485 clauses 6.4.2, 7.5.7, 7.5.5	✓*	
56	12.4	Procedure for Ionizing Radiation Sterilization	ISO 13485 clauses 6.4.2, 7.5.7, 7.5.5	✓*	
57	12.5	Procedure for Filtration Sterilization	ISO 13485 clauses 6.4.2, 7.5.7, 7.5.5	✓*	

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58	12.6	Appendix 1 – Record for Sterilization	ISO 13485 clause 7.5.5	✓*	
	13	**Software Validation**			
59	13	Procedure for Documentation and Validation of Computer Software	ISO 13485 clauses 4.1.6, 7.5.6	✓*	
60	13.1	Appendix 1 – Record of Software Validation	ISO 13485 clause 7.5.6	✓	
	14	**Warehousing**			
61	14	Warehousing Procedure	ISO 13485 clause 7.5.11	✓*	
62	14.1	Appendix 1 – Record for Temperature and Humidity Control	ISO 13485 clause 7.5.11	✓**	
63	14.2	Appendix 2 – Pest Control Record	ISO 13485 clauses 6.4.1, 7.5.11		
	15	**Nonconformities**			
64	15	Procedure for Control of Non-Conforming Products	ISO 13485 clauses 8.3, 8.3.4	✓	
65	15.1	Appendix 1 – Non-Conforming Product Record	ISO 13485 clauses 8.3.2, 8.3.4	✓	
66	15.2	Appendix 2 – Registry of Non-Conformities	ISO 13485 clause 8.3.2	✓	
67	15.3	Appendix 3 – Registry of Recalled / Withdrawn Products	ISO 13485 clause 8.3.3	✓	
	16	**Adverse Event Investigation**			
68	16	Procedure for Adverse Event Investigation and Reporting	ISO 13485 clause 8.2.3 MDR articles 87, 88, 89	✓	✓
69	16.1	Appendix 1 – Adverse Event Report	ISO 13485 clause 8.2.3 MDR article 87	✓	✓
	17	**Equipment Maintenance**			
70	17	Procedure for Equipment Maintenance and Measuring Equipment	ISO 13485 clauses 6.3, 7.6	✓	
71	17.1	Appendix 1 – List of Equipment	ISO 13485 clauses 6.3, 7.6		

No.	Doc. Code	Name of Document	ISO 13485 Clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
72	17.2	Appendix 2 – Plan for Preventive Maintenance of Equipment	ISO 13485 clause 6.3		
73	17.3	Appendix 3 – Maintenance and Calibration Record	ISO 13485 clause 7.6	✓	
	18	**Post-Market Surveillance**			
74	18	Procedure for Post-Market Surveillance System	ISO 13485 clauses 7.2.3, 8.2.2, 8.2.3, 8.3.3 MDR articles 15, 83		✓
75	18.1	Appendix 1 – Post-Market Surveillance Plan	ISO 13485 clauses 7.2.3, 8.2.2, 8.2.3, 8.3.3 MDR articles 15, 83, 84, MDR Annex III		✓
76	18.2	Appendix 2 – Post-Market Surveillance Report	ISO 13485 clauses 7.2.3, 8.2.2, 8.2.3, 8.3.3 MDR articles 15, 83, 85		✓
77	18.3	Appendix 3 – Periodic Safety Update Report	ISO 13485 clauses 7.2.3, 8.2.2, 8.2.3, 8.3.3 MDR articles 15, 83, 86		✓
78	18.4	Appendix 4 – Post-Market Clinical Follow-up Plan	ISO 13485 clauses 7.2.3, 8.2.2, 8.2.3, 8.3.3 MDR Annex XIV Part B		✓
	19	**Clinical Evaluation**			
79	19	Procedure for Clinical Evaluation	ISO 13485 clause 7.3.7 MDR article 61, MDR Annex XIV Part A		✓

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80	19.1	Appendix 1 – Clinical Evaluation Plan	ISO 13485 clause 7.3.7 MDR article 61, MDR Annex XIV Part A		✓
81	19.2	Appendix 2 – Clinical Evaluation Report	ISO 13485 clause 7.3.7 MDR article 61, MDR Annex XIV Part A		✓
82	19.3	Appendix 3 – Literature Research Protocol	MDR article 61, MDR Annex XIV Part A		✓
83	19.4	Appendix 4 – Declaration of Interest	MDR article 61, MDR Annex XIV Part A		✓
	20	**Internal Audit**			
84	20	Procedure for Internal Audit	ISO 13485 clause 8.2.4	✓	
85	20.1	Appendix 1 – Internal Audit Checklist	ISO 13485 clause 8.2.4		
86	20.2	Appendix 2 – Internal Audit Program	ISO 13485 clause 8.2.4	✓	
87	20.3	Appendix 3 – Internal Audit Report	ISO 13485 clause 8.2.4	✓	
88	20.4	Appendix 4 – Internal Audit Plan	ISO 13485 clause 8.2.4		
	21	**Corrective and Preventive Action**			
89	21	Procedure for Corrective and Preventive Action	ISO 13485 clauses 8.5.2, 8.5.3	✓	
90	21.1	Appendix 1 – Corrective/Preventive Action Request	ISO 13485 clauses 8.5.2, 8.5.3	✓	
91	21.2	Appendix 2 – Registry and Status of Corrective and Preventive Actions	ISO 13485 clauses 8.5.2, 8.5.3	✓	
	22	**Data Analysis**			

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92	22	Procedure for Data Analysis	ISO 13485 clause 8.4	✓	
93	22.1	Appendix 1 – Data Analysis Report	ISO 13485 clause 8.4	✓	
	23	**Management Review**			
94	23	Procedure for Management Review	ISO 13485 clauses 5.6.1, 5.6.2, 5.6.3	✓	
95	23.1	Appendix 1 – Matrix of Key Performance Indicators	ISO 13485 clause 5.6.2e) f)		
96	23.2	Appendix 2 – Management Review Minutes	ISO 13485 clause 5.6.1	✓	
	24	**Technical File**			
97	24	Technical File Procedure	MDR Annex II		✓
98	24.1	Technical File Template	MDR Annex II		✓
99	24.2	List of UDI-DI	MDR article 27		✓
100	24.3	Summary of Safety and Clinical Performance	MDR article 32		✓ ***
101	24.4	Technical Documentation Checklist			

* 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.

*** The document is mandatory only for implantable and class III medical devices.