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	Document name	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 MDR article 10(9); Annex II; Annex IX (Chapter I)	✓	
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**			

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
9	03	Quality Manual	ISO 13485 clauses 4.2.1; 4.2.2 MDR Annex IX (Chapter I)	✓	
	04	**Strategy for Regulatory Compliance**			
10	04	Strategy for Regulatory Compliance	MDR articles 8; 10(9); 15; 19; 25; Annex I; Annex IV; Annex IX; Annex X; Annex XI; Annex XIII		✓
11	04.1	Appendix 1 – General Safety and Performance Requirements (GSPR)	MDR article 10(9); Annex I		✓
12	04.2	Appendix 2 – GAP Analysis	MDR article 10(9)		
13	04.3	Appendix 3 – Statement for Custom-Made Devices	MDR Annex XIII		✓
14	04.4	Appendix 4 – Declaration of Conformity	MDR article 19; Annex IV		✓
15	04.5	Appendix 5 – List of Economic Operators and Authorities	MDR articles 10(9); 25		✓
	05	**Human Resources**			
16	05	Procedure for Human Resources	ISO 13485 clause 6.2 MDR article 10(9); Annex IX (Chapter I)	✓	
17	05.1	Appendix 1 – Training Program	ISO 13485 clause 6.2		
18	05.2	Appendix 2 – Training Record	ISO 13485 clause 6.2	✓	
19	05.3	Appendix 3 – Record of Attendance	ISO 13485 clause 6.2	✓	

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
	06	**Infrastructure and Work Environment**			
20	06	Procedure for Infrastructure and Work Environment	ISO 13485 clauses 6.3; 6.4.1; 6.4.2 MDR article 10(9); Annex IX (Chapter I)	✓	
21	06.1	Appendix 1 – Record of Infrastructure Maintenance	ISO 13485 clause 6.3	✓	
	07	**Risk Management**			
22	07	Procedure for Risk Management	ISO 13485 clause 7.1 MDR article 10(9); Annex I (Chapter I); Annex IX (Chapter I)	✓	✓
23	07.1	Appendix 1 – Risk Management Plan	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
24	07.2	Appendix 2 – Risk Management File	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
25	07.3	Appendix 3 – Risk Assessment Record	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
26	07.4	Appendix 4 – Risk Management Review	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
27	07.5	Appendix 5 – Identification of Hazards and Characteristics Related to Safety	ISO 13485 clause 7.1 MDR Annex I (Chapter I)	✓	✓
	08	**Sales**			

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
28	08	Sales Procedure	ISO 13485 clauses 7.2.1; 7.2.2; 7.2.3 MDR article 10(9)		
29	08.1	Appendix 1 – Product Requirement Review Record	ISO 13485 clause 7.2.2	✓	
	09	**Customer Complaints and Feedback**			
30	09	Procedure for Customer Communication, Feedback and Complaints	ISO 13485 clauses 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 MDR article 10(9)	✓	
31	09.1	Appendix 1 – Customer Feedback Report	ISO 13485 clause 8.2.1	✓	
32	09.2	Appendix 2 – Registry of Customer Complaints	ISO 13485 clause 8.2.2	✓	
33	09.3	Appendix 3 – Registry of Reports to the Authorities	ISO 13485 clause 8.2.3	✓	
	10	**Design and Development**			
34	10	Procedure for Design and Development	ISO 13485 clause 7.3 MDR article 10(9); Annex I (Chapter II); Annex IX (Chapter I)	✓	
35	10.1	Appendix 1 – Design and Development File	ISO 13485 clause 7.3.10	✓(1)	
36	10.2	Appendix 2 – Project Plan and Review	ISO 13485 clauses 7.3.4; 7.3.5; 7.3.6	✓	
37	10.3	Appendix 3 – Change Review Record	ISO 13485 clause 7.3.9	✓	
38	10.4	Appendix 4 – Design Review Minutes	ISO 13485 clause 7.3.4	✓	

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
39	10.5	Appendix 5 – Design and Development Verification and Validation Plans	ISO 13485 clauses 7.3.5; 7.3.6	✓	
40	10.6	Appendix 6 – Verification Report	ISO 13485 clause 7.3.6	✓	
41	10.7	Appendix 7 – Validation Report	ISO 13485 clause 7.3.7	✓	
42	10.8	Appendix 8 – Design and Development Transfer Record	ISO 13485 clause 7.3.8	✓	
	11	**Purchasing and Evaluation of Suppliers**			
43	11	Procedure for Purchasing and Evaluation of Suppliers	ISO 13485 clauses 4.1.5; 7.4 MDR article 10(9); Annex IX (Chapter I)	✓	
44	11.1	Appendix 1 – Checklist for Evaluation of Suppliers	ISO 13485 clause 7.4.1	✓ (1)	
45	11.2	Appendix 2 – List of Approved Suppliers	ISO 13485 clause 7.4.1		
46	11.3	Appendix 3 – Registry of Complaints about Suppliers	ISO 13485 clause 7.4.1		
47	11.4	Appendix 4 – Request and Order for Purchasing	ISO 13485 clause 7.4.2	✓ (1)	
48	11.5	Appendix 5 – Purchasing Verification Record	ISO 13485 clause 7.4.3	✓	
49	11.6	Appendix 6 – Quality Agreement for Critical Supplier	ISO 13485 clause 7.4.2	✓	
50	11.7	Appendix 7 – Quality Agreement for Subcontractor	ISO 13485 clause 4.1.5	✓	
	12	**Production and Service Provision**			

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
51	12	Procedure for Production and Service Provision	ISO 13485 clauses 7.1; 7.5 MDR article 10(9); Annex I (Chapter II); Annex IX (Chapter I)	✓ (1)	
52	12.1	Appendix 1 – Product Specification	ISO 13485 clauses 7.1a); 7.2.2; 7.5.2	✓ (1)	
53	12.2	Appendix 2 – Record of Product/Service Conformance	ISO 13485 clauses 7.1d); 7.2.2	✓	
54	12.3	Appendix 3 – Quality Plan	ISO 13485 clause 7.1		
55	12.4	Appendix 4 – Notification to a Customer about Changes on Property	ISO 13485 clause 7.5.10	✓ (1)	
56	12.5	Appendix 5 – Record of Production Process Validation	ISO 13485 clause 7.5.6	✓	
57	12.6	Appendix 6 – Record of Medical Device Installation	ISO 13485 clause 7.5.3	✓	
58	12.7	Appendix 7 – Record of Servicing Activities	ISO 13485 clause 7.5.4	✓	
	13	**Identification and Labeling**			
59	13.1	Procedure for Identification and Traceability	ISO 13485 clauses 7.5.8; 7.5.9 MDR Annex I (Chapter III); Annex IX (Chapter I)	✓	
60	13.2	Procedure for Labeling	MDR article 10(11); Annex I (Chapter III)		

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
61	13.3	Procedure for UDI System	ISO 13485 clauses 7.5.8; 7.5.9 MDR articles 10(9); 27; 28; 29; 31; Annex I (Chapter III); Annex VI		✓
62	13.4	List of UDI-DI	MDR article 27		✓
	14	**Sterilization**			
63	14.1	Procedure for EtO Sterilization	ISO 13485 clauses 6.4.2; 7.5.2; 7.5.5; 7.5.7 MDR Annex IX (Chapter I)	✓(1)	
64	14.2	Procedure for Steam Sterilization	ISO 13485 clauses 6.4.2; 7.5.2; 7.5.5; 7.5.7 MDR Annex IX (Chapter I)	✓(1)	
65	14.3	Procedure for Dry Heat Sterilization	ISO 13485 clauses 6.4.2; 7.5.2; 7.5.5; 7.5.7 MDR Annex IX (Chapter I)	✓(1)	
66	14.4	Procedure for Ionizing Radiation Sterilization	ISO 13485 clauses 6.4.2; 7.5.2; 7.5.5; 7.5.7 MDR Annex IX (Chapter I)	✓(1)	
67	14.5	Procedure for Filtration Sterilization	ISO 13485 clauses 6.4.2; 7.5.2; 7.5.5; 7.5.7 MDR Annex IX (Chapter I)	✓(1)	

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
68	14.6	Appendix 1 – Record for Sterilization	ISO 13485 clause 7.5.5	✓ (1)	
	15	**Validation**			
69	15	Procedure for Validation	ISO 13485 clause 7.5.6 MDR Annex IX (Chapter I)	✓	✓
70	15.1	Validation Master Plan	ISO 13485 clause 7.5.6	✓	
	16	**Software Validation**			
71	16	Procedure for Documentation and Validation of Computer Software	ISO 13485 clauses 4.1.6; 7.5.6 MDR Annex IX (Chapter I)	✓ (1)	
72	16.1	Appendix 1 – Record of Software Validation	ISO 13485 clause 4.1.6	✓	
	17	**Warehousing**			
73	17	Warehousing Procedure	ISO 13485 clauses 6.4.1; 7.5.11	✓ (1)	
74	17.1	Appendix 1 – Record for Temperature and Humidity Control	ISO 13485 clause 7.5.11	✓ (2)	
75	17.2	Appendix 2 – Pest Control Record	ISO 13485 clauses 6.4.1; 7.5.11		
	18	**Nonconformities**			
76	18	Procedure for Control of Nonconforming Products	ISO 13485 clause 8.3 MDR article 10(9); Annex IX (Chapter I)	✓	
77	18.1	Appendix 1 – Nonconforming Product Record	ISO 13485 clauses 8.3.2; 8.3.4	✓	

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
78	18.2	Appendix 2 – Registry of Nonconformities	ISO 13485 clause 8.3.2	✓	
79	18.3	Appendix 3 – Registry of Recalled / Withdrawn Products	ISO 13485 clause 8.3.3	✓	
	19	**Adverse Event Investigation**			
80	19	Procedure for Vigilance and Adverse Event Investigation and Reporting	ISO 13485 clauses 8.2.3; 8.3.3 MDR articles 10(9); 87; 88; 89; Annex IX (Chapter I)	✓	✓
81	19.1	Appendix 1 – Manufacturer Incident Report	ISO 13485 clauses 8.2.3; 8.3.3 MDR article 87	✓ (4)	✓
82	19.2	Appendix 2 – Periodic Summary Report	ISO 13485 clauses 8.2.3; 8.3.3 MDR article 87	✓ (4)	✓
83	19.3	Appendix 3 – Field Safety Corrective Action	ISO 13485 clauses 8.2.3; 8.3.3 MDR article 87	✓ (4)	✓
84	19.4	Appendix 4 – Field Safety Notice Customer Reply Form	ISO 13485 clauses 8.2.3; 8.3.3 MDR article 87	✓ (4)	✓
85	19.5	Appendix 5 – Trend Report	ISO 13485 clauses 8.2.3; 8.3.3 MDR article 88	✓ (4)	✓
	20	**Equipment Maintenance**			

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
86	20	Procedure for Equipment Maintenance and Measuring Equipment	ISO 13485 clauses 6.3; 7.6 MDR Annex IX (Chapter I)	✓	
87	20.1	Appendix 1 – List of Equipment	ISO 13485 clauses 6.3; 7.6		
88	20.2	Appendix 2 – Plan for Preventive Maintenance of Equipment	ISO 13485 clause 6.3		
89	20.3	Appendix 3 – Maintenance and Calibration Record	ISO 13485 clause 7.6	✓	
	21	**Post-Market Surveillance**			
90	21	Procedure for Post-Market Surveillance System	ISO 13485 clauses 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 MDR articles 10(10); 15; 83; 84; 85; 86; Annex III; Annex IX (Chapter I); Annex XIV (Part B)		✓
91	21.1	Appendix 1 – Post-Market Surveillance Plan	ISO 13485 clauses 7.2.3; 8.2.2; 8.2.3; 8.3.3 MDR article 84; Annex III		✓
92	21.2	Appendix 2 – Post-Market Surveillance Report	ISO 13485 clauses 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 MDR article 85		✓
93	21.3	Appendix 3 – Periodic Safety Update Report	ISO 13485 clauses 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 MDR article 86		✓

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
94	21.4	Appendix 4 – Post-Market Clinical Follow-up Plan	ISO 13485 clauses 7.2.3; 8.2.1; 8.2.2; 8.2.3; 8.3.3 MDR Annex XIV (Part B)		✓
	22	**Clinical Evaluation**			
95	22	Procedure for Clinical Evaluation	ISO 13485 clause 7.3.7 MDR articles 10(9); 61; Annex IX (Chapter I); Annex XIV (Part A)		✓
96	22.1	Appendix 1 – Clinical Evaluation Plan	ISO 13485 clause 7.3.7 MDR article 61; Annex XIV (Part A)		✓
97	22.2	Appendix 2 – Clinical Evaluation Report	ISO 13485 clause 7.3.7 MDR article 61; Annex XIV (Part A)		✓
98	22.3	Appendix 3 – Literature Research and Review Protocol	MDR article 61; Annex XIV (Part A)		✓
99	22.4	Appendix 4 – Declaration of Interest	MDR article 61		✓
100	22.5	Appendix 5 – Equivalence Table	MDR article 61; Annex XIV (Part A)		✓
101	22.6	Appendix 6 – Appraisal Tool	MDR article 61		
	23	**Technical Documentation**			
102	23	Technical Documentation Procedure	ISO 13485 clause 4.2.3 MDR article 32; Annex II; Annex III		✓
103	23.1	Technical Documentation for Medical Device	MDR Annex II		✓

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
104	23.2	Summary of Safety and Clinical Performance	MDR article 32		✓ (3)
	24	**Internal Audit**			
105	24	Procedure for Internal Audit	ISO 13485 clause 8.2.4 MDR Annex IX (Chapter I)	✓	
106	24.1	Appendix 1 – Internal Audit Checklist	ISO 13485 clause 8.2.4 MDR Annex IX (Chapter I)		
107	24.2	Appendix 2 – Internal Audit Program	ISO 13485 clause 8.2.4	✓	
108	24.3	Appendix 3 – Internal Audit Report	ISO 13485 clause 8.2.4	✓	
109	24.4	Appendix 4 – Internal Audit Plan	ISO 13485 clause 8.2.4		
	25	**Corrective and Preventive Actions**			
110	25	Procedure for Corrective and Preventive Action	ISO 13485 clauses 8.5.2; 8.5.3 MDR article 10(9); Annex IX (Chapter I)	✓	
111	25.1	Appendix 1 – Corrective/Preventive Action Request	ISO 13485 clauses 8.5.2; 8.5.3	✓	
112	25.2	Appendix 2 – Registry and Status of Corrective and Preventive Actions	ISO 13485 clauses 8.5.2; 8.5.3	✓	
	26	**Data Analysis**			
113	26	Procedure for Data Analysis	ISO 13485 clause 8.4 MDR articles 10(9); 88; Annex IX (Chapter I)	✓	

No.	Doc. code	Document name	ISO 13485 clause / MDR article	Mandatory document according to ISO 13485	Mandatory document according to MDR 2017/745
114	26.1	Appendix 1 – Data Analysis Report	ISO 13485 clause 8.4	✓	
	27	**Management Review**			
115	27	Procedure for Management Review	ISO 13485 clause 5.6 MDR article 10(9); Annex IX (Chapter I)	✓	
116	27.1	Appendix 1 – Matrix of Key Performance Indicators	ISO 13485 clauses 5.6.2e); 5.6.2f)		
117	27.2	Appendix 2 – Management Review Minutes	ISO 13485 clause 5.6.1	✓	

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

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

(3) The document is mandatory only for implantable and class III medical devices.

(4) The document is mandatory for each medical device used on the EU market