EU MDR Documentation Toolkit

https://advisera.com/13485academy/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	MDR article	Mandatory document according to MDR 2017/745
	01	**Strategy for Regulatory Compliance**		
1	01	Strategy for Regulatory Compliance	Articles 8; 10(9); 15; 19; 25; Annex I; Annex IV; Annex IX; Annex X; Annex XI; Annex XIII	✓
2	01.1	Appendix 1 – General Safety and Performance Requirements (GSPR)	Article 10(9); Annex I	✓
3	01.2	Appendix 2 – GAP Analysis	Article 10(9)	
4	01.3	Appendix 3 – Statement for Custom-Made Devices	Annex XIII	✓
5	01.4	Appendix 4 – Declaration of Conformity	Article 19; Annex IV	✓
6	01.5	Appendix 5 – List of Economic Operators and Authorities	Articles 10(9); 25	✓
	02	**Identification and Labeling**		
7	02.1	Procedure for Identification and Traceability	Annex I (Chapter III); Annex IX (Chapter I)	
8	02.2	Procedure for Labeling	Article 10(11); Annex I (Chapter III)	
9	02.3	Procedure for UDI System	Articles 10(9); 27; 28; 29; 31; Annex I (Chapter III); Annex VI	✓
10	02.4	List of UDI-DI	Article 27	✓
	03	**Adverse Event Investigation**		
11	03	Procedure for Vigilance and Adverse Event Investigation and Reporting	Articles 10(9); 87; 88; 89; Annex IX (Chapter I)	✓

No.	Doc. code	Document name	MDR article	Mandatory document according to MDR 2017/745
12	03.1	Appendix 1 – Manufacturer Incident Report	Article 87	✓
13	03.2	Appendix 2 – Periodic Summary Report	Article 87	✓
14	03.3	Appendix 3 – Field Safety Corrective Action	Article 87	✓
15	03.4	Appendix 4 – Field Safety Notice Customer Reply Form	Article 87	✓
16	03.5	Appendix 5 – Trend Report	Article 88	✓
	04	**Post-Market Surveillance**		
17	04	Procedure for Post-Market Surveillance System	Articles 10(10); 15; 83; 84; 85; 86; Annex III; Annex IX (Chapter I); Annex XIV (Part B)	✓
18	04.1	Appendix 1 – Post-Market Surveillance Plan	Article 84; Annex III	✓
19	04.2	Appendix 2 – Post-Market Surveillance Report	Article 85	✓
20	04.3	Appendix 3 – Periodic Safety Update Report	Article 86	✓
21	04.4	Appendix 4 – Post-Market Clinical Follow-up Plan	Annex XIV (Part B)	✓
	05	**Clinical Evaluation**		
22	05	Procedure for Clinical Evaluation	Articles 10(9); 61; Annex IX (Chapter I); Annex XIV (Part A)	✓
23	05.1	Appendix 1 – Clinical Evaluation Plan	Article 61; Annex XIV (Part A)	✓
24	05.2	Appendix 2 – Clinical Evaluation Report	Article 61; Annex XIV (Part A)	✓

No.	Doc. code	Document name	MDR article	Mandatory document according to MDR 2017/745
25	05.3	Appendix 3 – Literature Research and Review Protocol	Article 61; Annex XIV (Part A)	✓
26	05.4	Appendix 4 – Declaration of Interest	Article 61	✓
27	05.5	Appendix 5 – Equivalence Table	Article 61; Annex XIV (Part A)	✓
28	05.6	Appendix 6 – Appraisal Tool	Article 61	
	06	**Technical Documentation**		
29	06	Technical Documentation Procedure	Article 32; Annex II; Annex III	✓
30	06.1	Technical Documentation for Medical Device	Annex II	✓
31	06.3	Summary of Safety and Clinical Performance	Article 32	✓*

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