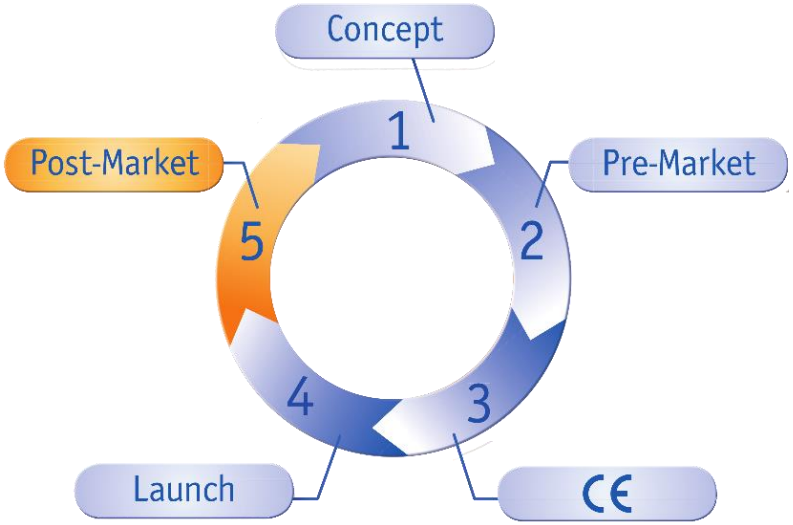
MDR: Required documents, corresponding standards & guidelines

Clinical Product Lifecycle – Required Documents and Records

Since now the medical device coordination group (MDCG) has published some new guidelines on how to implement the MDR (EU) 2017/745 more specifically pertaining to clinical investigation and clinical evaluation. And it is already an established fact that the documents and records required by the MDR is much more extensive than the previous directives governing the CE marking of medical devices. Furthermore, it is also very clear that depending upon the product's risk classification the complexity of the documentation may vary as well. Considering these circumstances, we compiled a more general checklist providing and overview of the mandatory documents that the manufacturers should create, up-date and archive for MDR compliance of the clinical product lifecycle and ongoing CE conformity of their products.



Further MDCG guidelines will be published, however, as long as these documents are not available it is worth to check the applicability of the guidelines from the international medical device regulators forum (IMDRF).

Manufacturer of high-risk devices should also take into account that the corresponding documents of these high-risk devices will go through much vigorous analysis for the CE conformity under MDR.

The following table gives an overview of the required documents and records that are essential as per MDR along with the corresponding guidelines clarifying the regulation for its effective and precise implementation of the clinical product lifecycle.

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Category	*Required Documents and Records*	*EU MDR Reference*	*Standards and Guidance documents reference*
Clinical evaluation	Clinical Evaluation Plan (CEP) [1]	Annex XIV, Part A, Requirement 1 (a)	MDCG 2020-5 MDCG 2020-6 MEDDEV 2.7/1 rev. 4 IMDRF MDCE WG/N56 IMDRF MDCE WG/N55
	Clinical Evaluation Report (CER)	Chapter VI, Article 61, Para 12 Annex XIV, Sec. 4, Para 4	
Clinical investigation	Informed consent	Article 63	EN ISO 14155 MEDDEV 2.7/4 IMDRF MDCE WG/N57
	Application form	Annex XV, Chapter II, Para 1	
	Investigator Brochure (IB)	Annex XV, Chapter II, Para 2	
	Clinical Investigation Plan (CIP)	Article 72 Annex XV, Chapter II, Para 3	
	Safety & performance statement	Annex XV, Chapter II, Para 4	

[1] Incl. Clinical Development Plan (CDP)

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Clinical investigation	Proof of insurance	Annex XV, Chapter II, Para 4	
	Arrangements description	Annex XV, Chapter II, Para 4	
	Clinical investigation report	Annex XV, Chapter III, Para 7	
Vigilance	Field safety corrective action's (FSCA)	Article 87	MDCG 2020-10/1 MDCG 2020-10/2 MEDDEV 2.7/3 rev. 3 SAE reporting form MEDDEV 2.12/1 rev. 8 Additional guidance on MEDDEV 2.12/1 rev. 8
	Adverse Event Report (AE-Report)	Article 87	IMDRF/AE WG/N43 (Edition 4) IMDRF/AE WG(PDl)/N43 (Edition 3)
Post-Market Surveillance	Post-Market Surveillance Plan (PMS-Plan)	Article 84, Annex III	
	Post-Market Surveillance Report (PMS-Report)	Article 85	IMDRF/NCAR WG/N14 (Edition 2) IMDRF/NCAR WG/N14

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Post-Market Surveillance	Periodic Safety Update Report (PSUR)	Article 86	
	Post-Market Clinical Follow-up Plan (PMCF-Plan)	Annex XIV, Part B, Para 6	MDCG 2020-7
	Post-Market Clinical Follow-up Evaluation Report (PMCF-Report)	Article 85	MDCG 2020-8 IMDRF/NCAR WG/N14 (Edition 2) IMDRF/NCAR WG/N14
	Summary of safety and clinical performance (SSCP)	Article 32, Para 1	MDCG 2020-9
General requirements	General Safety and Performance Requirements (GSPR)	Annex I	
	Risk management documentation	Annex I, Chapter I, Requirement 3	EN ISO 14971
	Device description and specification	Annex II, Para 1	MEDDEV 2.7/1 rev. 4
	Claim substantiation (Claim Sheets)	Annex I, Chapter III, Sec. 23.4(p)	MDCG 2020-6

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General requirements	Labels and instruction for use	Annex II, Para 2	IMDRF/GRRP WG/N52
	Results of different pre/clinical testing	Annex II, Para 6	

Do you find it helpful?

Your Professional CRO-Team for Medical Devices, with the expertise in regulatory & medical affairs, scientific writing and quality management provides you this checklist. CERES assists or can assist you in handling the requirements and documents. We are open to clarify your needs in the entire Clinical Product Lifecycle of your devices, including but not limited to the clinical evaluation plan & report, equivalence criteria and sufficiency of clinical evidence, clinical investigations, post market surveillance and clinical follow up.

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