13485 Academy
ISO 13485 Online Consultation Center

EU MDR Checklist of Mandatory Documents

Advisera
Making certification simple.

Table of Contents

Introduction

If you are going to sell or distribute medical devices in the European Union, then implementing a Quality Management System (QMS) will not be enough to meet the legal requirements. Even if you use ISO 13485:2016, the internationally recognized management system requirements for a QMS in the medical device industry, you will still need to meet the requirements of the European Union Medical Device Regulation (EU MDR) released in May 2017.

Without knowing exactly what is needed by this new EU regulation, it is easy to find yourself unnecessarily documenting too much in the belief that this will improve your QMS, or your medical device management, or you may even think that it is a requirement of the EU MDR regulation. It is true that the EU MDR has some necessary documentation to be able to distribute medical devices in the European Union, so it is helpful to know exactly what the regulation requires before you start.

Below is a listing of each of these mandatory pieces of information, and where it is identified in the EU MDR standard.

What are the required EU MDR documents and records?

Category	Mandatory Documents and Records	EU MDR Articles, Chapters, and Annexes
General requirements	EU Declaration of conformity	Article 10, Paragraph 8
	Quality management system	Article 10, Paragraph 9
	List of all UDI-DI	Article 27, Paragraph 7
	Summary of safety and clinical performance	Article 32, Paragraph 1
Risk management	Risk Management Plan	Annex I, Chapter I, Requirement 3
	Risk Management File	Annex I, Chapter I, Requirement 3
	Risk Management Report	Annex I, Chapter I, Requirement 3
Clinical evaluation	Clinical Evaluation Plan	Annex XIV, Part A, Requirement 1 (a)
	Clinical Evaluation Report	Chapter VI, Article 61, Paragraph 12 Annex XIV, Section 4, Paragraph 4
Clinical investigation	Informed consent	Article 63
	Application form	Annex XV, Chapter II, Paragraph 1
	Investigator brochure	Annex XV, Chapter II, Paragraph 2,
	Clinical investigation plan	Article 72 Annex XV, Chapter II, Paragraph 3
	Safety & performance statement	Annex XV, Chapter II, Paragraph 4
	Proof of insurance	Annex XV, Chapter II, Paragraph 4
	Arrangements description	Annex XV, Chapter II, Paragraph 4
	Clinical investigation report	Annex XV, Chapter III, Paragraph 7

Category	Mandatory Documents and Records	EU MDR Articles, Chapters, and Annexes
Post-Market Surveillance	Post-Market Surveillance Plan	Article 84, Annex III
	Post-Market Surveillance Report	Article 85
	Periodic Safety Update Report	Article 86
	Post-Market Clinical Follow-up Plan	Annex XIV, Part B, Paragraph 6
Vigilance	Field safety corrective actions	Article 87
	Adverse Event Report	Article 87
Technical file documentation	Device description and specification	Annex II, Paragraph 1
	Labels and Instruction of Use	Annex II, Paragraph 2
	Design information	Annex II, Paragraph 3
	Manufacturing process and validations	Annex II, Paragraph 3
	Site identification	Annex II, Paragraph 3
	Results of different pre/clinical testing	Annex II, Paragraph 6

While these are the documents and records that the EU MDR has identified as mandatory, it is important to note that this does not include any documented information necessary for the proper function of your Quality Management System. For the listing of information required for an ISO 13485:2016-compliant QMS, see this white paper: Checklist of Mandatory Documentation Required by ISO 13485:2016.

What is the best structure for EU MDR mandatory documents and records?

The documentation required by the EU MDR regulation needs to be in place before you apply for a CE mark certification. While there is no perfect solution on how the documentation needs to look, below are some important elements that you should understand and consider including within your documents required by the EU MDR.

For more information on how ISO 13485 relates to the CE marking, see: How to use ISO 13485 to get your devices approved for CE marking.

General Requirements

EU Declaration of Conformity

This is a formal document that officially certifies that your product fulfils the essential requirements needed to meet the applicable CE directives. This allows you to obtain a CE mark for your medical device.

Quality Management System

EU MDR article 10 states what needs to be included, at a minimum, in a Quality Management System (QMS) for medical device manufacturers. At the very least, the QMS needs to address aspects in the list below:

- A strategy for complying with regulations,
- Safety and performance,
- Management responsibility,
- Resource management,
- Risk management,
- Clinical evaluation,
- Product realization (planning, design, development, production and service),
- Verification of unique device identity assignment,
- Post-market surveillance system,
- Communication with authorities,
- Incident reporting,

- Corrective and preventive actions (with verification of effectiveness),
- Monitoring and measurement, data analysis, and product improvement.

The easiest way to ensure a good QMS that meets all of these requirements is to use the ISO 13485:2016 standard, which is an internationally recognized set of requirements for a medical device manufacturer's QMS. It is also the only Quality Management System standard mentioned on the EU harmonized list, a collection of all the standards that are applicable for the medical device industry published by the EU.

For more information on using ISO 13485 to meet the QMS requirements of the EU MDR, see the article: How can ISO 13485 help with MDR compliance?

List of all UDI-DI

The EU MDR regulation includes a Unique Device Identification (UDI) system for medical devices. The manufacturer must send to the UDI database a list of all UDI-DI (Unique Device Identification - Device Identifier) applicable for the medical devices they manufacture.

Summary of safety and clinical performance

The summary of safety and clinical performance is mandatory for implantable devices and for class III devices. The manufacturer must write the summary to be easily understandable for the patient and submit the summary to the Notified Body.

The summary of safety and clinical performance must include at least the following:

- Identification of the device and the manufacturer, including the UDI,
- Intended purpose of the device, target population, indications and contraindications, if any,
- Description of the device or device family, an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist,
- Description of any accessories, if applicable,
- Information about the usage of the medical device in alternative diagnostic and therapeutic use, if applicable,
- Reference to applicable harmonized and other standards,
- Summary of clinical evaluation report,
- Summary of post-market clinical follow-up, if any,
- Suggested users and training needed for medical device usage,
- Summary of residual risks, undesirable effects, warnings and precautions, if any.

Risk Management

As a critical consideration of the EU MDR, risk management needs to be done for each medical device and appropriately documented to demonstrate your abilities to assess and control the risks that are posed by your medical device throughout the life cycle of the product. As risk is the effect of uncertainty, you must consider what uncertainty exists that can lead to potential failures so that you can identify the controls that are needed to mitigate these potential effects.

The purpose of providing the risk process is to describe the process of identification, evaluation, and addressing of the risks that arise from design and production processes for your medical devices. The intent of the risk assessment process is to verify that the right materials are being used, to conform to customer specifications, and to ensure that government regulations are being met, before finalizing the product design. The overall goal is to identify any potential failures that could be caused by the manufacturing processes, assembly processes, machines, fixtures, and production methods.

The general process for risk assessment includes the following:

- Identify foreseeable hazards associated with the device,
- Estimate and evaluate the risks,
- Eliminate or control the risks,
- Estimate the residual risk,
- Define the benefit/risk ratio.

One common method of risk assessment is the failure modes and effects analysis (FMEA), which provides a systematic way to identify and assess the potential failure. It is important that you choose a systematic method, as this is the best way to ensure that nothing is missed during the risk assessment process.

Risk Management Plan

The Risk Management Plan needs to include all of the information required to assess the risk of a particular medical device. For the best effect, the plan needs to include the following information:

- Identification of the medical device,
- Description of the medical device,
- Lifecycle stages,
- Risk assessment methodology,
- Risk acceptance criteria,
- Methods used to evaluate residual risk,
- Verification activities, and
- Methods for post-production information collection.

You want to ensure that the Risk Management Plan includes all details necessary that are unique to the medical device in question. This allows your assessment to consider the risks that are present from the raw material used through to the disposal of the medical device at the end of life, and it verifies that you fully understand the potential impacts that the risks pose.

Risk Management File

The Risk Management File details all of your risk management activity for each of the medical devices you produce. This file references back to your Risk Management Plan, and needs to include:

- The results of risk assessment, including risk acceptance,
- The controls you have put in place for the risks,
- The risk/benefit analysis of any remaining risks.

When compiling your Risk Management File, ensure that you have considered the intended use of your medical device as well as the safety characteristics you have put in place.

Risk Management Report

The Risk Management Report compiles and summarizes the data obtained in the process of risk management for formal review. All relevant functions in the organization must review to ensure that the Risk Management Plan is properly implemented, that the overall residual risk is acceptable, and that appropriate methods are in place for reviewed production and post-production data. Relevant senior management needs to know and understand the risk management activities of the medical devices being produced by the company.

For more information on risk management of medical devices, see: How to use ISO 14971 to manage risks for medical devices.

Clinical Evaluation

How do you know that your medical device will function as planned? This is the purpose of clinical evaluation. The purpose of clinical evaluation is to provide a system to demonstrate medical device safety and effectiveness.

Clinical Evaluation Plan

The Clinical Evaluation Plan must include information concerning the safety or performance of the medical device that is generated from actual use of the device. The plan needs to include performance information from at least the following sources:

- Clinical investigation(s) of the actual device,
- Reports of equivalent devices reported in scientific literature,
- Reports published in peer reviewed scientific literature, and
- Relevant information from post-market surveillance.

Clinical evaluation must be planned once per year for implantable medical devices and class III medical devices, and every two years for other medical devices.

Clinical Evaluation Report

After conducting the literature research, the Clinical Evaluation Report is created. The Clinical Evaluation Report must outline:

- Description and technology of the medical device,
- Intended use of the device,
- Claims made about the device's clinical performance or safety,
- Nature and extent of the clinical data,
- How the referenced information demonstrates the clinical performance and safety of the device,
- Conclusion that the device(s) performs as intended,
- Conclusion that the device(s) does not pose any undue safety concerns, and
- Justification that any residual risks are acceptable when weighed against the benefits.

Clinical Investigation

Clinical investigation is a systematic evaluation or study using human subjects to determine the safety and performance of a medical device. Clinical investigation must be performed for all medical devices for which it is not possible to prove intended use by literature research and equivalence with other similar devices.

Usually, clinical investigation is performed for the following devices:

- All class III medical devices,

- Completely new medical devices from classes I and II, that have not existed so far on the market and for which there is not any evidence of clinical use, safety, or performance.

Since the conduct of clinical research is very complex, it is most often performed by companies specializing in clinical investigation, and manufacturers of the medical devices usually hire such companies for this research. Upon completion of the research, companies specialized in clinical investigation will provide all the needed documents to the manufacturer.

This is a critical step in the EU MDR, before a device is allowed to be distributed, which contains several required documents.

Informed consent

Each participant in a clinical investigation must agree to be part of that clinical investigation. This document must be written, dated, and signed by the participant, and kept as a record of the consent.

Application form

Before starting the clinical investigation, an application form must be written and submitted. The form includes a short description of the device, details of the investigation, responsibilities within the investigation, and other important elements about the clinical investigation.

Investigator brochure

The investigator's brochure (IB) must contain all of the relevant clinical and non-clinical information on the medical device being investigated that is available at the time of application. Any updates to the IB or other relevant information that are newly available need to be brought to the attention of the investigators in a timely manner.

Clinical investigation plan

The clinical investigation plan (CIP) is designed to set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping, and the method of analysis for the clinical investigation. In particular, it must contain the information as laid down in the EU MDR, or include reference to other documentation if part of the information is submitted in a separate document.

Safety & performance statement

A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements.

Proof of insurance

Proof of insurance coverage or indemnification of subjects in case of injury, pursuant to Article 69 and the corresponding national law.

Arrangements description

Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data.

Clinical investigation report

The clinical investigation report, signed by the investigator, is intended to contain a critical evaluation of all the data collected during the clinical investigation, and shall include any negative findings.

Post-Market Surveillance

Post-market surveillance needs to be done for all medical devices that you produce and distribute into the European Union. Your post-market surveillance system allows your organization to know at all times what happens to medical devices once they go out of production and are distributed.

Post-Market Surveillance Plan

Your plan for post-market surveillance needs to be inclusive of all information available about your medical devices as they are in use. This data may include:

- Serious field safety incidents,
- Trend reporting,
- Non-serious incidents,
- Customer complaints and feedback, and
- Scientific or technical literature.

When creating your plan, consider all the places that you can gather information and data about your medical device that will help you to track what is happening to identify and address any potential field usage problems early.

Post-Market Surveillance Report

The Post-Market Surveillance Report is used to provide a record of your assessment of the post-market information gathered about your medical devices. A Post-Market Surveillance Report must be created for all class I medical devices. The critical information to be contained in your report includes:

- A summary of the post-marketing surveillance data,
- Conclusions of your assessment of each type of data,

- Corrective actions taken to address issues identified.

There is no reason to collect data unless you are going to periodically review that information and gather corrections and improvements for the medical devices you produce. Any new risks, changes to risks, or changes to the frequency of occurrences must be noted and new documents for the clinical evaluation report, risk analysis, or both must be prepared.

Periodic Safety Update Report

For class IIa, class IIb, and class III devices, you need to prepare a Periodic Safety Update Report for each device or, where relevant, for each category or group of devices. This report must summarize the results and conclusions of the analyses of the post-market surveillance data from the Post-Market Surveillance Plan. In addition to the elements listed for the Post-Market Surveillance Report, the Periodic Safety Update Report also requires the following:

- Conclusions from the risk-benefit consideration,
- Estimation of population size using the device, and
- Usage frequency in the case of reusable devices.

The frequency of preparing the PSUR is every two years for class IIa, and once a year for class IIb and class III.

Post-Market Clinical Follow-up

Maintaining your post-market surveillance aims to continuously verify the clinical benefits of medical devices and to identify previously unknown risks by observing and analyzing daily practical usage. However, if your procedure for post-market surveillance does not provide sufficient data, post-market clinical follow-up studies regarding the manufacturer may become necessary. When you decide it is necessary to initiate post-market clinical follow-up, you must prepare a Post-Market Clinical Follow-up Plan. This plan needs to include:

- The design for your study,
- Sites to investigate,
- Population of the study, number of subjects, and duration,
- Criteria for patient inclusion,
- Objectives of the study,
- Details on data to be collected,
- Criteria to terminate the study early, and
- Data analysis methods.

Your post-market clinical follow-up must become a part of your QMS management review.

Vigilance

Reporting of serious incidents and field safety corrective actions is a necessity of the EU MDR. The form for field safety corrective actions and the Adverse Event Report are usually prescribed by the national agencies for drugs.

Field safety corrective actions

A field safety corrective action is a corrective action taken by a manufacturer, with the purpose being to prevent or reduce the risk of a serious incident. A serious incident is considered any of the following:

- Any incident that led to temporary or permanent serious deterioration of the patient's health,
- Any incident that directly or indirectly led to the death of a patient,
- Any incident that may cause a serious threat to the public health,
- Any incident that caused a serious accident or injury to a user of the medical device or to any other person who has been in contact with the medical device.

Adverse Event Report

An adverse event is any unexpected medical occurrence, unintended disease or injury, or any unexpected clinical signs, in subjects, users, or other persons. A serious adverse event means any adverse event that led to:

- Death,
- Serious deterioration of the subject's health,
- Life-threatening disease or injury,
- Permanent disability of the patient,
- Hospitalization or prolongation of hospital stay,
- Medical or surgical intervention to prevent life-threatening illness or injury,
- Permanent damage to the subject's body or body function,
- Chronic diseases,
- Fetal death, fetal distress, or any other birth defect.

Technical File Documentation

Technical files need to be created in order to ensure compliance of the medical device(s) with the MDR. Technical documentation for a medical device consists of a completed technical file summary and applicable annexed reports (e.g., sterilization validation reports, biocompatibility report, packaging validation report, etc.). If certain sections from the Technical File are applicable for the medical device, but will not be included in the Technical File, justification must be provided.

The Technical File documentation includes:

- Device description and specification – this needs to include all variants and accessories applicable to the medical device.
- Labels and Instruction of Use – the labeling that will be on the device, and the instructions to use your medical device, must be included.
- Design information – the detailed design of the medical device needs to be included for appropriate review and approval.
- Manufacturing process and validations – the EU must know the processes you will use, and the proof that these processes are validated to ensure consistently safe and functioning medical devices.
- Site identification – identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.
- Results of different pre/clinical testing.

Technical files must be updated under the following situations (at a minimum):

- Change in supplier of raw material,
- Change in dimensions or other characteristics of the medical device,
- Change in address of the manufacturer,
- Change in relevant standards,
- Update in certificates or accreditation of suppliers and/or testing laboratories, and
- When new risks for safety of the medical device occur during post-market surveillance.

For more information on the related medical device files requirements of ISO 13485, see: How to meet ISO 13485:2016 requirements for medical device files.

Sample Documentation Templates for ISO 13485 & MDR

Here, you can download a free preview of the ISO 13485 & MDR Integrated Documentation Toolkit - in this free preview, you will be able to see the Table of Contents of each of the above-mentioned documents, as well as a few sections from each document.

13485 Academy
ISO 13485 Online Consultation Center

Advisera Expert Solutions Ltd
for electronic business and business consulting
Zavizanska 12, 10000 Zagreb
Croatia, European Union

Email: support@advisera.com
U.S. (international): +1 (646) 759 9933
United Kingdom (international): +44 1502 449001
Toll-Free (U.S. and Canada): 1-888-553-2256
Toll-Free (United Kingdom): 0800 808 5485
Australia: +61 3 4000 0020

EXPLORE **ADVISERA**

EUGDPR Academy · 27001 Academy · 9001 Academy · 14001 Academy · 45001 Academy · 13485 Academy · 9100 Academy

16949 Academy · 17025 Academy · 20000 Academy · Conformio · eTraining · AdviseraBooks

Advisera
Making certification simple.