

MEDQDOC IVDR TECHNICAL DOCUMENT TEMPLATES

**Supporting your medical device compliance
to the In Vitro Diagnostic Medical Device
Regulation (EU) IVDR 2017/746**

medqdoc.com

medqdoc

A QUALITY MANAGEMENT SYSTEM (eQMS) DESIGNED FOR THE MEDICAL DEVICE INDUSTRY

Connecting quality and
regulatory compliance with a
human touch

COMPLY EASILY
WITH



ISO
13485



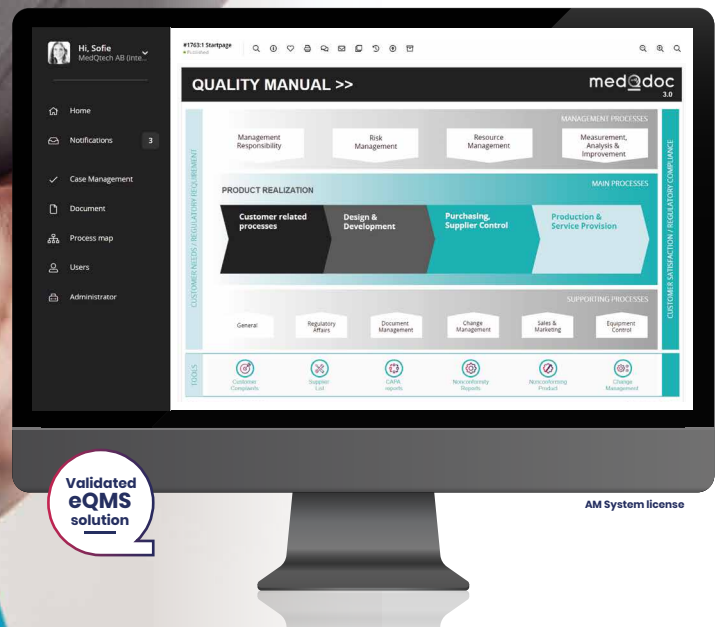
ISO
14971



MDR
2017/745



IVDR
2017/746



MedQdoc offers a range of templates to support the technical documentation for your medical device and help your organisation meet regulatory requirements.

In this document, you will find a list of MedQdoc's templates for IVDR technical documentation, that can be used to ensure your medical device complies with In Vitro Diagnostic Medical Device Regulation (EU) IVDR 2017/746.

Table of contents

1.	Introduction	4
2.	General	4
2.1	Device description and specification	4
3.	Information to be supplied by the manufacturer	5
3.1	Design and manufacturing information	5
3.2	General safety and performance requirements	5
3.3	Benefit-risk analysis and risk management	6
3.4	Product verification and validation	6
3.5	EU declaration of conformity (MDR, Annex IV)	6
3.6	Post market surveillance (MDR, Annex III)	6

1. Introduction

MedQdoc provides 28 templates to support you in putting together the correct technical documentation for your medical device, to meet regulatory requirements.

The MedQdoc configuration is built around the requirements of IVDR Annex II, and includes a predefined structure for you to record your technical documentation. The structure of this technical documentation is shown below.

0. General	0 Document(s)
1. Device Description and Specification	0 Document(s)
2. Information to be supplied by the manufacturer	0 Document(s)
3. Design and manufacturing information	0 Document(s)
4. General safety and performance requirements	0 Document(s)
5. Benefit-risk analysis and risk management	0 Document(s)
6. Product verification and validation	0 Document(s)
7. DoC, EC Certificate etc	0 Document(s)
8. Post Market Surveillance (Annex III)	0 Document(s)

2. General

This initial section provides the overview documents for your technical documentation.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Regulatory Strategy (IVDR)
Template	Summary Technical Documentation (IVDR, Annex II)

2.1 Device description and specification

This section of the technical documentation should include a brief description of the device. The description needs to allow for a basic understanding of the design, characteristics and performance of the device.

The following supporting templates are available in MedQdoc:

Type	Title
Template	General Product Description (IVDR)
Template	Qualification & Classification (IVDR, Annex VIII)
Template	Qualification of MD as Software (IVDR)

3. Information to be supplied by the manufacturer

This part of the product's technical documentation requires a complete set of the labelling associated with the device, including the following:

- + The label(s) on the device and on its packaging (eg. single unit packaging, sales packaging, transport packaging in case of specific management conditions).
- + The instructions for use.
- + Any promotional material.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Example of IFU
Template	Example of Label Specification

3.1 Design and manufacturing information

This section requires details of the product's design and manufacturing information including the following:

- + Information to allow the design stages applied to the device to be understood.
- + Complete information and specifications, including details of the manufacturing processes and their validation, their adjuvants, the continuous monitoring process and the final product testing. Full data should be included in the technical documentation.
- + Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Design Review
Template	Design & Development Plan
Template	Design Input & Output Matrix
Template	Design Transfer Plan/Report
Template	Production Quality Plan
Template	Verification of Purchased Material/Product

3.2 General safety and performance requirements

This section relates to the documentation that demonstrates that the product conforms with the general safety and performance requirements set out in Annex I.

The following supporting templates are available in MedQdoc:

Type	Title
Template	General Safety and Performance Requirement Checklist IVDR, Annex I

3.3 Benefit-risk analysis and risk management

This part of the technical documentation covers risk management and should contain information on the following.

- + The benefit-risk analysis referred to in Sections 1 and 8 of Annex I.
- + The solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Risk Management Plan
Template	Risk Management Report
Template	Risk Analysis
Template	Risk Analysis with Attachment
Template	Checklist – ISO/TR 24971:2020, Annex A

3.4 Product verification and validation

This section relates to the results and critical analyses of all verification and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this regulation. In particular, the documentation should cover the applicable general safety and performance requirements.

Note: The content of these documents varies significantly depending on your specific device and applied standards.

Type	Title
Template	General Design & Development Verification Plan
Template	General Design & Development Verification Report
Template	General Design & Development Validation Plan
Template	General Design & Development Validation Report

3.5 EU declaration of conformity (IVDR, Annex IV)

This part of the product technical documents refers to the EU declaration of conformity. The EU declaration of conformity shall state that the requirements specified in MDR have been fulfilled in relation to the device that is covered.

In MedQdoc the following supporting templates are available:

Type	Title
Template	EU Declaration of Conformity

3.6 Post market surveillance (IVDR, Annex III)

This section refers to the technical documentation on post-market surveillance, that should be drawn up by the manufacturer in accordance with Articles 83 to 86.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Post Market Surveillance Plan
Template	Post Market Surveillance Checklist (Article 78)
Template	Post Market Surveillance Report

ACCELERATE YOUR MEDICAL DEVICE COMPLIANCE WHILE ENHANCING YOUR QUALITY MANAGEMENT SYSTEM

MedQdoc provides medical device companies with a ready-to-use streamlined quality management software solution that can quickly and effectively guide you through the quality journey, enabling medical device regulatory compliance.

Over 130
Ready-to-use
templates
including technical
documentation

01.

02.

03.

medqdoc
medqdoc.com/demonstration

West Coast office:

T: +46(0) 70 58 60 200
E: info@medqdoc.com

MedQdoc, Rörviksvägen 40A
457 95 Grebbestad, Sweden

East Coast office:

MedQdoc,
Kontorett
Köpmangatan 1
852 31 Sundsvall, Sweden

To arrange a
consultative
approached video
meeting, or if you
have questions
about eQMS,
please reach out.

