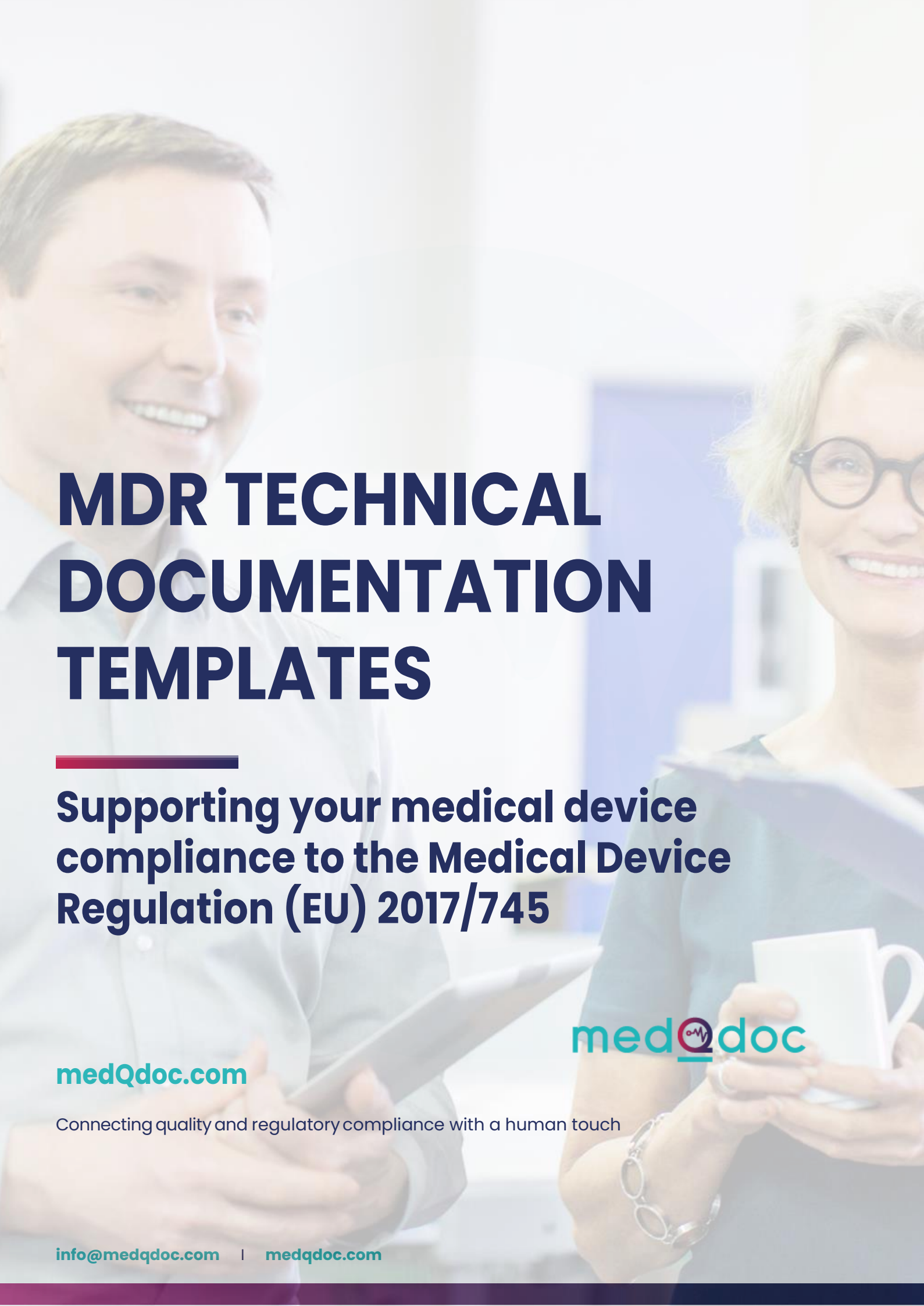

MDR TECHNICAL DOCUMENTATION TEMPLATES

Supporting your medical device compliance to the Medical Device Regulation (EU) 2017/745

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In this document, you will find a list of MedQdoc's templates for MDR technical documentation, that can be used to ensure your medical device complies with the Medical Device Regulation (EU) 2017/745.

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1 Introduction

MedQdoc provides 42 templates to support you in compiling the correct technical documentation for your medical device, to meet regulatory requirements.

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

1.1 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 (MDR)
Template	MDR Code Assessment
Template	Summary Technical Documentation (MDR, Annex II)
Template	Technical documentation Checklist
Template	Appointment letter - Person responsible for regulatory compliance

1.1 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 (MDR)
Template	Qualification & Classification (MDR, Annex VIII)
Template	Qualification of MD as Software (MDR)

1.2 Information to be supplier 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

1.3 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	Product Concept Report
Template	Design Review
Template	Design & Development Plan
Template	Software Development Plan
Template	Design Input & Output Matrix
Template	Usability Interface Specification
Template	Design Transfer Plan/Report
Template	Production Quality Plan
Template	Verification of Purchased Material/Product

1.4 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 (MDR, Annex I)

1.5 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

1.6 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	Design & Development Verification Plan
Template	Design & Development Verification Report
Template	Design & Development Validation Plan
Template	Design & Development Validation Report
Template	Formative/Summative Test Protocol
Template	Formative/Summative Evaluation Test Report
Template	Usability Interface Evaluation Plan
Template	Usability Engineering Report
Template	Clinical Evaluation Plan (CEP)
Template	Clinical Evaluation Report (CER)
Template	Checklist – Information required on the label and IFU

1.7 EU declaration of conformity (MDR, Annex IV)

This part of the technical documentation relates to the EU declaration of conformity. The declaration should state that the requirements specified in MDR have been fulfilled in relation to the device that is covered.

The following supporting templates are available in MedQdoc:

Type	Title
Template	Declaration of Conformity
Template	Post Market Clinical Follow-up plan
Template	Periodic safety update report

1.8 Post market surveillance (MDR, 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 Checklist
Template	Post Market Surveillance Plan
Template	Post Market Surveillance Report
Template	Post Market Clinical Follow-up plan
Template	Periodic Safety Update Report

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