[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

TECHNICAL DOCUMENTATION PROCEDURE

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to explain how to handle technical documentation in order to ensure compliance of the medical device(s) with the MDR.

This document applies to all medical device technical documentation that [organization name] has, independent of the class of medical device.

Users of this document are [members of top and mid-level management] of [organization name].

Commented [AES4]: Include the name of your organization.

Commented [AES5]: E.g., CEO, Management Representative, department managers

Commented [AES6]: Include the name of your organization.

2. Reference documents

- ISO 13485 standard, clause 4.2.3
- MDR 2017/745 article 32, Annex II and Annex III
- [any other regulation/standard that is applicable for your medical device]
- List of UDI-DI

Commented [AES7]: You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES8]: E.g., related ISO standards, MEDDEV guidelines, MDCG (Medical Device Coordination group) guidelines https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "13_Identification_and_Labeling".

3. Preparing technical documentation for medical devices

3.1. General responsibilities

[Job title] appoints person or persons responsible for preparing and maintaining the technical documentation. One person can be responsible to prepare technical documentation for one or more medical devices (medical device groups).

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Technical documentation can be prepared for one medical device or for a medical device group. Medical device groups contain devices that have the same intended use, belong to the same class, and share the same design file. Variations between devices in one medical device group can be of color, dimensions, length, and similar.

[redacted]

[redacted]

Commented [AES11]: You can find more information about UDI - DI's on the following link

3.2. Technical documentation structure

Technical documentation for a medical device consists of a completed Technical Documentation template and different annexed reports (e.g., sterilization validation reports, biocompatibility report, packaging validation report, etc.).

Depending on the type of medical device, the person responsible for the technical documentation must decide which sections of the Technical Documentation template are not applicable for the particular medical device and can delete those sections.

[illegible]

3.3. Filling out the Technical Documentation template

The person responsible for the technical documentation completes all necessary sections of the Technical Documentation template. The person responsible for the technical documentation completes the Technical Documentation template by:

- Writing the entire description/information required in the Technical Documentation template
- [illegible]

The person responsible for the technical documentation is responsible to send samples of the medical device to all relevant laboratories and gather the reports and complete the appropriate sections in the Technical Documentation template. [illegible]

The person responsible for the technical documentation must use the Internal Audit Checklist for Technical Documentation according to MDR in order to verify that the following are valid and completed correctly:

- General safety and performance requirements
- [illegible]
- [illegible]

3.4. Summary of safety and clinical performance

For implantable and class III medical devices, the person responsible for the technical documentation must prepare, besides the regular Technical Documentation file, the Summary of Safety and Clinical Performance. [illegible]

3.5. Technical documentation maintenance

The person responsible for the technical documentation must update the Technical Documentation file at least in the following situations:

Commented [AES12]: E.g., If the medical device produced does not need any kind of sterilization, that section can be deleted from the Technical Documentation file.

Commented [AES13]: E.g., if usability testing is not performed because the medical device has been on the market for a long time, [illegible]

Commented [AES14]: E.g., Stability Report, Software [illegible]

Commented [AES15]: E.g., Stability Report, Software [illegible]

Commented [AES16]: You can find a table with this checklist in [illegible]

Commented [AES17]: E.g., laboratory accreditation certificate, [illegible]

Commented [AES18]: E.g., Stability Report, Software [illegible]

Commented [AES19]: You can find more information about EDUAMED on the following link [illegible]

- when the supplier of raw material is changed
- when the dimensions or other characteristics of the medical device within the same intended use are changed
- when the address of the manufacturer has changed
- [illegible]

The person responsible for the technical documentation must follow all relevant standards for the medical device for which the Technical Documentation file is prepared.

The person responsible for the technical documentation must prepare gap analyses each time the relevant standard has been changed and check if it is necessary to change certain documents and reports in the Technical Documentation file. [illegible]

The person responsible for the technical documentation must check the validity of the certification and accreditation of the supplier and/or laboratory at least once every three months. If the certificate has expired, the person responsible for the technical documentation must contact the supplier/laboratory and ask for an updated certificate. [illegible]

Commented [AES20]: These are mandatory; you can include

Commented [AES21]: E.g., harmonized standards published by

Commented [AES22]: E.g., choose a sample of the medical device that will be sent to testing, find an adequate laboratory (with

Commented [AES23]: Adapt to the organization's practice.

Commented [AES24]: This should be someone from top

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		[illegible]	[illegible]	[illegible]
Technical Documentation for Medical Device	PR23.1	[illegible]	[illegible]	[illegible]
Summary of Safety and Clinical Performance	PR23.2	[illegible]	[illegible]	[illegible]

Commented [AES25]: If the record is in electronic form, write the name of the folder on the [responsible person]'s computer.

Commented [AES26]: If the record is in electronic form, write the name of the folder on the [responsible person]'s computer.

5. Appendices

- Technical Documentation for Medical Device
- [illegible]

[job title]
[name]

_____

[signature]

Commented [AES27]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.