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**TECHNICAL DOCUMENTATION PROCEDURE**

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# 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].

# 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

# Preparing technical documentation for medical devices

## 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).

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.

The person(s) responsible for maintaining technical documentation needs to read the whole MDR and to be aware of which requirements are applicable for the medical device for which the Technical

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