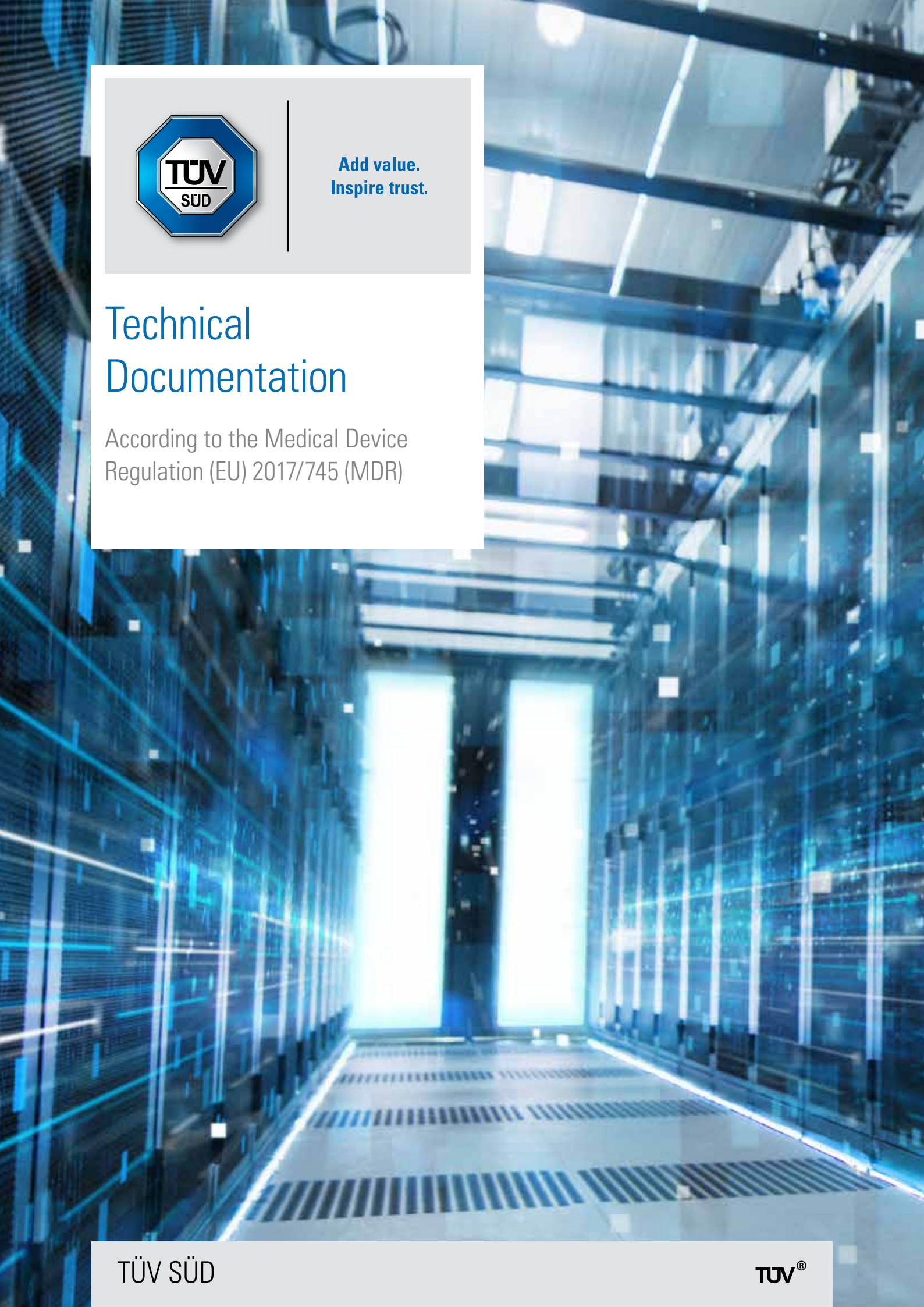

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Technical Documentation

According to the Medical Device Regulation (EU) 2017/745 (MDR)

Contents

Introduction

Manufacturers of medical devices seeking to place their products on the EU Single Market or put medical devices into service that are not placed on the market need to have the conformity of their products assessed according to the applicable conformity assessment procedures set forth in the Medical Device Regulation (EU) 2017/745 (MDR) Annexes IX to XI [Art. 52 (1) (2)].

Depending on the conformity assessment procedure selected, manufacturers may also have to involve a notified body. However, in any case they need to draw up Technical Documentation for their medical devices and keep it up to date. This Technical Documentation shall allow assessment of the conformity of the device with the relevant requirements of the MDR [Art. 10 (4)].

This document aims to familiarise stakeholders with the requirements set forth in Annex II to the Medical Device Regulation. It provides information on the elements that need to be included in the Technical Documentation and how said Technical Documentation can be provided to TÜV SÜD.

Conformity Assessment Procedures under MDR

Class I

To demonstrate the conformity of class I devices, manufacturers draw up the Technical Documentation according to Annexes II and III and issue an EU Declaration of Conformity (DoC). For devices that are placed on the market in a sterile condition, have a measuring function or are reusable surgical instruments, manufacturers shall apply the conformity assessment procedure based on a quality management system and on assessment of Technical Documentation explained in Chapters I and II of Annex IX, or conformity assessment based on product conformity verification according to Part A of Annex XI. In case of class I devices, the role of notified bodies is limited to certain aspects [Art. 52 (7)].

Class IIa

Class IIa devices are subject to conformity assessment based on a quality management system as specified in Annex IX, Chapters I and II and an assessment of Technical Documentation (Annex IX, Chapter II, Section 4) of at least one representative device for each category of devices [Art. 52 (6)]. Alternatively, manufacturers can draw up the Technical Documentation according to Annexes II and III and opt for a conformity assessment based on production quality assurance and product verification as specified in Sections 10 and 18 of Annex XI. The assessment of the Technical Documentation shall apply for at least one representative device for each category of devices [Art. 52 (7)].

Class IIb

Class IIb devices are subject to conformity assessment based on a quality management system as specified in Annex IX, Chapters I and III and an assessment of the Technical Documentation (Annex IX, Chapter II, Section 4) of at least one representative device per generic device group. For class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the Technical Documentation according to Annex IX, Chapter II (4) shall apply for every device [Art. 52 (4)].

Class III and Class IIb defined in Article 52 (4)

Class III devices and class IIb devices as defined in Article 52 (4) shall be subject to a conformity assessment according to Annex IX based on a quality management system and on assessment of the Technical Documentation relating to the device which the manufacturer plans to place on the market or put into service and which is covered by the quality management system. Alternatively, the manufacturer may choose to apply for a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI [Art. 52 (3)].

Submission of Technical Documentation

The data included in the Technical Documentation is preferably taken from the manufacturer's systems. The Technical Documentation retrieves information from one or several databases and presents it in human-readable form.

At most medical device manufacturers, the data used in the Technical Documentation are spread over different sources and IT systems. Given this, TÜV SÜD will continue to accept Technical Documentation in PDF format with a systematic file structure.
Accepted formats are:

- PDF, searchable, Optical Character Recognition (OCR) applied
- Microsoft Office documents
- In future as XML using a format or an interface provided by TÜV SÜD

Accepted formats for graphical information:

- JPG, PNG, BMP, GIF or any other common graphic file format that can be viewed without specific software
- Constructional and design drawings can be also provided as files
- Videos – any common file format that can be viewed without specific software

For the structure of the Technical Documentation, see Annex II, which provides useful guidance. Bookmarks, links, glossaries and indexes help to navigate the Technical Documentation.

To merge several PDF files into one very large PDF or PDF portfolio shall be avoided. Complex folder structures in submissions may make it more difficult to search for evidence or understand the Technical Documentation. Long file names might affect compatibility to the IT infrastructure and must therefore be avoided.

How to submit your Technical Documentation to TÜV SÜD

Provision of access to your Technical Documentation is critical for exchanging information. As a manufacturer, you aim to make sure that your data is protected and cannot be accessed by unauthorised parties. Given this, a password-protected and controlled environment for file submission is key. Files provided through a non-password-protected static link are unacceptable in terms of data security.

> As a manufacturer, you aim to make sure that your data is protected and cannot be accessed by unauthorised parties.

If you wish to share huge files, either use your company's in-house solution or ask your TÜV SÜD representative for the best way of submitting your Technical Documentation to TÜV SÜD. Do not send a Technical Documentation via email as this is not a suitable way to transfer huge file packages.

There are various tools that support the e-submission process and further tools are under development. Ideally, all files should be packed into a single, or a small number of, downloadable ZIP archive(s). Please use a file sharing platform that allows collective download of these files. Do not submit vast numbers of documents as separate downloadable files.

Content Requirements – Technical Documentation Guidance Annex II

According to the introduction to Annex II to the MDR, Technical Documentation shall include the elements listed in Annexes II and III to the MDR. Annex II basically provides a checklist of mostly well-established elements to be included in the Technical Documentation.

Annex II comprises 6 sections which will be described in more detail below.

SECTION 01 Device description and specification, including variants and accessories

Each Technical Documentation shall begin with a section providing a device description, device specifications, a list of variants, combinations and model numbers/names as well as a list of accessories which are intended to be used with the device. Accessories shall not only be limited to those delivered with the device (e.g. in the same sterile package) but shall also cover those accessories generally used with the device to support its intended purpose. The device-related Basis UDI-DI shall be provided for each variant as well as device related nomenclature such as MD coding as per implementing regulation 2017/2185, EMDN (CND) code to additionally support TÜV SÜD assessment of Technical Documentation.

Further information to be provided in this section include explanations of novel features, i.e. features that are new in a device compared to the predecessor device or similar devices on the market. Where necessary, reference can be made to attachments to the Technical Documentation (e.g. the justification for classification of the device when prepared as a checklist based on Annex VIII).

Please note that section 1 of the Technical Documentation is important for the basic understanding of the device and should therefore be clear and easily readable.

Provision of all information in the form of attachments might not make for easy reading and understanding. A document that guides the reader (reviewer) through the required elements of the Technical Documentation will be easier to read and avoid misunderstandings.

SECTION 02 Information to be supplied by the manufacturer

Section 2 covers all information that manufacturers need to provide along with the medical device under assessment. This firstly includes labels and instructions given to users and/or patients but also information provided by other means as well as the implant card where applicable. Labels and instructions must be provided in the languages accepted by the Member States where the device is envisaged to be sold. This might prove a challenge, in particular when translations of such information are still pending. However, the MDR does not include any requirement that medical devices must be placed on the entire EU market right from the start. Manufacturers can thus choose the markets where the device is envisaged to be sold and adjust the languages of the Technical Documentation accordingly. TÜV SÜD will accept information in this section in the languages German or English for assessment and will check the compliance to language requirements during audit activities. For support this approache TÜV SÜD will request to receive the applicable procedure for translation of such information, therefore, please include it from the beginning in your Technical Documentation. In case several variants of a medical device exist it will not be sufficient to provide one exemplary set of information but the complete set of information for all variants in German or English.

SECTION 03 Design and manufacturing information

This section includes one of the most significant changes compared to MDD/AIMDD requirements on Technical Documentation and Design Dossiers.

Manufacturers must submit information to allow the Design Stages applied to the device to be understood. In other words, they must furnish evidence that the device went through design stages and explain changes between individual design stages of the device (if any) in a manner comprehensible to the reader (reviewer).

To fulfil this requirement, manufacturers need to submit device-related evidence (submission of a Design and Development SOP is not enough). Such information is typically found in a Design History File of a device.

As a conformity assessment procedure for a medical device is mainly a combination of auditing, testing and review activities, the overall conformity assessment procedure must cover all relevant elements.

When manufacturers request a conformity assessment procedure under the MDR for a device that was placed on the market under the AIMDD/MDD and was thus developed prior to the MDR, the information they submit must include any design iterations performed after the product had been made available on the market initially.

The Technical Documentation of such a device must reflect the current design stage, including all changes made in the past. The information submitted must be such that the reader can understand the reasons for any changes effected in the post-marketing phase.

Under letter (b), this section requires information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. All elements listed under (b) and the data associated shall be fully included in the Technical Documentation.

As a conformity assessment procedure for a medical device is a combination of auditing, testing and review activities, the overall conformity assessment procedure must cover all relevant elements. While the Technical Documentation shall also include process-related data, these data are ideally assessed in the on-site audit at the manufacturer. In order to assess a reasonable set of information in this section, TÜV SÜD requests the following device specific information to be included in the Technical Documentation:

- Manufacturing procedure including a flow chart and information about used adjuvants
- Quality control measures (i.e. continuous monitoring and final product testing)
- Manufacturing master validation plan and the associated summary report referencing individual IQ/OQ/PQ plans and reports
- IQ/OQ/PQ plans and reports for non-critical/crucial processes shall be on file at the manufacturer or EU representative and shall be provided to TÜV SÜD upon request

- IQ/OQ/PQ plan and reports for critical/crucial processes (e.g. sterilisation, packaging, and others) shall be provided initially with the Technical Documentation to TÜV SÜD

In case clarification is needed if a process validation shall be included in the Technical Documentation initially or can be kept available and be provided upon request get in touch with your TÜV SÜD client manager.

Section 3 also requires identification of all sites that perform design and manufacturing activities, including sites of suppliers and subcontractors. The requirement very clearly specifies “all” sites, (...) suppliers and subcontractors. In addition, the Technical Documentation must provide manufacturing information on aspects such as processes and their validation, a list of suppliers and subcontractors (...) that carry out design and manufacturing activities either individually or in combination with each other. Manufacturers also might have to check and update supplier agreements to make sure they contain all information that is relevant for the conformity of a medical device. As manufacturers have sole legal responsibility for their medical devices, they must have access to all conformity-related information, including that of suppliers and subcontractors. Information about manufacturing and design activities at suppliers and subcontractors is part of the conformity assessment and might be assessed by TÜV SÜD. Such information must be provided by the manufacture directly and cannot be accepted from the supplier or subcontractor directly, bypassing the manufacturer.

A limitation to suppliers which have direct relations to the manufacturer, might be acceptable in some cases. However, in other cases such limitation might not be acceptable (e.g. for materials of animal or human origin or other critical materials or components).

SECTION 04 General safety and performance requirements (GSPR)

“The Technical Documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I.”

The MDR does not require submission of a checklist, even though checklists are commonly used to provide all relevant information connected to the General Safety and Performance Requirements (GSPRs). The readers of the Technical Information must be able to understand which GSPRs are applicable and which are not. Manufacturers must provide reasons if they consider a GSPR to be not applicable; simply identifying said GSPR by “n/a” or “not applicable” is not considered an explanation.

Other information required in this context are “methods used to demonstrate conformity with the applicable” GSPRs. Methods in this context include test plans, standards, common specifications or other inputs which explain how a manufacturer approaches a specific GSPR.

In case a manufacturer uses harmonised standards, common specifications (CS) or other solutions, information about these elements must be included in the Technical Documentation.

To facilitate locating the evidence of conformity with the harmonised standards, CS or other solutions, under Annex II, Section 4, lit. d manufacturers must provide the precise identify of the controlled document that offers such evidence of conformity and include a cross-reference to the exact location of such evidence in the full Technical Documentation.

As the Technical Documentation must be clear and unambiguous, a general reference to a specific folder that includes a large number of documents is not acceptable. Instead, a clear identifier, pointer or link to the evidence shall be provided.

GSPR-related information is extremely complex. Databases and requirements tracking tools combined with unique information units are emerging as one possible solution for appropriately handling these huge amounts of data.

SECTION 05 Benefit-Risk Analysis and Risk Management

As risk management has always been the backbone of development, manufacturing, and conformity assessment of medical devices, Section 5 of Annex II does not include new requirements compared to the past.

General information on benefit-risk analysis, solutions adopted and the results of risk management shall be provided according to this section.

Solutions adopted can include a variety of possibilities, from design-related solutions to protective measures, warnings, instructions, functional-safety elements, training and other measures.

Stricter requirements related to the management of risks, such as those connected to the use of medical devices, are introduced through GSPRs and must be addressed by the documents referenced in this section of the Technical Documentation. TÜV SÜD expects to receive information based on requirements according to ISO EN 14971 for risk management plans, reports, clear overall risk benefit statement as well as other risk management related information (e.g. use risks or cyber security related information) with the Technical Documentation.

SECTION 06 Product Verification and Validation

According to Section 6 of Annex II, “the documentation shall contain the results and a critical analysis of all verification and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable GSPR”.

Per definition, the information to be submitted here goes far beyond mere test reports. Test reports are used “only” to demonstrate conformity with the GSPRs. This section however, covers all results used to demonstrate that the device is in conformity with the MDR. To enable improved understanding and ensure clear and unambiguous Technical Documentation, manufacturers must consider that information providing this level of detail must be readable and understandable for the reviewer. While a simple list of all tests and studies performed together with all verification and validation results will not satisfy this requirement, a list or table might prove helpful to reference information. Elements addressed in previous sections of the Technical Documentation might be useful for clear referencing, e. g. novel design features and the results of verification, validation and studies associated with these features may be of specific interest to the reviewer.

To enable improved understanding and ensure clear and unambiguous Technical Documentation, manufacturers must consider that information providing this level of detail must be readable and understandable for the reviewer.

Section 6.1 requires pre-clinical and clinical data to be part of the Technical Documentation and defines such data as follows: “results of tests such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device”.

The definition in this section goes beyond the principle of providing pre-clinical data from animal studies only, and lays down the information that needs to be provided: “detailed information regarding test design, complete test or study protocols, methods and data analysis, in addition to data summaries and test conclusion regarding in particular:

- The biocompatibility (…)
- Physical, chemical and microbiological characterisation
- Electrical safety and electromagnetic compatibility
- Software verification and validation (…)
- Stability, including shelf life
- Performance and safety”

If no new testing has been undertaken for a new device because the manufacturer decided to use testing from a predecessor device, the reasons underlying this decision shall be explained and supported with documented evidence of the predecessor device in the Technical Documentation.

Sections 6 and 4 are closely related to each other and information provided on GSPR and on verification and validation will overlap widely.

Section 6.2 lists additional special requirements for specific devices, such as devices incorporating medicinal substances, devices utilising material of human or animal origin, and other specific devices. Where a TÜV SÜD assessment report is available that already covers the assessment of individual elements of an ongoing conformity assessment a clear reference to that TÜV SÜD report (by report number) shall be provided to facilitate the assessment. Please note that an MDR conformity assessment is a completely new assessment of the medical device in question and information from early AIMDD/MDD assessments of the same device cannot simply be transfered over to the MDR assessment.

In order to comply to the overall requirements for a readily searchable Technical Documentation all information provided in this section - as in all previous sections - must be provided in a format that allows searching and thus requires Optical Character Recognition for PDFs.

Files that are provided here must show evidence that they are controlled records and that they have been properly released in the document control system either by means of signature (handwritten or digital) or by other means implemented in your document control system. An evidence without proof of proper document control cannot be part of the conformity assessment report at TÜV SÜD and will thus not be acceptable.

IMPORTANT NOTICE
Technical Documentation according to the Medical Device Regulation (EU) 2017/745
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Stay up-to-date with the new requirements with TÜV SÜD

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