# How to handle your Medical Device Technical Documentation?


## 1. Goal of this publication

The goal of this publication is to help you in the development of the technical documentation associated to your medical device and in its presentation. The earlier you start with a clear vision of its structure and its presentation for submission, the easier it will be to develop it efficiently without impacting drastically your development activities.

## 2. Targeted audience

The information gathered in this publication should be particularly useful for:

- Project Managers,
- Quality & Regulatory Managers.

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# 4. Introduction

When planning to commercialize medical devices in European Union, 2 highly regulated activities are mandatory: development and maintenance of a Quality Management System (QMS) and technical documentation development. Those two activities are closely correlated as the QMS shall describe the way you plan to structure and develop your technical documentation. However, the QMS documents many other activities. The technical documentation writing is led by the project manager and validated by the quality and regulatory manager.

For submission purposes, you will have to develop a guidance/summary document allowing the reviewer to easily navigate in the set of documents you submit him/her.

In addition, if your commercialization plan aims at international reach, you must adapt your QMS and your technical documentation to multiple regulations.

## 4.1. What is a Quality Management System (QMS)?

The QMS is the set of documents including but not limited to the quality policy, quality manual, processes, procedures, work instructions and templates used to describe the activities of the company and the rules to generate records for the various activities of the company.

The QMS allows to document the company activities, to develop a continuous improvement approach and to demonstrate the compliance of company activities with applicable regulations.

## 4.2. What is a Medical Device Technical Documentation ?

The Technical Documentation is documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices. It consists in a collection of documents prepared by the manufacturer in a clear, well-organized, readily searchable, and unambiguous manner to allow for a complete and efficient review by authorities.

## 4.3. What is the Summary Technical Document (STED)?

The Summary TEchnical Document (STED) is the proposed harmonized format used for regulatory submissions by the Global Harmonization Task Force (GHTF). The STED format is recognized by US and European regulators, as well as in other markets. It consists in a guidance document for the reviewer that will allow him to go step by step through your Technical Documentation.

## 4.4. Relationships between QMS, Technical Documentation and STED

The relationship between the three previously defined concepts is illustrated in the Figure 1. In summary:

- The QMS shall cover the entire set of activities of your company, including technical documentation and Summary Technical Documentation writing and submissions to authorities.
- The Technical Documentation is the term used to define the entire set of documents you create while designing and developing your medical device.
- The E.P. Checklists are the Essential Principles checklists to check correct answer to the Essential Requirements established by the MDR.
- The Summary Technical Documentation is an introduction and guidance document to allow efficient review by authorities or their representatives.

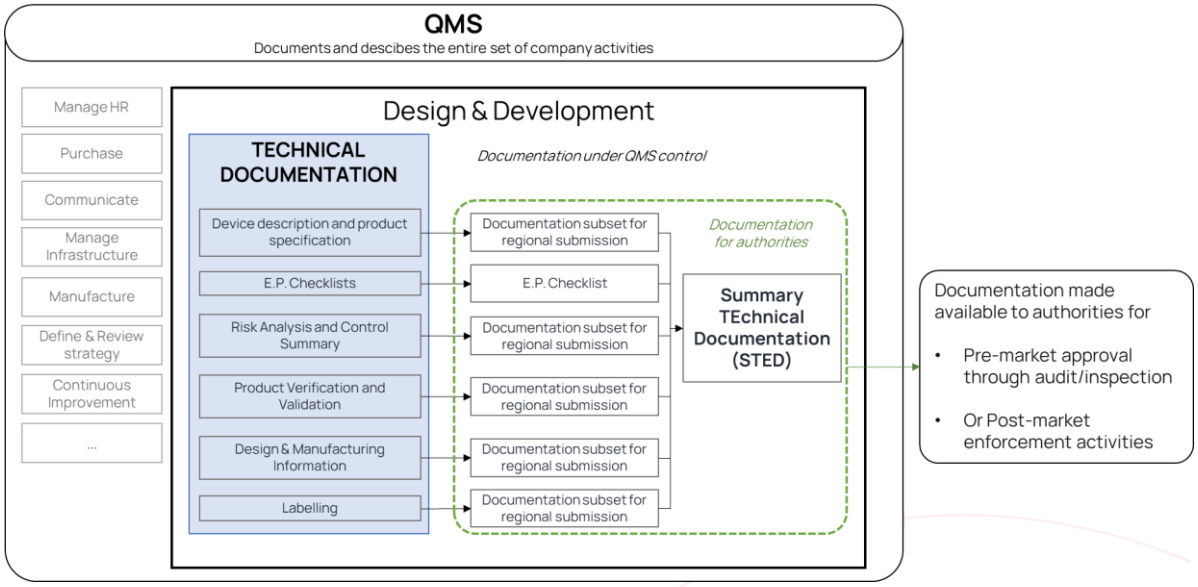


*Figure 1. Relationships between QMS, Technical Documentation and STED*

## 4.5. When Technical Documentation is necessary ?

To access European market, no matter what classification your medical device bears or which pathway you are taking, a technical documentation is mandatory. If your device is of a higher class than Class I a Notified Body will be involved and will review it before allowing you to assign the CE mark. In addition, it will review and usually certify your QMS, but this part is out of the scope of this publication.

For class I device, the manufacturer is allowed to self-declare its product. No Notified Body is involved in the homologation process. The manufacturer is allowed to self-declare the

compliance of its QMS and of its technical documentation with the applicable legal framework. No audit of the QMS or review of the technical documentation is necessary before market entry but in case of doubt or abusive claims from the manufacturer, authorities can decide to audit your company and you should better be compliant with what you claimed. The damage to your reputation, the impact on your development plan and the financial costs when having to solve possible gaps between what you did and what you should have done is tremendous and can really impact your company.

## 4.6. What is the US equivalent of EU Technical Documentation ?

Technical documentation is a term usually used only for European market access. For US market entry, the analogous documentation is the regulatory submission to FDA (for example through 510(k) submission).

The regulatory submission to FDA relies on key and well identified documents:

- The **Design History File** is a compilation of documentation that describes the design history of a finished medical device. It lists all document versions that were created and validated during the execution of a Design and Development project and allows to demonstrate the proper application of a compliant design and development process.
- The **Device Master Record** is a compilation of all the production and assembly instructions, drawings, test plans, and other records that are needed to produce a compliant product.
- The **Device History Record** contains all the information related to the produced products such as production date, quantity, and labels of the final products as well as the customer related information (including identity information and Installation Qualification, Performance Qualification and Operational Qualification test results when applicable).

The STED document can also be used for US submission as it allows you to provide additional background and guidance information that will allow the FDA to efficiently review your documentation.

## 4.7. How to develop a global approach ?

When developing your QMS, your technical documentation and your various regulatory submissions for your targeted countries you may have to gather a significant amount of documentation for each region you target. If you do not develop a global approach early-on in your development process, you will spend a significant amount of time to adapt or re-generate your documentation to be compliant with the specific regulations of the country you want to enter.

Debiotech highly recommends:

- Identifying the countries, you want to reach at the beginning of your development project and understand the structures of the technical documentation or regulatory submission that they are expecting. You can then define a way to store your project files that will be independent from those various structures but that will allow your teams to easily collect all necessary documents and information and format and re-organize them to generate each specific regulatory submission you plan.

- Storing your master records in a project Technical Documentation folder/space where their content will be developed, reviewed and validated, where all the necessary information for the various targeted countries finds its place and that will be used as the source to generate your STED and the complete regulatory submissions. Most of the expected content is similar between targeted regions, but specific details and expectations vary significatively from one region to another.

To plan properly your documentation structure and describe an optimum documentation process, you must keep in mind that multiple versions of your documents will be generated and that multiple versions of your various regulatory submissions will also exist.

The Figure 2, illustrates possible folders structure to store your files.

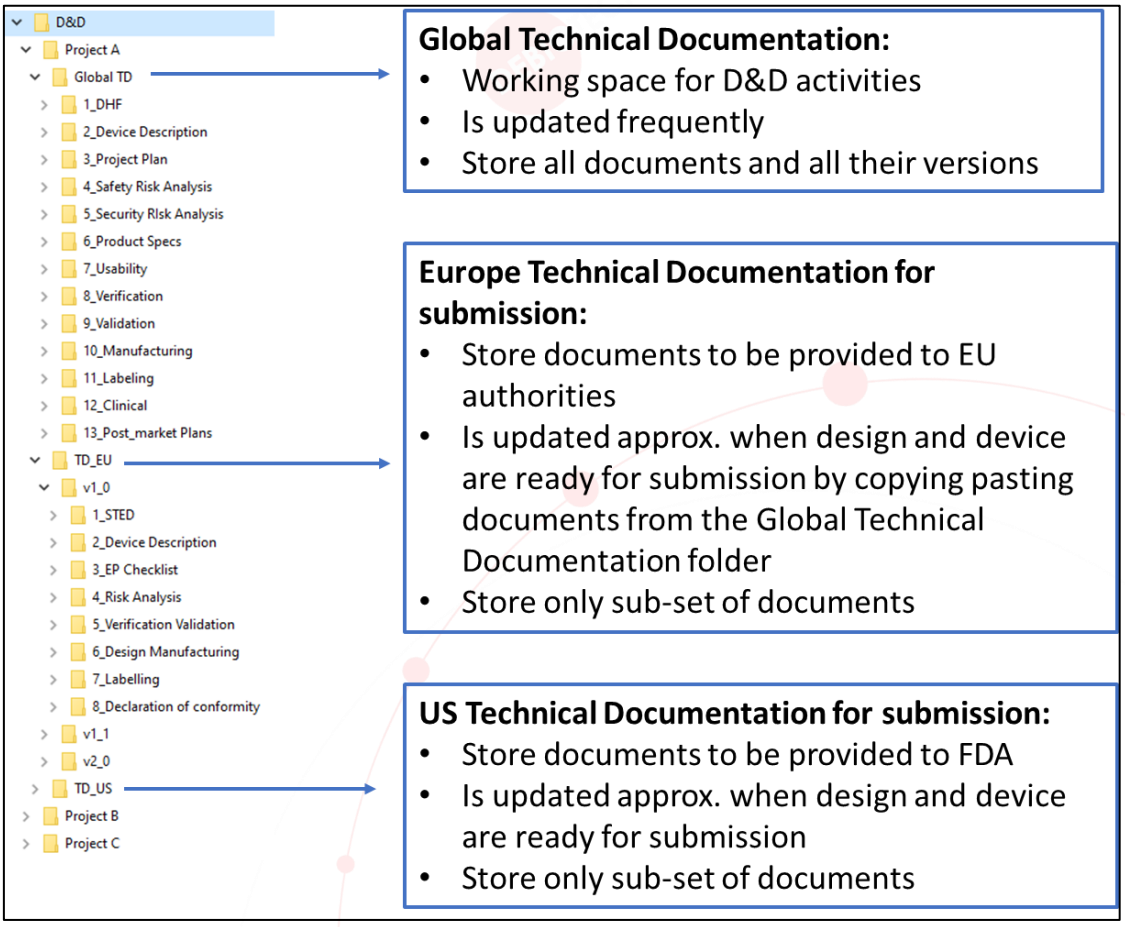


*Figure 2. Illustration of possible folder structure for your Technical Documentation*

## 4.8. Who handle Technical Documentation writing ?

Once the structure defined and the D&D procedure established, your project team should be able to generate the technical documentation. Review and validation from the quality team to review documents and ensure they have been generated according to the rules set by your QMS are mandatory (for example during gate or phase reviews).

Once your project is at a status that will allow submission (verification and validation test results collected and analyzed and clinical evaluation and design transfer finalized) the project manager, the quality team and the regulatory team can work together to generate your technical files for submission by copying and pasting the necessary subset of your existing documents.

## 4.9. How to handle incomplete technical documentation?

It is usually not recommended to submit incomplete technical documentation. Some activities are mandatory at the early stage of your project, and you cannot forget them in your submission (as for example your different plans: project, quality, usability, risk management, verification, and validation plans). However, as submission date is usually set in advance, it can happen that the status of your project is not as advanced as expected when you signed your contracts with your Notified Body. In this case, it is foreseeable that you do not have the entire set of test results (verification, validation or clinical) you expected, and you should be transparent about it with your Notified Body. In worst cases, you are also missing some components of your system and you cannot even provide a detailed architecture. Cancellation fees for such technical files review is often relatively important that is why we recommend you to be clear on what is not available and when and how you plan to obtain it. This way, you inform the reviewer about what he or she can already review and what will be submitted later. This is in our opinion the best way to proceed in such cases.

# 5. Technical documentation content

## 5.1. High level requirements

The Medical Device Regulation states that medical device manufacturers must:

- Prepare technical documentation before placing a product on the market,
- Ensure technical documentation is made available to the market surveillance authorities as soon as the product is placed on the market. For class IIa, IIb or III devices, this technical documentation shall be reviewed by certified Notified Bodies, competent in your technical and clinical field.
- Keep records of technical documentation for 10 years (15 years for implantable devices) from the date the last product has been placed on the market.

The content of this technical documentation is defined in the next chapters.

## 5.2. Expected content

The expected content for the technical documentation is described in the Annex II and III of the MDR (EU 2017/745) and shall include:

- Device description and specification, including variants and accessories,
- Information to be supplied by the manufacturer (labeling and instructions for use),
- Design and manufacturing information,
- General safety and performance requirements,
- Benefit-risk analysis and risk management,
- Product verification and validation,
- Pre-clinical and clinical data,
- Additional information required in specific cases,
- Post-market surveillance plan.

More details about their exact expectations are provided in the next chapters.

### 5.2.1. Device description and specifications

The following information regarding device description and specifications shall be provided:

- Product or trade name with a general description of the device including its intended purpose and the description of its intended users,
- Product unique identifier or other unambiguous reference allowing traceability and compliant with the UDI system (MDR Annex VI) as soon as this system is in place.
- Description of the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, and warnings.
- Principles of operation of the device and its mode of action, scientifically demonstrated if necessary.
- The rationale for the qualification of the product as a device.
- The risk class of the device and the justification for the classification rule(s) according to MDR Annex VIII.
- Explanation of any novel features.
- A description of the accessories or other devices and products which are intended to be used in combination with your device.
- A description or complete list of the various configurations/variants of the device that are intended to be made available on the market.
- A general description of its functional elements (e.g., parts and components), composition, functionality and where relevant its qualitative and quantitative composition.
- A description of the raw materials incorporated into key functional elements and making either direct or indirect contact with human body parts.

- Technical specifications, such as features, dimensions and performance attributes of the device and any variants/configuration and accessories

In addition, references to previous and similar generations of your device:

- An overview of the previous generation(s) of the device produced by the manufacturer,
- And/or an overview of identified similar devices available on the European Union or international markets.

### 5.2.2. Labelling and instructions for use

Your technical documentation shall include:

- A description of the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions.
- The instructions for use in the languages accepted in the Member States where the device planned to be sold.

### 5.2.3. Design and manufacturing information

Your technical documentation shall include:

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

### 5.2.4. General safety and performance requirements

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I of the MDR that are applicable to the device considering its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

- The general safety and performance requirements that apply to the device and an explanation as to why others do not apply,
- The method or methods used to demonstrate conformity with each applicable general safety and performance requirement,
- The harmonized standards, Common Specifications (CS) or other solutions applied,
- The precise identity of the controlled documents offering evidence of conformity with each harmonized standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to

under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

### 5.2.5. Benefit-risk analysis and risk management

The documentation shall contain information on:

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

### 5.2.6. Product verification and validation

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and the applicable general safety and performance requirements.

#### 5.2.6.1. Pre-clinical and clinical data

The documentation shall contain:

- Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, considering its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications,
- Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:
  - The biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user,
  - Physical, chemical, and microbiological characterization,
  - Electrical safety and electromagnetic compatibility,
  - Software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer),
  - Stability, including shelf life.
  - Performance and safety. Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council ( 1 ) shall

be demonstrated. Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service,

- The clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV of the MDR,
- The PMCF (Post Market Clinical Follow-up) plan and PMCF evaluation report referred to in Part B of Annex XIV of the MDR or a justification why a PMCF is not applicable.

#### 5.2.6.2. Additional information required in specific cases

In the following specific cases, the technical documentation shall additional information:

- Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product, including a medicinal product derived from human blood or human plasma.
- Where a device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives.
- In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body.
- In the case of devices containing CMR or endocrine-disrupting substances.
- In the case of devices placed on the market in a sterile or defined microbiological condition.
- In the case of devices placed on the market with a measuring function.
- If the device is to be connected to other device(s) to operate as intended.

### 5.2.7. Post-market surveillance plan

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 of the MDR shall be presented in a clear, organized, readily searchable and unambiguous manner.

- The post-market surveillance plan shall address the collection and utilization of available information, in particular: information concerning serious incidents, including information from PSURs, and field safety corrective actions; records referring to non-serious incidents and data on any undesirable side-effects; information from trend reporting; relevant specialist or technical literature, databases and/or registers; information, including feedbacks and complaints, provided by users, distributors and importers; and publicly available information about similar medical devices.

- The post-market surveillance plan shall cover at least: a proactive and systematic process to collect any information referred to in previous point. The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market; effective and appropriate methods and processes to assess the collected data; suitable indicators and threshold values that shall be used in the continuous reassessment of the benefitrisk analysis and of the risk management; effective and appropriate methods and tools to investigate complaints and analyses market-related experience collected in the field; methods and protocols to manage the events subject to the trend report, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period; methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users; reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86; systematic procedures to identify and initiate appropriate measures including corrective actions; effective tools to trace and identify devices for which corrective actions might be necessary; and a PMCF plan as referred to in Part B of Annex XIV of MDR, or a justification as to why a PMCF is not applicable.

## 5.3. Technical Documentation Summary Format

### 5.3.1. Introduction

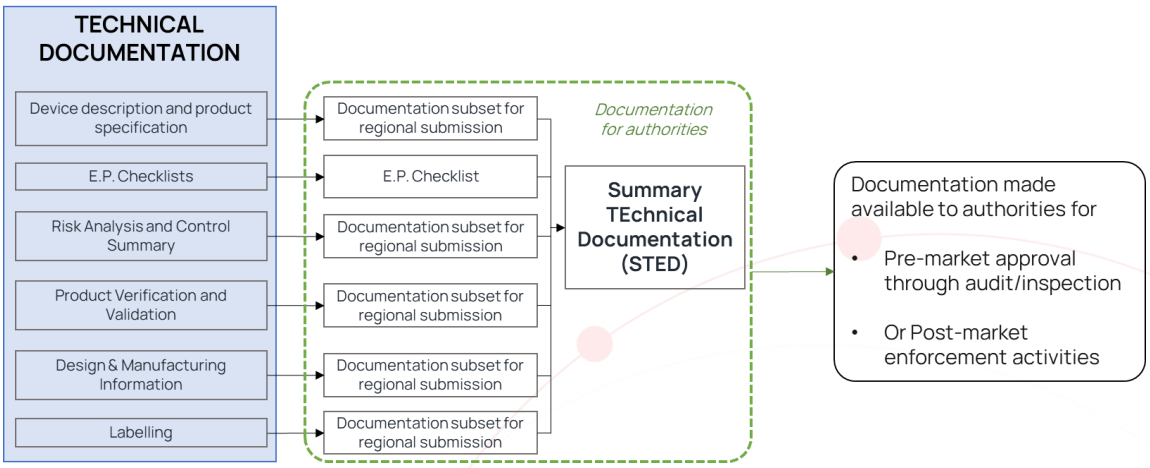


*Figure 3. Illustration of STED and associated files*

Without proper formatting, the most meticulously researched and prepared medical device market application can fail to pass regulatory review, costing the applicant time and money. The entire set of documentation provided by the manufacturer is usually introduced with a summary document. Once again having a clear structure for this summary document will help your reviewers. The Summary Technical Document (STED) is the proposed harmonized format used for regulatory submissions by the Global Harmonization Task Force (GHTF). The STED format is recognized by US and European regulators, as well as in other markets.

Despite this well-defined content, each project is unique and might require some adaptations. You can adapt this structure, when necessary, but it is usually a base compatible with most of the projects.

### 5.3.2. Content structure

The proposed structure for your technical documentation summary file is described in details in the STED documentation provided by the GHTF: GHTF SG1 Essential Principles of Safety and Performance of Medical Devices (STED) (imdrf.org)

A summary is provided here:

#### 5.3.2.1. Device description & product specifications

The STED should include the following device descriptive information:

- a general description of the device including its intended use/purpose,
- the intended patient population and medical condition to be diagnosed and/or treated by the device and other considerations such as patient selection criteria,
- the principles of operation of the device,
- the Class of the device and the applicable classification rule according to GHTF/SG1/N15:2006 Principles of Medical Devices Classification etc.
- an explanation of any novel features,
- a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the device,
- a description or complete list of the various configurations/variants of the device that will be made available,
- a general description of the key functional elements of the device, e.g., its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include labelled pictorial representations of the device (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.
- a description of the materials incorporated into key functional elements of the device and those making either direct or indirect contact with a human body.

The STED should include the following information about product specifications:

- A list of the features, dimensions and performance attributes of the medical device, its variants, and accessories (if such are within the scope of the STED), that would appear typically in the product specification made available to the end user.
- Reference to previous generation(s) or similar devices,

- Where relevant to demonstrating conformity to the Essential Principles, and to provide general background information, the STED should provide an overview of:
  - the manufacturer's previous generation(s) of the device, if such exist,
  - similar devices available on the market.

#### 5.3.2.2. Essential Principles (EP) Checklist

The STED should include an EP checklist that identifies:

- the Essential Principles of Safety and Performance,
- whether each Essential Principle applies to the device and if not, why not,
- the method used to demonstrate compliance with each Essential Principle that applies,
- the precise identity of the controlled document/s that offers evidence of compliance with each method used.

The method used to demonstrate compliance may be:

- compliance with recognized or other standards,
- compliance with a commonly accepted industry test method,
- compliance with in-house test methods,
- comparison to a similar device already available on the market.

The EP checklist should include a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the STED (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).

A sample checklist is included in Appendix A of the STED detailed description by the GHTF (GHTF SG1 Essential Principles of Safety and Performance of Medical Devices (STED) (imdrf.org)).

#### 5.3.2.3. Risk analysis and control summary

The STED should summarize the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. This risk analysis should be based upon international or other recognized standards, and be appropriate to the class of the device , its complexity, and its novelty.

#### 5.3.2.4. Product Verification and Validation

For STED documentation of product verification and validation, the level of detail will vary, and be determined by:

- the class of the device
- the complexity of the device
- the novelty of the device

As a general rule, the STED should summarize the results of verification and validation studies undertaken to demonstrate compliance of the device with the Essential Principles that apply to it. Such information would typically cover:

- engineering tests,
- laboratory tests,
- simulated use testing,
- any animal tests for demonstrating feasibility or proof of concept of the finished device,
- any published literature regarding the device or substantially similar devices.

Summary information may include:

- declaration/certificate of compliance to a recognized standard and summary of the data if no acceptance criteria are specified in the standard,
- declaration/certificate of compliance to a published standard that has not been recognized, supported by a rationale for its use, and summary of the data if no acceptance criteria are specified in the standard,
- declaration/certificate of compliance to a professional guideline, industry method, or in-house standard, supported by a rationale for its use, a description of the method used, and summary of the data in sufficient detail to allow assessment of its adequacy,
- a review of published literature regarding the device or substantially similar devices.

As a general rule, the STED should include detailed information on:

- sterilization,
- biocompatibility,
- software verification and validation,
- biological safety of devices incorporating animal or human cells, tissues or their derivatives,
- medicinal substances, if any, incorporated into the device, including compatibility of the device with the medicinal substance,
- animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted,
- clinical evidence.

These topics are not applicable to all devices.

Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions.

#### 5.3.2.5. Sterilization

Where the device is supplied sterile, the STED should contain the detailed information of the initial sterilization validation including bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. Evidence of the ongoing revalidation of the process shall also be provided in the form of the most recent validation report. Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed against the standards, and a summary of the results against the protocol.

#### 5.3.2.6. Biocompatibility

Details should be provided on all biocompatibility tests conducted on materials used in the device. At a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device. All materials that are significantly different from materials known to be biocompatible should be characterized. Information describing the tests, the results and the analyses of data should be included.

#### 5.3.2.7. Software Verification and Validation

The correctness of the software cannot be fully verified in the finished device. The manufacturer should provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments.

#### 5.3.2.8. Biological Safety

In the case of a medical device manufactured from or incorporating animal or human tissue or their derivative, detailed information should be provided substantiating the adequacy of the measures taken about the risks associated with transmissible agents. This will include viral clearance results for known hazards. Donor screening concerns should be fully addressed. Methods of harvesting and long-term registries should also be fully described.

Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

#### 5.3.2.9. Animal Studies

Reports of animal studies should be included, when these studies are conducted to support the probability of effectiveness in humans. These studies should be undertaken using good laboratory practices. The objectives, methodology, results, analysis, and manufacturer's conclusions should be described. The study conclusion should address the device's interaction with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the animal model should be discussed.

#### 5.3.2.10. Medicinal Substances

Yet there is no specific advice on device-medicinal combination products, but it is anticipated that the GHTF will develop recommendations in the future, at which time it will be referenced within this document.

#### 5.3.2.11. Clinical Evidence

The STED should summarize the results of clinical evaluation studies undertaken to demonstrate compliance of the device with the Essential Principles of Safety and Performance that apply to it and should take the form of the summary Clinical Evaluation Report described in guidance published by Study Group 5 of the GHTF.

#### 5.3.2.12. Design and Manufacturing information

##### Manufacturing process

The manufacturing processes for the finished device should be provided in the form of an overview of the activities and quality management system associated with the fabrication of the device. This would include design, production, assembly, final product testing and packaging of the finished medical device.

##### Design and manufacturing sites

If multiple facilities are involved in the design and manufacture of a device, the overview of activities for each facility should be included in the STED. If the information is identical for several sites, this should be noted. This does not include identification of sub-contractors supplying components incorporated into the device.

#### 5.3.2.13. Labelling

The STED should contain all labelling associated with the device as described in GHTF guideline SG1/N043:2005 Labelling for Medical Devices (revised). Information on labelling will include the following subsets:

- labels on the device and its packaging,
- instructions for use, including an overview of any end-user training materials offered by the manufacturer and not included within them,
- promotional material.

#### 5.3.2.14. Declaration of conformity

The Declaration of Conformity is not part of the STED. However, it may be annexed to the STED once the conformity assessment process has been completed. The content of the Declaration of Conformity is described in GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.

## 5.4. Technical documentation review

Once your technical documentation is complete, you should run it through some internal checkpoints before submitting it for final review by a notified body. Debiotech recommends assembling a cross-functional team with the project manager, quality and regulatory collaborators and other critical stakeholders (manufacturing, clinical, etc.).
The person responsible for regulatory compliance shall validate that the technical documentation and the EU declaration of conformity are drawn up and kept up to date.

After submission, the technical documentation is reviewed by your Notified Body, which will have a critical analysis of this documentation in regards of European requirements. After review, he might come back to you with requests of changes or for additional information. That is not rare and should not create unnecessary stress. At this point you will know exactly what is missing or insufficient.

## 5.5. Technical documentation review timing

Planning your development activities and your market reach is of critical importance for your reputation. However, contrary to the FDA, the European Notified Bodies do not have a maximum delay to answer you, which can create hurdles in the planning of your activities.

You should have in mind that typical delay when dealing with Notified Bodies is the following:

- Delay between contract and expected Technical Files review: at least 6 months but possibly more as European Notified Bodies are currently under an important workload due to the MDD-MDR transition.

- Necessary timing for your Technical Files review: this highly depends on the N.B. workload and the type and characteristics of your device. Debiotech has seen some Technical Files reviewed in 2 days for projects with low patient risks up to 6 months for complex and high patient risks system as X-ray devices. This delay has to be clarified when you start the contract discussions with your Notified Body.
- And finally, to plan your market entry you need to ensure that before or in parallel of the technical files review you have (in most of the situations) to certify your QMS. In theory, it is more logical to first get your QMS certified and then submit your Technical Files but in practical situation, it can sometimes be parallelized.

# 6. Applicable regulatory landscape

This publication does not aim at answering completely to a specific standard or regulation but provide recommendations on multiple aspects that should be established early on in your development to ensure the efficiency of your team. However, it covers directly or indirectly multiple requirements from following standards and regulations:

- Europe: MDR

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# 8. Next steps

Debiotech is glad to have the opportunity to share its knowledge with innovative companies from the MedTech industry. Your feedbacks on this publication are welcome and will be used to update it or to create new publications on topics you care about.

Continue your education on medical device development by:

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- Following Debiotech on LinkedIn to be notified on new publications: https://www.linkedin.com/company/debiotech-sa
- Contacting us to ask a question or request personalized support: contact@debiotech.com

Debiotech would be proud to be your partner and support you with:

- Medical device design & development services:
  - Software: Digital Health, Firmware, Embedded, SaMD
  - Electronics: Design, Verification and Validation
  - Mechanics: Design for micro-fabrication & fluidics systems
  - Supply chain development and optimization

- Support in medical innovation management:
  - Market analysis and segmentation
  - IP management
  - Business plan consolidation
  - Partnership development