Preparing a European CE Technical File for a Medical Device

Getting started, common elements, guidances, clinical evaluation and formatting and more

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So You Want to Sell Your Medical Device in Europe?

If you're reading this, chances are good that you're considering introducing a device in Europe. Maybe you have been tasked with preparing a technical file. Whatever the case, in this white paper, we will discuss the purpose of a technical file, the data and documentation included, and formatting, among other topics.

What is a Technical File?

A CE Technical File is a comprehensive description of your device and demonstrates compliance with the requirements of the applicable European Union Directive, such as the Medical Devices Directive 93/42/EEC (MDD), In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD) or Active Implantable Medical Devices Directive 90/385/EEC (AIMDD).

Compiling your technical file (or Design Dossier for Class III devices) is a critical step in the CE Marking process and includes detailed information about the design, function, composition, use, claims, and clinical evaluation of your medical device.

Brief Overview: CE Marking Process for Devices under the MDD

Preparing and submitting the technical file is just one step in the CE Marking process. Early steps in the regulatory procedure determine if a Notified Body is required to review your technical file or design dossier and what information to include in your submission. Basic steps in the CE Marking process are listed below:

1. Determine if your product is a medical device and which EU Directive applies to your device: Medical Devices Directive (MDD), In Vitro Diagnostic Device Directive (IVDD), or Active Implantable Medical Device Directive (AIMDD)?
2. Determine the classification of your device: Class I (non-sterile, non-measuring), Class I (sterile, measuring), Class IIa, Class IIb, or Class III.
3. Implement a Quality Management System (QMS). Exception: Class I (non-sterile, non-measuring) devices.[1]
4. Prepare a Technical File for your device (Class I, IIa, IIb) or Design Dossier (Class III).
5. Select an Authorized Representative (EC REP) if you have no location in Europe.
6. Have your QMS and Technical File/Design Dossier audited by a Notified Body, unless your device is Class I non-sterile, non-measuring.
7. Upon successful completion of your Notified Body audit, you will receive a European CE Marking certificate (and an ISO 13485 certificate depending on the route to conformity assessment selected). There may be some additional registration requirements, though this is contingent upon the Competent Authority where your Authorized Representative is based, as well as the classification of your device.
8. Prepare the Declaration of Conformity (DoC), which states that your device complies with the appropriate Directive.

Identifying the appropriate device classification before you begin work on your technical file is important. For example, you may need to include detailed clinical data and test reports, depending on your device's risk level. If you have a low-risk device, your technical file will have fewer requirements.

No two technical files will look exactly the same because the type of device dictates the information included in the document. Three primary factors determine what is required for your technical file:

1. **Essential Requirements.** The Essential Requirements establish basic characteristics that you must comply with to mitigate risk to the user /patient, supplying information and documentation with your device, and labeling your device. These can be found in Annex I of the MDD. Overall, the Essential Requirements, Chapter 1, Section 1-6, apply to all medical devices. However, some specific requirements apply only to certain device types, such as measuring devices or those using radiation or electricity. Manufacturers generally use standards to address compliance, and particularly European Norm harmonized standards published in the Official Journal of the European Union (OJEU).

2. **Device Classification.** Device classification further dictates the contents of a technical file or design dossier. The European device classification scheme follows a risk continuum: lowest risk devices are Class I (non-sterile, non-measuring) and the highest risk devices are Class III. However, the factors that determine risk level are complex. The classification of your device defines, in part, your device's "route" to conformity assessment, as the MDD indicates additional conformity requirements based on your classification. Once your device is properly classified, you can accurately identify the rules that apply to your device. Classification criteria can be found in Annex IX of the MDD.

3. **Conformity Assessment.** Conformity assessment is the purpose of the technical file: the information in the file should demonstrate that your device conforms to the rules laid out for your device type and class in the MDD. These rules relate to every aspect of your device's lifecycle: from design and function to quality systems and manufacturing. In formal terms, conformity assessment refers to the Notified Body audit in Step 6 of the registration process. However, some low-risk devices are not required to complete the audit. In this case, a thorough technical file should prove your compliance and you should feel confident signing a DoC. Conformity assessment procedures are discussed in Article 11 of the MDD.

According to paragraph 10, Article 11 of the MDD, the "notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure." In other words, you should provide any information requested by the NB to demonstrate that your device conforms with the Essential Requirements. If you believe specific requirements do not apply to your device, you must justify your position with sufficient data to assure the device complies with the Directive.

Common Elements of a Technical File/Design Dossier

Consider a technical file as a narrative document divided into sections. The reports or documents supporting the contents of the sections and the ER should be appended to the technical file as attachments. In certain circumstances, these supporting files may be referenced. The following elements are recommended, though this list is not exhaustive nor prescriptive:

- **Description of the device.** This section might include the following information: design, characteristics, performances, representative images, intended purpose, patient population, medical condition, accessories, brief market history, classification (see Annex IX, Classification Criteria) and rationale, as well as the selected conformity assessment route. You may also add data about the device's materials.
- **The Essential Requirements (ER) checklist.** The ER checklist should be reproduced verbatim from the Directive and presented as a table with labeled columns, such as ER, applicable applied standard, demonstration of compliance, and location of documentation. Address each ER and indicate whether it is applicable. If the ER is applicable, reference the standard or procedure used. Name the explicit document meeting the requirement and its location – the reviewer should be able to identify the specific document. If the ER is not applicable, provide an explanation supporting your position. The ER checklist functions as a signpost that provides identification and location of the supporting documentation.

Note:
The ER checklist should guide design and development of the medical device, as failure to align with the Essential Requirements will inhibit the marketability of your device in Europe until conformity is achieved.

- **Risk assessment.** In this section, discuss conclusions and outcomes from risk assessment activities. The risk assessment document should be included as an attachment. (Use of EN ISO 14971:2012 is strongly encouraged, as NBs will expect a manufacturer to comply with that standard.)
- **Bench testing.** Include a synopsis from test reports (if applicable) that substantiate the device's performance and safety: in-vitro performance or safety; mechanical, physical, chemical and/or animal studies; biocompatibility; packaging; shelf life; stability; and sterilization. (Note: You may address packaging, shelf life, and sterilization in separate sections.)
- **Manufacturing.** Provide a manufacturing flow chart and rudimentary description of the method of manufacturing to demonstrate inspection and preventive monitoring steps, conditions of manufacture, quality system certifications held by the manufacturer or critical subcontractors, labeling control, and traceability. A flow chart is useful when contractors perform multiple functions or when the manufacturer relies heavily on outsourcing.
- **Clinical evaluation.** This section is a summary of the Clinical Evaluation Report (CER), with the full CER attached to the summary. When Directive 2007/47/EC was transposed into national law in December 2008 and applied in March 2010, all medical devices seeking CE Marking were required to produce a CER, regardless of their classification. CERs will be discussed in greater detail later in this paper.
- **Labeling.** Include a draft of your device's labeling. You may also include the CE marking with the four-digit NB identification number, if relevant. Use of symbols, particularly those described within EN 980, are encouraged.
- **Declaration of Conformity.** Issue this document as a draft; however, each NB and reviewer may have its own expectations as to what the document should contain. The DoC draft, which could reference the NB-issued CE marking certificate number, is signed and issued after the manufacturer has met all the requirements of the directive. DoCs will be discussed in greater detail later in this paper.

Clinical Evaluation Reports

As previously discussed, all medical device manufacturers are required to produce a compliant Clinical Evaluation Report (CER). The CER documents results of the clinical evaluation of your device. A compliant CER demonstrates that the clinical evaluation process conforms with that outlined by the MDD. The evaluation process should support strong clinical evidence that your device achieves its intended purpose without exposing users and patients to further risk.

Approach the CER as a standalone document even though you will include it as an attachment to your technical file or design dossier. A list of possible elements to include in your report, as recommended in the Guidelines on Medical Device 2.7.1 rev. 3, Appendix E. is as follows:

- General information: device and manufacturer name
- Concise physical and technical device description and intended application
- Outline of intended therapeutic or diagnostic claims
- Clinical evaluation and data types
- Summary of clinical data and review
- Describe analyses used to assess performance, safety, and relevance/accuracy of product literature
- Conclusions about safety, performance, and conformity

Note:
You are required to prepare and submit a CER for NB review with your technical file as part of the CE Marking/conformity assessment process. However, this is just the beginning of your CER's lifecycle. Consistent updates to the CER should occur from ongoing clinical evaluations, if needed, or as part of your post-market surveillance, risk management, and vigilance operations.

Declaration of Conformity

The Declaration of Conformity (DoC) is a legally binding document that declares you are in compliance with all the applicable legislation necessary to sell your product in the European Union. Specifically, it states that your device conforms with the Essential Requirements and the MDD. All medical device manufacturers must complete a DoC, regardless of their device's classification.

Elements of a DoC vary depending on the guidance of your Notified Body. And, there is no mandatory format. Note the proposed MDR has Annex III which discusses the EU DoC in detail. Nonetheless, it should be printed on company letterhead and written in one of the European Union's official languages, which includes English. Although the DoC is a short document, it should clearly convey that your company and device conform to the necessary requirements. Most DoCs include the following elements:

- Device trade name and model number
- Device classification (Class and Rule)
- Your company name and address
- Name of quality management representative
- Notified Body name and ID number (if applicable)
- CE certificate number (if applicable)
- Date CE Marking was first applied
- Authorized Representative contact information
- Route to compliance (example: Annex II, V, VII)
- Standards applied (optional)
- Name and signature of company officer

The DoC is prepared and signed as the last step in the regulatory process. However, some NBs require a sample DoC with your Technical File. The sample DoC should not be signed by your company's senior executive until you have passed the conformity assessment, where applicable.

A guidance document is an "official recommendation" from a regulatory entity for how to approach device submissions. Many entities publish guidance documents on the topic of technical file content and formatting. While you are not required to follow guidance documents, it is highly recommended, as they may reduce the need to make changes and corrections to your technical file during the conformity assessment.

Guidance from Notified Bodies

Some NBs publish extensive documents describing their position on content and formatting. And, you can assume the NB reviewer assesses your documentation based on a checklist established from its guidance documents. If you have already identified a NB, you may want to request guidance from the NB as well. NBs have unique expectations about the appearance of technical files, so keep this in mind should you change NBs during the conformity assessment process.

Technical files and design dossiers are viewed as controlled documents, for the most part. NBs expect clearly numbered pages for easy identification and review. Present your information in an organized, concise, and coherent manner to facilitate evaluation by the NB, using synopses and conclusions, if applicable. Tables and flow charts are effective tools to provide summary results. Generally, documents that demonstrate compliance with the ER are summarized in the text of the technical file or design dossier and included as an attachment or appendix.

Summary Technical Document Preparation

Summary TEchnical Document (STED) is a harmonized format for submitting information for regulatory approval of devices. The format was created by the former Global Harmonization Task Force (GHTF) to harmonize the regulatory requirements among different jurisdictions (GHTF members included Australia, Canada, the European Union, Japan, and the United States, as well as other signatories).[2]

STED may be used to describe how the device was developed, designed, and manufactured, and also to demonstrate how the device meets the "Essential Principles of Safety and Performance of Medical Devices." Then it may be submitted as the regulatory documentation globally, not withstanding country specific requirements.

STED guidance documents often provide detailed instructions about formatting your submission as well. You can expect instructions about the required information and how to organize it, as well as how to quote and cite references. You will also find specific instructions about how to format your document, from paper and font sizes to printing and page numbering.

Conclusion

Quality preparation is essential to the success of your technical file. Lay a firm foundation for the project by identifying the applicable directive, accurately classifying your device, and identifying the appropriate route to conformity. Carefully choose your Notified Body and heed the directions provided in guidance documents. Most of all, reference conformity and regulatory requirements early in your endeavor to avoid any surprises or costly corrections.

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About the Author

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References:

1 A registrar can be engaged to issue a certification to the QMS for a manufacturer of a Class I self-certified medical device.

2 The MDR Annex II, proposes the STED format for the technical documentation.