



LNE/G-MED North America, Inc.
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Tech File Evaluation

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The technical file is the key to a medical device's certification for CE marking because it contains the most important information about the device, how it works, how it is manufactured, and how it meets the applicable regulatory requirements. This file can often make or break a device's certification, especially if the file contains inconsistencies or has missing parts. In Europe the content of the technical file is governed by the relevant Directive(s). These guidelines are a foundation for the regulations that outline the contents of the technical file, or technical documentation. It is essential that manufacturers to follow the jurisdiction's requirements for the technical file because if a manufacturer cannot follow the requirements, a market may be completely closed to the manufacturer.

What the Technical File Should Contain

A technical file for CE marking has two parts. The first part includes all the necessary administrative information and a summary of the most important technical data to help the reviewer understand the significance of the detailed technical data.¹ The second section is the specific documents necessary to verify that the manufacturer meets all the claims and performance requirements and controlled the risks.²

According to the Directive and the Guide, the technical file must include:

- Details about the manufacturer and its European Representative (when applicable), such as the name and address;
- The device's identifying information;
- The device's class, class rationale, and the directives and standards that apply;
- A general description of the product and its variants;
- Product designs and any explanations to make the designs easy to understand;

¹ NB-MED/2.5.1/Rec5 section 4.1

² NB-MED/2.5.1/Rec5 section 4.2

- A risk management file;
- Any inspection results and design calculations;
- Pre-clinical evaluation including evidence that the device complies with the standards and meets the claimed performance;
- The clinical evaluation, including the analyzed clinical data
- The manufacturing process, equivalent to the Device Master Record as defined in the US QSR);
- Any sterilization methods used, including demonstrating controlling the product's sterility where applicable;
- The solutions the manufacturer adopts so the device conforms to essential requirements listed in Annex I of the applicable Directive; and
- The device's labeling (label on product and packaging, and instructions for use).

Additionally, the technical file is not built to simply collect dust on a shelf. Instead, the technical file is a living document that must be updated to reflect any changes in the device. It is also important that the manufacturer controls the documents so any changes to the file can be traced. These changes include, among others:

- Design changes;
- Labeling changes;
- Manufacturing process changes;
- Results of post-marketing surveillance; and
- Updates of the risk management file AND THE CLINICAL EVALUATION.

The following tables show, for each device class, which annex describes of the technical files depending on the assessment route chosen by the manufacturer:

Figure 1: Medical Device Directive (93/42/EEC) and Active Implantable Medical Device Directive (AIMD – 90/385/EEC)

<u>Annex</u>	<u>Class I</u>	<u>Class IIa</u>	<u>Class IIb</u>	<u>Class III and AIMD</u>
II.4 (Design Examination)		✓	✓	✓
III (Type Examination)			✓	✓
VII (Declaration of Conformity)	✓	✓		

Figure 2: In Vitro Diagnostic Directive (98/79/EC) Annexes for Each Type

<u>Annex</u>	<u>Ann. II List A</u>	<u>Ann. II List B</u>	<u>Self-Testing</u>	<u>Other</u>
III (Declaration of Conformity)			✓	✓
IV.4 (Design Examination)	✓	✓	✓	
V (Type Examination)	✓	✓	✓	

The information in these items is critical for a notified body to assess the device's conformity and ensure that it meets the safety and design standards that apply to the device. Each directive that governs each device may have specific details and need additional information to add to the device's technical file.³ It is very important to include all the information required by the respective regulations to ensure that necessary certificates are obtained in a timely manner, and that the CE Declaration of Conformity can be approved.

How Notified Bodies Assess Technical Files

The directives and guidelines (MEDDEV, NBOG Best Practice Guide, NB-MED) also outline the factors a notified body should use when assessing the technical file. The information included in the technical file may be quite similar for devices regardless of the class. The main difference is the extent to which the notified body assesses the file. Because the European Directives classify devices based on their risk, the directives give different instructions for notified bodies to assess a technical file depending on the class of the device.⁴ Note that even though there are no requirements for the manufacturer to structure the technical file a specific way, knowing how the notified body will review the file helps with the structure.

Reasonably, the more risky the device, the more thorough the assessment is as a result of its complexity and the risk of harm to patients. While notified bodies assess each product's technical documentation, the highest risk products will undergo a systematic and comprehensive assessment of their technical documentation. Medium risk products will typically be assessed on a sampling basis. The sampling rate is lower with class II.a than for class II.b products. When deciding which representative sample to use, the notified body looks at the novelty of the device and its technology, the intended use of the device, and any similarities that it may have with an existing device. The notified body should also look at any previous tests performed on the device. When reviewing the technical file, the notified body should keep in mind the class of the device, if the device or technology is new, the degree to which the device will intervene in a person, and the complexity of the design and technology.⁵ Devices assessed according to design or type examination must undergo this assessment for not only the initial certification but also for any changes to the device.

³ NB-MED/2.5.1/Rec5 1

⁴ NBOG BPG 2009-4.

⁵ NBOG BPG 2009-4 4.3.

Common Pitfalls in Assembling a Technical File

Given the complexity of the directives governing the technical file it can be easy to forget to include a document or misunderstand an instruction. Some common mistakes in a technical file include:

- Inconsistencies within the file: contradictory information on different documents in the file;
- Missing risk management system data: manufacturers must include the risk management system data for the lifecycle of the device, not simply for its performance;
- Keeping trade secrets: while notified bodies are sympathetic, manufacturers must still provide proprietary information so the notified body can accurately assess the device;
- Unstructured technical documentation, making it difficult for the notified body to find the information they look for;
- No gap analysis: If a product was tested and marketed for many years, the tests and trials the manufacturer initially performed may not comply with new directives. Manufacturers must include information on how the devices may not comply; and
- Building a set of documents without “binding” them together so that the data’s significance or the reasons for its inclusion is not explicit.

Preventing these mistakes is requires diligently following the Directives and guidelines. Notified Bodies inform manufacturers of any issues in the technical files, but fixing the technical file may stall the process and ensure the device does not reach the market as quickly.

The Summary Technical Documentation by the GHTF

The Global Harmonization Task Force (GHTF) created the *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*.⁶ The GHTF created this document to aid manufacturers addressing the different jurisdictions expectations. Actually, while the harmonization initiatives aim at limiting the variations between international regulations, especially in term of criteria for safety and effectiveness of the devices, the schemes for the assessment of the evidence of compliance vary. For example, the European Union has not adopted the STED. The basic idea is that all the regulations require a similar set on information, to be complemented specifically to each submission and/or assessment. Structuring the information as proposed in this STED guidance document helps managing the different files to provide to the

⁶ GHTF/SG1/N011:2008.

competent authorities and/or certification bodies. Today, Canada and Brazil are 2 Countries that explicitly refer to the STED.

The technical file aims to demonstrate your device's compliance with the essential requirements. As a result, manufacturers must build it keeping in mind that someone who is unfamiliar with the device will review it with limited possibilities for a manufacturer's explanation. Your device's technical file is a key part of your device's certification. Ensuring that it is correct and complete gives your device a clear path to the market, and to your bottom line. If you would like our expert and technical team to help you with this key part of your device's certification, [contact us](#).

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