



Congenius Whitepaper Series | Technical Documentation

# Part 1 | Technical Documentation Essentials

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## In this whitepaper...

**A thorough understanding of regulatory requirements is essential for creating technical documentation (TD) that meets compliance standards across multiple jurisdictions. But there are several challenges to overcome that underscore the urgent need for a more efficient approach to TD management.**

Before we dive into the challenges of maintaining TD and how to overcome these hurdles however, this whitepaper, the first of our TD whitepaper two-part series, will outline the essentials regarding the collation of the required documentation. Due to the impact of MDR and IVDR on TD requirements, we'll begin by looking at the EU, before expanding to other global regulatory frameworks and standards. The following pages will cover:

- [Defining Technical Documentation in the EU](#)
- [How to structure Technical Documentation in the EU](#)
- [Navigating the TD requirements for global regulatory frameworks](#)
- [Balancing regional regulations & global standards](#)



# Defining Technical Documentation in the EU



## Defining Technical Documentation the EU

### What is Technical Documentation (TD) in the EU, and why is it important?

Often referred to as the "Technical File," TD is the foundation of the conformity assessment process and a non-negotiable requirement for medical device certification.


It serves as comprehensive proof that a medical device complies with the General Safety and Performance Requirements (GSPRs) outlined in the Medical Device Regulation ([MDR 2017/745](#)) and the In Vitro Diagnostic Medical Devices Regulation ([IVDR 2017/746](#)).

As you may already know, these regulations have dramatically expanded the scope and complexity of technical documentation, requiring manufacturers to navigate a more intricate landscape than ever before.

As a vital record of compliance, **TD applies to all device classes**, regardless of risk, and must satisfy regulatory authorities (e.g., the European Medicines Agency) and notified bodies to achieve CE conformity.

**Annexes II and III of the MDR and IVDR** provide detailed guidance on the required content and structure of the TD, raising the bar from the previous MDD and IVDD directives. With stricter requirements, particularly regarding post-market surveillance criteria (Annex III), the emphasis is now on meticulously organised documentation, and there's a stronger focus on lifecycle management.

Within this landscape, managing technical documentation is no longer just a box to tick by regulatory teams - **it's a strategic, company-wide imperative for navigating approvals and ensuring ongoing compliance.**



**How to structure your  
Technical Documentation  
in the EU**



## How to structure your Technical Documentation in the EU

The EU MDR and IVDR demand that manufacturers maintain meticulously organised technical documentation to prove compliance with essential safety and performance requirements.

Far from a mere formality, the TD must adhere to stringent guidelines prescribing its format and content - here's a summary of what it entails:

### Device description & specification

Labelling &  
Instructions for Use

Design &  
manufacturing  
information

Compliance methods,  
standards, alternative  
approaches

Benefit-risk analysis &  
risk management  
system

Product verification &  
validation

Post-Market  
Surveillance  
documentation

## How to structure your Technical Documentation in the EU

### Device description & specification

The **device description and specification** section serves as a foundation, offering a detailed overview of the device, including its trade name, intended purpose, user demographics, and technical specifications. This section also requires information on the device's risk classification, operational principles, novel features, configurations, and accessories, while referencing prior generations and similar devices on the market to establish traceability and context.

### Labelling & Instructions for Use

Information to be supplied by the manufacturer encompasses **comprehensive labelling for device and packaging at all levels** - single unit, sales, and transport - across languages accepted in target markets. **Instructions for use** must also be provided in these languages to meet local regulatory and user expectations.

### Design & manufacturing information

The **design and manufacturing information** section delves into every stage of the device's development, offering details on specifications, manufacturing processes and validation procedures, monitoring, and final product testing. It includes data on suppliers and subcontractors, ensuring transparency across all design and manufacturing locations.



## How to structure your Technical Documentation in the EU

### Compliance methods, standards, alternative approaches

To meet the General Safety and Performance Requirements outlined in Annex I, manufacturers must document and validate **compliance methods**, including justifications for inapplicable requirements. This section also details the **standards or alternative approaches used**, with precise references to supporting documents within the technical file.

### Benefit-risk analysis & risk management system

Risk management is a critical component, incorporating a **benefit-risk analysis** that demonstrates the device's ability to achieve its intended purpose safely and effectively under normal conditions. It outlines a robust **risk management system** addressing the entire lifecycle, with measures to mitigate risks, manage residual hazards, and provide safeguards and training.

### Product verification & validation

The **product verification and validation** section compiles the results of all tests and analyses conducted to ensure the device's safety and performance. This includes preclinical and clinical data, biocompatibility studies, and specialised evaluations for unique device features, such as sterility or use of biological materials. Where new testing is unnecessary, clear justifications must be provided to confirm compliance.

## How to structure your Technical Documentation in the EU

### Post-Market Surveillance documentation

Finally, the **Post-Market Surveillance (PMS)** documentation is key to ensuring ongoing safety and efficacy after market entry. A structured PMS plan outlines processes for collecting and evaluating data from incidents, literature, and feedback, with thresholds for risk reassessment. This includes periodic safety update reports (PSURs) or PMS reports, ensuring regulatory compliance and accountability.

#### A note on IVDS...

For in vitro diagnostics (IVDs), the technical documentation must also address analytical and clinical performance requirements, with additional considerations based on the risk classification of the device.

Together, these elements create a structured, dynamic framework that serves as the backbone of regulatory compliance while promoting safety, efficacy, and market confidence.



**Navigating the TD  
requirements for  
global regulatory  
frameworks**

## Navigating the TD requirements for global regulatory frameworks

**Medical device authorisation requirements vary significantly across jurisdictions, including the EU, US, Canada, China, and Japan.**

While all regulatory systems mandate the preparation of technical documentation, the content and structure often differ, forcing internationally active manufacturers to compile and adapt their documentation multiple times. This can lead to inefficiencies, adding complexity without proportionate value.

To address this, many regulators, manufacturers, and notified bodies align with international standards set by the IMDRF, adopting the STED ([Summary Technical Documentation](#)) or its successor, the nIVD ToC ([Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents](#)). These frameworks, often used alongside regional regulations or standards like the EU MDR and IVDR, provide a unified structure that simplifies compliance across multiple markets.



## Navigating the TD requirements for global regulatory frameworks

The **FDA**, while actively contributing to the development of STED and ToC, is charting its own path with the [eSTAR](#) format, a digital and data-driven submission model. However, eSTAR integrates a mapping to the ToC structure, offering a bridge for manufacturers navigating global frameworks.

Similarly, **Health Canada**, initially favouring the ToC model, has embraced the [eSTAR format in a pilot program](#), reflecting closer collaboration with the FDA.

**China's NMPA** has mandated the use of the [ToC format](#), solidifying its role in regulatory submissions, while **Japan's PMDA** continues to rely on the older STED framework. In southeast Asia, the ASEAN CSDT ([Common Submission Dossier Template](#)) provides a region-specific structure for technical documentation, further diversifying the landscape.

For manufacturers seeking guidance, legacy documents like the [NB-MED 2.5/1](#) recommendation remain practical resources, offering clarity in cases of ambiguity. As regulatory systems evolve, leveraging these global and regional frameworks ensures technical documentation not only meets diverse compliance requirements but also minimises duplication, enhancing efficiency and consistency across markets.



A teal-tinted photograph of an operating room. In the foreground, a large, circular surgical light fixture is prominent, with its mesh-like interior visible. Below it, another similar light fixture is partially seen. The background shows various pieces of medical equipment, including what appears to be an anesthesia machine with multiple dials and screens, and other instruments on stands. The overall scene is brightly lit, typical of a surgical environment.

# Balancing regional regulations & global standards

## Balancing regional regulations & global standards

To navigate the complexities of global market access, manufacturers must complement regional regulations like the MDR, IVDR, and eSTAR with detailed standards such as ISO 14971, IEC 62304, IEC 60601-1, and IEC 62366-1 that provide the necessary technical granularity. Regulations are intentionally high-level frameworks, relying on horizontal or vertical standards to address the specifics.

While international standards provide a solid foundation, they are not always exhaustive. So, depending on product-specific requirements, manufacturers may need to deviate from or build upon these standards, developing customised methods to ensure comprehensive compliance and optimal safety.

In the EU, the use of harmonized standards is highly emphasised, as they are referenced in the MDR and provide a presumption of conformity. However, manufacturers should note that:

- Harmonized standards may not always reflect the most up-to-date versions
- A global shift away from harmonization toward region-specific interpretations of international guidelines increases complexity, meaning manufacturers must remain agile, adapting to diverse regulatory demands while maintaining compliance across evolving markets

**Although specific requirements may vary, most regulatory frameworks for medical devices share common documentation themes, including design verification, risk management, and post-market surveillance.**

Familiarity with these shared elements can help manufacturers create a robust documentation system that meets requirements across multiple regulatory bodies. This cross-jurisdictional approach to technical documentation is crucial in achieving efficient regulatory compliance and global market access.



**Should you have a  
Technical Documentation challenge,  
please do get in touch – our Regulatory  
team is ready and happy to help.**