BRING YOUR TECHFILES UP TO DATE AND CONFORM WITH MDR/IVDR REQUIREMENTS!

TechFile Factory

The new Annexes II and III of the Regulation (EU) 2017/745 on medical devices and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices contain detailed requirements for the technical documentation for all medical devices. It is crucial to update existing medical device technical files in order to meet the MDR's and IVDR's new general safety and performance requirements as provided in the respective Annex I.

Due to the high resource investment for the evaluation of existing files and the subsequent closing of gaps, we have developed a flexible and efficient concept to address these needs. We perform an in-depth gap assessment of the MDD or IVD compliant technical documentation, identify gaps and provide recommendations for closing those gaps. As an additional step, we also rewrite and compile the documentation to finally assemble an MDR/IVDR compliant technical file. The entire process is supported by a crossfunctional team of experts to ensure high quality results.

Why Use NSF's TechFile Factory?

- Using our validated software system, proven tools and processes, as well as our extensive experience and network of experts we work with you to identify all necessary data and existing technical documentation.
- Using our well-structured templates and expertise, we reduce the workflow effort for TechFile reviews, and we can spot inconsistencies and nonconformities.
- Based on your processes and input, we cover core topics such as risk management, usability, labelling, clinical evaluation, software, cybersecurity documentation and post-marketing surveillance.
- You will increase your device and regulatory expertise through lessons learned and project feedback cycles from face-to-face meetings, web or telephone conference calls.

Our team is also in close contact with notified bodies and regulatory bodies as part of project work and networking activities, such as workshops and symposia. The result of our service(s) is an easy to understand, searchable and clearly structured technical documentation that can be used to demonstrate compliance with the regulation on medical devices (as well as in vitro diagnostic medical devices) and for acceptance in markets worldwide.

Technical Documentation Training

We show you how to cover the legal and normative requirements with your technical documentation in accordance with regulations such as EU MDR/IVDR. We cover the conformity assessment procedures for Europe and help you with the classification of medical devices.

You get a complete overview of the purpose and benefits for a compliant technical documentation. Using practical examples and project experience, we detail current and new requirements according the STED format, Annex II and Annex III of the EU Regulations as well as the preparation of the general safety and performance requirements (Annex I) checklist.

For more information email **info-medicaldevices@nsf.org**

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