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MEDICAL DEVICES SERVICES

The TechFile Factory

Technical documentation for medical devices is essential in order to show compliance to underlying regulations and to support safety and effectiveness of the products. It is a mandatory prerequisite to place products on international markets. The trigger for the creation of such documentation usually is given in form of new product developments or in form of changes necessary to maintain the current state of the art.

In addition to extensive specialist knowledge, lack of resources often challenges manufacturers to timely and consistently create and maintain the required documentation.

NSF's "TechFile Factory" is a team of experienced experts to support you with these tasks.

Due to our market experience and communication with authorities and notified bodies, we are able to compile a technical documentation taking into account not only the regulatory foundation including applicable standards and guidances but also key aspects and topics that authorities and notified bodies pay specific attention to.

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Our Services

Documentation Preparation

To ensure that the complete technical documentation complies to the current state of the art and reflects relevant, consistent and correct information, the extended remediation activities may include the update or creation of all relevant documents that are part of the technical documentation for various registration purposes, such as but not limited to the

Summary of Technical Documentation (STED) containing:

- Essential Principles Checklists (e.g. GSPR checklist acc. to Annex I EU-MDR / EU-IVDR)
- Declaration of Conformity
- Risk Management documentation acc. ISO 14971
- Usability Engineering documentation acc. IEC 62366-1
- Software documentation acc. IEC 62304
- Labeling documentation acc. ISO 15223-1 and ISO 20417
- Post-Market Surveillance documentation acc. to Regulation (EU) 2017/745 on medical devices or Regulation (EU) 2017/746 on in vitro diagnostic medical devices

The experts of the TechFile Factory can create all required documentation so you can focus on your priorities. The preparation may be based on our internal NSF procedures or on yours.

Our experts respond to the individual wishes and requirements of our customers and create a customized solution tailored to your specific needs. The documentation package can then be used to maintain international market authorization or be used to compile submission dossier on an international scale, e.g. PMA or 510k submission for US American Food and Drug Administration (FDA) or technical documentation according to Annexes II and III of the EU-MDR / EU-IVDR.

Evaluation of existing Documentation

Many manufacturers struggle with the maintenance of the technical documentation due to the huge variety and complexity of international regulations. This results in outdated technical documentation for their medical devices and may lead to problems when notified bodies visit for unannounced audits or FDA visits for an inspection.

NSF offers gap assessments of your technical documentation to help you identify gaps and provide recommendations for efficient addressing of such gaps.

Our gap assessment services include:

- Identification of gaps related to regulations and specified applicable standards
- Provision of recommendations for closing gaps
- Provision of general recommendations for improvement
- Identification of applicable standards
- Identification of outdated applied standards
- Consistency check throughout the technical documentation
- Outline of strong and weak areas
- A detailed discussion of the analysis results