BRING YOUR TECHFILE 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.

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

NSF INTERNATIONAL
Beim Strohhause 17, 20097 Hamburg
E info-medicaldevices@nsf.org
www.nsf-prosystem.com | www.nsf.org