Technical File (TF)

The evidence of conformance to the MDR is documented in the Technical File (TF). The TF covers design, manufacture and intended use of the product and evidence for safety and performance and demonstrates compliance with the GSPR. The TF is submitted to the Notified Body for review and acceptance (except for class I devices). The TF covers the following items (with software section detailed out):

○ General aspects ○ Device description ○ Risk management file ○ List of used harmonized standards ○ GSPR checklist ○ Performance ○ Electrical safety and EMC ○ Usability ○ Sterilization ○ Packaging and shelf life ○ Biocompatibility ○ Clinical evaluation ○ Manufacturing information ○ Labeling ○ Animal tissue ○ Drug/device combinations	• Software Safety Classification and rationale • Software version submitted • Software Requirement Specifications • Software Architecture description • Traceability between requirements and verification/validation activities • Verification / Validation plan • System level test reports • Verification and validation summary • Bugs or Defects including rationales • Release notes • Information how SOUP was validated • IEC62304 compliance report