MDR - Technical File Documentation Requirements of Medical device Regulation (EU 2017/745)

- Duration: 2 Days
- **Main Contents:**
  - Device description, Drawings/formulation, Design, Product Specifications
  - General Safety and Performance Requirements Checklist
  - Test reports in accordance with harmonized standards, CS or other solutions applied
  - Risk Analysis and Usability
  - Chemical, physical and biological tests, In Vitro Testing, Preclinical Studies, Clinical Investigation
  - Biocompatibility Tests, Biostability Tests
  - Microbiological Safety, Animal origin tissue, Using Medicinal Product
  - Clinical Evaluation, PMS & PMCF
  - Package Qualification and Shelf life
  - Labels & Instructions for use
  - Manufacturing Process
  - Sterilization Requirements
  - Declaration of Conformity

Contact Us

How can you register?

You can register online or contact your local DNV GL office for more details and information.

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