ChemSafe®

Your lighthouse in a sea of rules

MEDICAL SERVICES

- **Strategic/Regulatory Consultancy MDR/IVDR** (Regulation (EU) 2017/745 and Regulation (EU) 2017/746))
- **Feasibility Studies**
- **Data Gap Analysis**
- **Pharmacological Evaluation Report**
- **Toxicological Evaluation Report**
- **Biological Evaluation** (ISO 10993-1) (BEP and BER)
- **Clinical Evaluation** (CEP and CER)
- **Performance Evaluation Report**
- **Study Monitoring**
- **Risk Management** (ISO 14971)
- **Preparations/Review of Technical Documentation**
- **Implementation of Quality Management System** (ISO 13485)
- **Contacts with Competent Authorities** (EU and non-EU)
- **Role of Responsible Person for Regulatory Compliance** (PRRC)
- **Role of Authorised Representative** (AR)
- **Economic Operator** and **Devices Registration in Eudamed**

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ISO 9001 BUREAU VERITAS Certification