



# MedTech

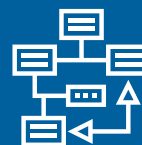
## MD, IVDs, Combination Products

**Asphalion provides comprehensive support during development, certification, registration and post marketing of Medical Devices, IVDs and Combination Products in Europe, US as well as other regions.**

- MedTech Regulatory Roadmaps and Feasibility Assessments for Europe & US
- MedTech EU & US Classification Strategy
- MedTech EU Certification Procedure assistance: CE Marking (including selection and management of communication with Notified Bodies and Technical Documentation submission)
- MedTech EU Technical Documentation preparation, compilation and maintenance (General Safety and Performance Requirements Checklist, Benefit-Risk Analysis and Risk Management activities, Clinical Evaluation Reports, Performance Evaluation Reports, Pre-Clinical Testing activities, Labelling, Post-Market Surveillance and other Technical Documentation core-parts preparation and/or evaluation)
- Support for EU country-specific regulatory requirements (including assistance with local Competent Authorities communication, product registration, facilities licenses, etc.)
- Support in Eudamed registration (economic operators, UDI and devices)
- Assessment and training on 2017 EU Medical Device and In-Vitro Diagnostics Regulations requirements and regulatory impact
- Definition, development and implementation of Quality Management System (QMS) according to ISO 13485, US 21 CFR 820 and MDSAP
- Maintenance of QMS and annual audits programme (including ISO 13485, US 21 CFR 820, UK Medical Device Regulation and MDSAP)



**Regulatory Roadmaps & Feasibility Assessments (EU & US)**



**Classification Strategy**



**Country Specific Regulatory Support**



**Conformity Assessment & CE Mark**



**Technical Documentation**



**Assessment & Training**