Achieve conformity and compliance of your medical devices, IVDs and combination products

SFL's cross-functional team provides strategic advice, operational assistance and tailored support to conformity assessment and post-market related activities.

Our expertise and services cover the entire range of medical devices, IVDs, and combined products, including active devices, software, devices with ancillary medicinal product, medicinal products with integral device components and co-packaged combined products. Our team has extensive experience in gap analysis and classification assessment, review of technical documentation, risk assessments, clinical evaluation reports, interacting globally with Notified Bodies and Competent Authorities, supporting with QMS creation/update as well as with audit preparation and hosting inspections.

STRATEGIC ADVICE

Classification
Gap analysis MDR/IVDR
Regulatory strategy
Article 117, Rules 14 and 21

CONFORMITY ASSESSMENT

Notified Body engagement
GSPR conformity
Audit support
Consultation process

OPERATIONAL SUPPORT

Clinical evaluation
Quality management system
Technical documentation
Trainings

POST-MARKET ACTIVITIES

Regulatory compliance
Post-market surveillance
Post-market clinical follow-up
Vigilance & PSUR

We would be happy to set up a 30-minutes call or meeting free of charge to discuss your project and how we could support you. Take advantage of our expertise and ensure compliance at each step of your product development.

Please contact us at BD@sfl-services.com

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