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History and Mission

ISS AG, Integrated Scientific Services provides services to medtech companies for the development of medical devices, their introduction into the market and their maintenance. Typical services include embedded software development, regulatory affairs and writing clinical evaluation report, CRO, quality management, qualification and validation.
The combination of these services with scientific work methods and project management puts ISS AG into a unique position as a service provider for the medtech industry.

Highlights

ISS already has submitted successfully clinical evaluation reports according to MEDDEV 2.7/1 Rev. 4 and MDR.

With successful product registrations in 99 countries of the world, we are the right partner when it comes to the registration of your product.

Our highly qualified team of software engineers develops embedded and standalone medical software according to IEC 62304.

CRO for medtech and in vitro diagnostics clinical studies

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BVMA member since 2016
Audits passed in 2016 and 2019

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A MEDTECH COMPANY

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Services

Clinical Services
- Clinical Project Management: Study planning (strategy & design), site selection, medical writing and submission of essential documents to Ethics and Comp. Authority, conducting of clinical study (incl. site initiation, routine monitoring, close out, data management and statistics), and completion of the study (data base lock, final statistical analysis, study report, medical writing)
- Clinical Evaluations according to MEDDEV 2.7/1 Rev. 4, MDR

Regulatory Affairs
- Product registrations worldwide
- REGULA™, our submission management software
- RA-Intelligence Services, "on demand" and "push"
- Definition of regulatory strategy within business development processes and projects

Quality Management & Engineering Support
- Building and maintaining Quality Management Systems for MedTech (ISO 13485)
- Creation of and support all around the Technical Documentation
- Interim Quality Manager Services
- Audit Support, V&V
- CAPA, Complaint handling

Software Development (IEC 62304)
- Software Development for medical devices of all risk classes (embedded and stand-alone)
- Software project management
- Strong track record in the fields of medical image analysis, numerical simulations, hardware and system related development (firmware), security applications for medical devices (RFID supported