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BVMA member since 2016
Audits passed in 2016, 2019 and 2022

iss
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

www.iss-ag.ch

History and Mission

ISS AG, Integrated Scientific Services, was founded in 2003 and is specialised in the MedTech and IVD sector.
We offer high-quality and sustainable services that create long-term added value and security for clients and patients. Through our high level of professional competence and the interconnecting of our various areas of expertise, we make an important contribution to the joint success of our customers in the interest of the entire healthcare system.

Highlights

- Swiss service provider (German and French)
- Legal representative for US & EU companies
- Strategic consulting to determine the optimal market approach
- CRO for medtech & in vitro diagnostics clinical studies
- Clinical evaluation reports according to MDR
- Product registrations in more than 100 countries
- Support on clinical and regulatory questions, e.g. PMS needs including PMCF topics
- Development of embedded and standalone medical software according to IEC 62304

REGULATORY AFFAIRS
WORLDWIDE

QUALITY MANAGEMENT
ISO 13485

CLINICAL SERVICES - CRO
EVALUATIONS & STUDIES

SOFTWARE DEVELOPMENT
IEC 62304

REGULATORY AFFAIRS SOFTWARE
REGULA™

Services

Clinical Services
- Clinical Project Management
- Study planning (strategy & design)
- Medical writing and submission of essential documents to Ethics Committee and Competent Authority
- Conducting and completion of clinical study
- Various clinical support (e.g. site selection and initiation, routine monitoring, close out, data management and statistics)
- Clinical Evaluations

Digital MedTech
- Software project management
- Software development for medical devices of all risk classes (IEC 62304)
- Specific knowledge for embedded Software development
- Specific knowledge for stand-alone Software development (e.g. Apps)
- Medtech specific IT services

Compliance Services
- Support on regulatory strategy within business development processes and projects
- Product registrations worldwide
- REGULA™, submission management software
- RA-Intelligence Services
- Quality Management System
- Technical Documentation
- Tailor made PMS / PMCF

Corporate Services
- Scientific Due Diligence for all types of M&A activities
- Para-legal services e.g. for administrative procedures
- Emergency support for urgent projects