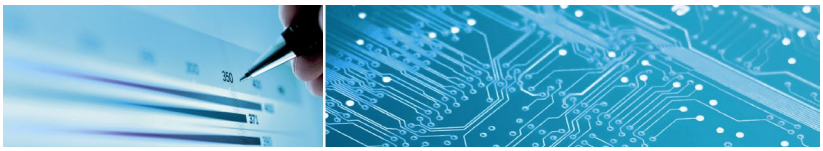
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY



swiss made software

MEDTECH SOFTWARE ENGINEERING

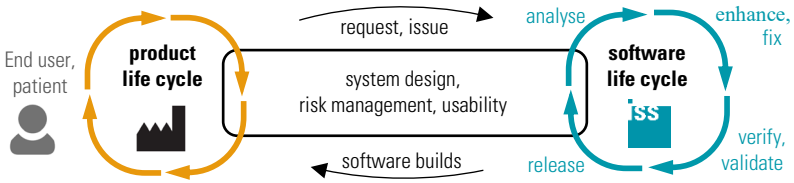
You want to be fast on the market and with a reliable product ? You want to de-risk your project by getting prepared for the regulatory hurdles ?

You have to make sure the development of your software (SW) is done according to the latest applicable requirements for medical devices.
To be successful, you need the right partner, endowed with enough strategic and practical expertise in Digital MedTech.
Our long-standing experience in medical software engineering and regulatory affairs allow us to support you in achieving the development of Digital MedTech products, their registration and maintenance on the market of your choice, worldwide.

What we provide

- Market-ready medical device SW
- Registration strategy and operational support, incl. technical documentation preparation
- Knowledgeable and experienced developers specialised in Digital MedTech

Life cycle management
You have the possibility to use our ISO 13485 certified infrastructure and validated tools. We are compliant with state-of-the-art regulatory framework (EU MDR/IVDR, FDA 21 CFR part 820, IEC 62304, IEC 82304-1, ISO 14971…). This relieves you from some mandatory requirements while ensuring an efficient project process. We manage the whole software life cycle, incl. issue tracking, maintenance processes and software release as needed.



Project management
We lead the SW sector within bigger projects. We manage the corresponding activities and ensure that the development is done according to the applicable regulatory requirements.

Development
We develop the SW part of your medical device. We know all the required processes and we use validated tools. All source codes belong to you.

Verification and validation
We take care of the rule-consistent verification, validation and documentation.

Usability studies
We prepare the usability study or the complete usability dossier according to the IEC 62366.

Gap analysis
We can assess the compliance of your new SW or legacy devices. Our focus is on the registration pathway, risk and quality management, system design, scalability, error handling and maintenance. If needed, ISS AG assists you for the gap filling, incl. via knowledge transfer.

Why ISS

We know how. Relying on many years of experience in Digital MedTech product development, our expertise in all key medical devices fields allow us to provide lean, sustainable and integrated solutions.

Your benefit is the most important part of our services. Therefore, our offer is tailored to your needs and resources. We commit also to focus on your product, your wishes and constraints, and exploit all the synergies of our teams in order to develop the most appropriate SW answering your user requirements.

Your contact

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