ISS
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

MARKET-READY MEDICAL DEVICE SOFTWARE

Our track record of expertise in medical software engineering, regulatory affairs and product management renders us the preferred partner to achieve and maintain marketability and the CE certification for medical device software.

The challenge

The placement of software onto the market does not only require the fulfillment of the customers needs, but also imposes the need of meeting commercial, licensing and quality standards. In addition, software for medical devices and software that classifies as a medical device by itself has to comply with legal requirements of the respective target market (such as the Medical Device Directive MDD, the Medical Device Regulation MDR, FDA or CFDA).

This applies as well to software that is established as a part of, or in combination with existing products for a long time already (so called "legacy software"), but does not incorporate state of the art techniques or current regulatories any more.

Either way, measures to achieve or maintain marketability and certification are inevitable.

Our Services

The expertise of ISS AG includes the applicable regulations and standards, as well as a thorough knowledge of the paths and pitfalls in the terrain of "medical device software" and "software as a medical device".

The marketability of software can be assessed within reasonable effort. The focus is on:
– Classification (medical device classification, software safety classification)
– Software quality, error handling and maintainability
– Scalability of software and system design
– Dependencies on third parties, licences and IP
– Risk and quality management
– Development according to standards
– Certification strategies
– Proof of conformity for the target markets

By performing a gap analysis, the regulatory demands (broken down to single paragraphs of standards and laws as needed) are compared to the existing documentation. Furthermore, ISS AG can professionally assist you to fill the gaps with examples, workshops, direct involvement or even take care of entire projects for you.

Your benefit

ISS AG helps setting up a target-oriented and well timed schedule of activities in order to make your product fit for certification and for the placement onto the market, thus significantly reducing your time-to-market.

Your contact

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