



HOW CAN YOU KEEP **HEALTH SOFTWARE** SAFE LONG-TERM?

IEC 82304-1 HEALTH SOFTWARE PRODUCT CERTIFICATION & SGS HSP MARK

Mobile apps, web portals, and desktop applications with IT-network connectivity are overwhelming the healthcare ecosystem. The safety, security and performance of health software depends very much on its development process, accompanying documentation and product related post market activities.

THE BENEFITS

IEC 82304-1 Health Software Product certification allows you to generate evidence towards presumption of regulatory conformity, based on risk assessment.

The SGS HSP Mark makes you stand out from the competition through strong post market activities follow-up. It also allows eventual phased step-up from an initial non-medical classified HSP towards "Software as a Medical Device" regulatory scrutiny.

MARKET

Software only products for health use, hosted or running on generic devices without specific sensors.

HOW THE CERTIFICATION PROCESS WORKS

- Step X – Optional pre-evaluation of readiness and weaknesses
- Step A – Tailored proposal from SGS
- Step B – Formal assessment of documents, records and key development system elements
- Step C – IEC 82304-1 certification
- Step D – SGS HSP Mark contract
- Step E – SGS HSP Mark pre-licence visit
- Step F – SGS HSP Mark attribution
- Step G – Yearly surveillance visits to check validity and evaluate eventual product changes

Re-certification assessment after three years.

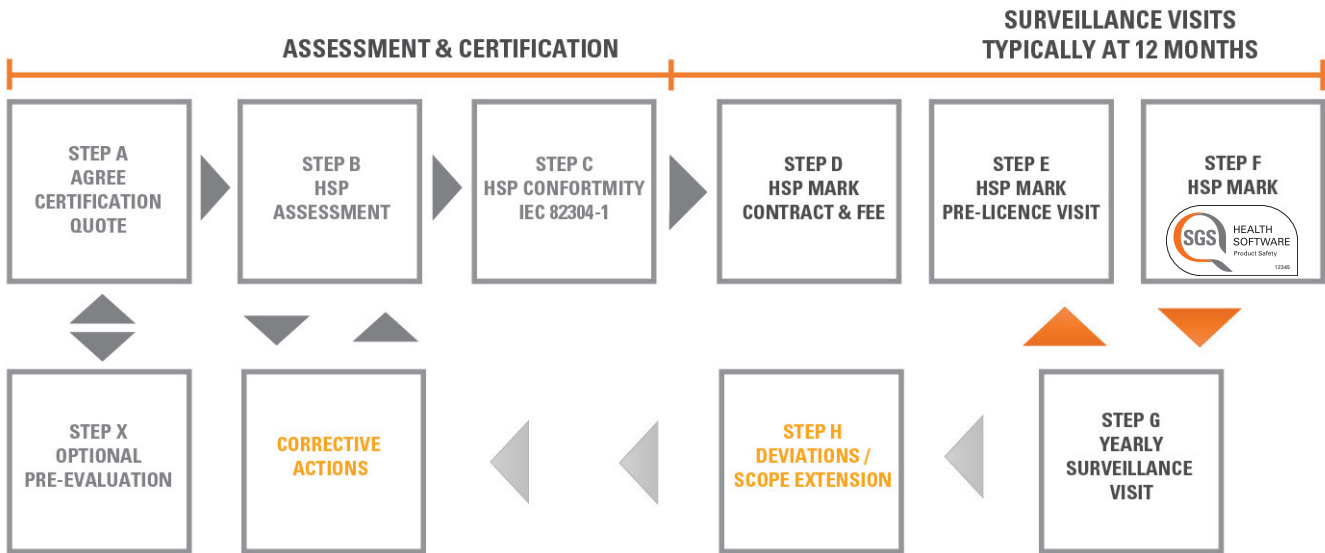


RELATED SERVICES

- IEC 82304-1 application training
- Consumer/health device product certification
- Medical device product certification
- Pre-evaluation of product readiness and weaknesses

IEC 82304-1 CERTIFICATION PROCESS

HSP MARK PROCESS



WHY SGS?

SGS is the world’s leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity.

With more than 90 000 employees, SGS operates a network of over 2 000 offices and laboratories around the world.

Enhancing processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your

services and value chain by increasing performance, managing risks, better meeting stakeholder requirements and managing sustainability.

With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

TO LEARN HOW SGS CAN HELP YOU TO KEEP YOUR HEALTH SOFTWARE SAFE, VISIT WWW.SGS.COM/EE OR CONTACT CEBEC.INFO@SGS.COM FOR MORE INFORMATION.

SGS IS THE WORLD’S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.