Brightsight MedTech cybersecurity evaluation services

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By SGS

MedTech cybersecurity solutions solutions

We support the medical device industry with comprehensive training, testing, evaluation and certification services. We cover a full range of products and components that may be evaluated in one sector and then shared across multiple industries, including MedTech. Our scope encompasses the entire product life cycle from product design to post-market with tailored services.

PRE-EVALUATION

- Workshops/training;
  - Awareness training
  - Regulatory and guidance landscape
  - Secure product life cycle
  - Threat modelling and risk assessment
  - Design and architecture
- Pre-evaluation testing on specific components of the full product (e.g. module, security mechanism, etc.)

EVALUATION

- Technical documentation review against:
  - Market regulations – FDA, MDR, NMPA, etc.

- Vendor requirements
- Global standards – IEC TR 60601-4-5, IEC 81001-5-1, DTSec, etc.
- Conformance testing:
  - Vulnerability scans
  - Penetration testing
  - Source code review
  - Binary code review
  - Reverse engineering, etc.

CERTIFICATION

- SESIP, CLS (MD), etc.
- SGS Cybersecurity Mark

MedTech device regulations are becoming stricter, with calls for mandatory certification accelerating around the world. In a complex, fragmented regulatory landscape encompassing global standards (ISO/IEC) and regional requirements (US FDA, EU MDR, China NMPA, etc.), how can you efficiently and cost-effectively deliver secure and safe devices that are compliant to global markets?

Brightsight offers comprehensive solutions to help you successfully access target markets with compliant products, enabling risk mitigation and market differentiation.

The health sector is designated a critical infrastructure according to the EU's Network and Information Systems Directive 2 (NIS2) and US FDA data shows cyberattacks are on the increase, causing greater disruption and possible mortality.

MedTech offers multiple advantages to patients and health services but there are inherent vulnerabilities in terms of cybersecurity if a device is not correctly designed, tested and updated.

In this rapidly evolving security landscape, regulators are now demanding manufacturers adopt a risk-based approach using good cybersecurity protocols. Evidence of cybersecurity management is a mandatory requirement in many markets.

MedTech manufacturers and suppliers must ensure their devices meet recognized standards for safety and security to ensure compliance, reduce liability and differentiate their product in competitive markets.

SESIP – use component certification for device certification

A medical or healthcare device can be built upon secure and certified components (chips, real-time operating systems, software, apps, etc.). This chain of trust is provided by composite evaluation, as supported by SESIP. Composition – re-using certified components to create a cybersecure device – enables cost reductions while expediting time to market.

SGS is an active collaborator in SESIP – Security Evaluation Standard for IoT Platforms. We verify components from multiple industries, including MedTech, providing you with an opportunity to speed up the evaluation process and reduce costs.

MEDTECH ACCREDITATIONS

STANDARDS&REGULATION

Why choose Brightsight?

With over 40 years of experience in cybersecurity and a growing global network of specialist testing facilities, Brightsight is the world's number one independent security evaluation service provider for the MedTech sector. We hold the largest number of Common Criteria accreditations in the market and perform 700+ evaluations a year. We understand the market and the technical requirements relevant to your MedTech device.

Our experts support the streamlining of evaluation criteria into a single assessment process that incorporates all relevant global, regional and vendor requirements – one evaluation, multiple certifications.

Brightsight is your first choice for independent testing and certification services when you want to efficiently deliver safe and compliant MedTech devices to global markets.

BRIGHTSIGHT IS PART OF SGS.
THE WORLD'S LEADING TESTING,

BRIGHTSIGHT MEDTECH TEAM

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