



Italia

Scegli la certezza.
Aggiungi valore.

Functional safety for medical devices

Assuring safety and reliability
for patients and users.

Your challenges

Medical devices are among the most highly regulated products in the world today. A single functional failure can mean the difference between life and death for patients. The World Health Organisation has recommended that governments worldwide make national regulations for medical devices an integral part of their overall national health system.

What is functional safety in medical devices?

Traditional safety assessment focuses on potential hazards from electrical, mechanical or other aspects of a design occurring during usage. Functional safety is an additional step focussing on the reliability of the product to function correctly and safely in response to its inputs. It provides assurance that safety-related systems in the device will offer the necessary risk reduction required to minimise the severity and probability of harm in the event of malfunction.

Why is functional safety important for your business?

Ensuring the functional safety of medical devices is critically important for manufacturers, importers and resellers, as these devices can impact the health and wellbeing of the operators and patients that use them. By undertaking risk analysis and manufacturing medical devices that are functionally safe, your company benefits from increased market acceptance and positive brand associations. Failure to ensure functional safety can have dire consequences.

Functional safety expertise from TÜV SÜD

Having developed the first functional safety certification programme for professionals in the process industry over 10 years ago, TÜV SÜD is a pioneer in functional safety services. We are one of the few third-party conformity assessment bodies with functional safety experts for medical devices who can provide functional safety tests.



Our functional safety testing assessment services

Functional safety should be addressed at an early stage to avoid costly rework. TÜV SÜD excels in this area, providing unrivalled testing for functional safety assessment services from the onset.

■ Independent safety assessment (ISA)

TÜV SÜD's team of experts can test the functional safety concept of a medical device after it is prototyped and before implementation of routine production. We also offer ISA on the overall risk management system to determine if it is sufficient for the stringent requirements placed on medical devices.

■ Software safety assessment

A software glitch in sophisticated medical equipment such as MRI and X-Ray machines can have catastrophic consequences for patients and operators. That is why TÜV SÜD's functional safety programme emphasises the assessment of medical software against safety standards such as IEC 60601 and IEC 62304.

■ Product testing

We also offer electrical safety testing, electromagnetic compatibility testing and environmental testing services for medical devices.

Your business benefits

- **Cultivate a trusted brand** – built upon a line of products known to be functionally safe with fewer incident reports.
- **Save time and money** – by minimising corrective actions in the field as well as the cost of re-engineering products with poor functional safety.
- **Gain a competitive edge** – by working with our diverse industry-leading experts, who will provide you with the highest quality reports that keep you one step ahead of the competition.

Why choose TÜV SÜD?

TÜV SÜD experts preside on standardisation committees for functional safety and can keep you informed of emerging standards and regulations so that you stay ahead of the competition. In the field of medical devices, we are one of the largest Notified Bodies in the world, having over 400 dedicated Medical and Health Services (MHS) experts situated in major markets worldwide. In addition, we have a dedicated Regulatory Foreign Affairs & Clinical Department for monitoring and understanding updates in medical health services and devices regulations worldwide.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certification. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Assessments of clinical evaluations
- Electrical, mechanical and software safety
- Expertise in high-risk medical devices
- IEC 60601-1 (Edition 3.1)