



Add value.
Inspire trust.

IEC 62304

Certify your medical device software to international standards.

Your challenges

Medical device software is highly complex and requires a different development approach compared to hardware. The approach also differs according to whether the software is a stand-alone software only product, or whether it is integrated into a medical device. Potential hazards resulting from the use of commercial off the shelf software must also be accurately evaluated. For all new or modified medical device software, the challenges of software safety classification, commercial software and segregation must all be addressed.

What is IEC 62304?

IEC 62304 is an international standard which creates a common framework for the software development lifecycle. This process includes software development planning, requirement analysis, architectural design, software design, unit verification, software integration and testing, system testing, and software release. The documentation detail and depth of tests required vary according to the criticality of the software.

IEC 62304 focuses on the software development process, defining the majority of the software development and verification activities in five stages:

- Development
- Maintenance
- Risk management
- Configuration management
- Problem resolution process

IEC 62304 requires that a software safety classification is assigned to each software system:

- A** - no injury possible
- B** - no serious injury possible
- C** - serious injury or death possible

Segregation allows separate safety classifications to be assigned to individual software items within the final medical device.

IEC 62304 CERTIFICATION PROCESS

Initial certification - Review of the quality management system documentation in accordance with the IEC 62304 standard, and assessment of life-cycle documentation of the relevant software product (stand-alone software or embedded software).

Certificate updates - Notify the certification body of any software changes. Following a change review, the number of the software revision is updated on the certificate. Minor bug fixes that do not result in a usage change or change in the accompanying documentation need not be reported.

Recertification - Recertification of IEC 62304 is typically combined with the ISO 13485 recertification. During IEC 62304 recertification, all relevant changes to the software lifecycle processes will be reviewed in addition to software changes covered by IEC 62304.

Why is IEC 62304 important for your business?

IEC 62304 enables medical device manufacturers to follow good development practise and produce high-quality software. It demonstrates product compliance with international standards. Harmonised by the European Union, it meets software development requirements in all three Directives: Medical Devices Directive (93/42/EEC), Active Implantable Medical Device Directive (90/385/EEC) and In Vitro Diagnostic Directive (98/79/EC). Similarly, it is harmonised by the United States and is a Food and Drug Administration (FDA) recognised standard.

Our IEC 62304 services

Clients wishing to become IEC 62304 certified must hold a valid TÜV SÜD certificate for ISO 13485, a quality management system standard which encompasses aspects of the ISO 9001 standard, plus additional industry-specific medical device requirements.

Our IEC 62304 services include:

- Gap analysis** - of your existing processes and documentation against IEC 62304 requirements.
- Testing and certification** – in accordance with the IEC 62034 standard.
- Software evaluation** - addressing the challenges of software safety classification, commercial software use and segregation.
- Training** - addressing the requirements and challenges of IEC 62304.

Your business benefits

- Reduce time to market** – by meeting software requirements of global markets with an internationally recognised standard.
- Save time and money** – by avoiding costly delays in redesign through product compliance from the early stages of the development.
- Gain a competitive edge** – through working with our diverse industry-leading experts, who will provide you with the highest quality services that keep you one step ahead of the competition.
- Work with a single-source partner** – that is an internationally recognised testing body with a strong presence in all major markets worldwide.

Why choose TÜV SÜD?

With over 500 dedicated medical health and services experts situated in major markets worldwide, TÜV SÜD is one of the largest Notified Bodies in the world. In addition to regulatory and quality assurance expertise, TÜV SÜD's experts are also skilled in advanced medical device assessments for software and functional safety, particularly for areas related to essential performance. With in-depth knowledge and experience of the key medical device markets around, our dedicated team provide assessments that cover the full lifecycle of your medical device.

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TÜV SÜD is a premium quality, safety, and sustainability solutions provider specialising in testing, inspection, auditing, certification, training, and knowledge services. Represented by more than 22,000 employees across 800 locations worldwide, TÜV SÜD's service portfolio adds value to businesses, consumers and the environment.

Related services

- TÜV SÜD provides the following related services:
- IEC 60601-1
 - Functional safety for medical devices
 - EC certification
 - Expertise in high-risk medical devices