



Medical Device Testing

**Add value.
Inspire trust.**

Providing trusted medical device assessments in all major markets

How TÜV SÜD can support you quickly and efficiently

We understand how important it is for you to get innovative medical products to market in a quick and efficient manner. We recognize that patients need medical products as soon as possible and that missed timelines, or incorrectly tested products can prevent lives from being saved.

The medical devices sector is undergoing rapid changes driven by technological advancements, increasing costs, and changing regulations. Challenges faced by manufacturers include:



Expertise

- We actively contribute to groups that drive global standards and regulations, ensuring that your device is compliant with the latest requirements.
- Our global team of experts combines their industry and laboratory testing experience to ensure that testing is done in accordance with state-of-the-art standards and global regulatory requirements. All TÜV SÜD laboratories are ISO 17025 accredited.



Customer service

- We believe that all customers are created equal. Customer representatives will work with you to ensure timely responses that help you get answers when you need them.
- Our teams maintain consistent communication throughout the entire process. From your initial inquiry to completion, our team will always keep you informed of your project's status.



Time to market

- We understand the importance of minimizing time-to-market for competitive advantage which is why we offer market-competitive turnaround times, including standard and expedited services.



Comprehensive testing solutions

- TÜV SÜD's global network of laboratories offers one of the widest arrays of medical device testing. We provide testing where you want, when you want, and in the language you want.
- Our team of product and testing experts guide you through the requirements for your specific product, and can customize your testing project based on your needs.

How can we help you?

TÜV SÜD has supported medical device manufacturers with testing for more than 30 years. Our global team of medical experts works in state-of-the-art laboratories to provide trusted assessments across the wide spectrum of medical devices services.

Our experts have in-depth knowledge and experience of global regulatory requirements. They can support you with testing products in the early design phase, as well as product validation, routine monitoring, and product modifications. We believe that the quality of testing, as well as a unique design and test setup for each specific product,

are crucial for demonstrating the overall safety of medical products, because how it's tested matters. Our rigorous and data-driven testing methodologies ensure optimal device performance, leading to improved patient outcomes and increased market adoption:

Our medical device testing services

TÜV SÜD is a full-service provider with a strong focus on cardiovascular, orthopedics, reusable products, active medical implants, and sterile medical products. From concept to market, our team is dedicated to providing you testing services that get your innovative products to market efficiently.

Specialized services

	Biocompatibility
	Microbiological
	Packaging
	Electrical & EMC
	MRI
	Cybersecurity

Testing types

• Biocompatibility - cytotoxicity, genotoxicity, hemocompatibility, in-vitro irritation. • Chemical characterization - GC-MS, HS-GC-MS, ICP-MS, ICP-OES, LC-QToF, TOC, ECH & EO Residuals, IC, FTIR • Reprocessing – cleaning validation, disinfection validation, sterilization validation. • Toxicological risk assessment	
• Bacterial endotoxin test (BET), bioburden, microbial incubation + enumeration, microbial water testing, sterility validation	
• Accelerated aging, bubble leak test, climatic stressing, distribution testing, loose load vibration, random shock, random vibration, dye penetration, environmental simulation, heat seal test, ISTA 3A, vacuum leak, visual inspection	
• Battery testing • Electrical safety • Electromagnetic compatibility (EMC)	• Functional safety / single fault safety • Radio equipment – testing & global market access
• MRI safety testing - force, torque, RF heating, artifact detection	
• Cybersecurity testing - penetration tests & fuzz testing	

Why choose TÜV SÜD?

TÜV SÜD is globally recognized as an independent third-party with a comprehensive service portfolio along the entire value chain. Our suite of medical device testing services helps manufacturers and suppliers to meet global regulatory standards and optimize time to market. The collective expertise of our global network of professionals makes TÜV SÜD a trusted partner of choice for manufacturers seeking accreditations in line with medical device regulations on a worldwide scale.

TÜV SÜD is also one of the largest EU notified bodies in the world. Our technical professionals are actively involved in medical device standards development and participate in many key standards committees. Our extensive certification expertise also provides a sense of clarity to our customers.

We are also compliant with many global regulatory agencies including the FDA and PMDA.

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specializes in testing, certification and auditing. Since 1866, the company has remained committed to its purpose of enabling progress by protecting people, the environment and assets from technology-related risks. Through more than 25,000 employees across over 1,000 locations, it adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.