

For more than 30 years, TÜV SÜD has provided testing services for manufacturers and suppliers of medical devices.

Recognizable Quality Assurance



By choosing TÜV SÜD, a dedicated team of global experts is committed to working with you to mitigate risks and access global markets through a comprehensive portfolio of testing.

TÜV SÜD provides global recognition, backed by trusted people and products.

Experts in testing services for manufacturers and suppliers of medical devices.

Start your journey today

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TÜV SÜD Labs Healthcare
and Medical Device Services

Ensuring
Regulatory
Compliance and
Improving Patient
Outcomes

Add Value.
Inspire Trust.



Navigating the Path to Market Approval

From product creation to routine production, the journey for medical device manufacturers can be complex and challenging.

Addressing design, development and manufacturing challenges is time-consuming and investment-intensive, and it can take several years for a product to reach market approval.



Common challenges device manufacturers face include:

- **Regulatory compliance:** Medical devices must comply with stringent regulatory requirements to ensure their safety and effectiveness for patients.
- **Product design and development:** Developing medical devices requires expertise in design and engineering to optimize product functionality that meets the needs of users.
- **Quality control and manufacturing:** Medical devices must be manufactured to the highest quality standards.
- **Cost management:** Medical device manufacturing can be expensive due to the high cost of materials, regulatory challenges and supply chain issues.
- **Competitive landscape:** As a highly competitive industry, medical device manufacturers must continue to innovate and develop new technologies and products to stay ahead of the competition.
- **Ethical considerations:** Ethical issues related to the safety, efficacy, and privacy of patients is a growing concern that requires precise solutions for medical device manufacturers.



Global Market Access

- Identify and evaluate regulations and standards that are applicable in target countries
- Guidance on application document completion and sample preparation

Specific Services:

- General Training and Education Services (through TÜV SÜD Academy)

Testing

- Reliable and comprehensive worldwide lab network
- Test the product against applicable technical standards and national variations

Specific Services:

- Biocompatibility Testing
- Electrical Safety Testing
- Environmental Testing
- Performance Testing
- Microbiology Testing
- Usability Testing
- EMC Testing
- Safety Testing
- Packaging Testing
- Reusable Device Testing
- MRI Safety Testing



When Quality Matters

Our global network of more than 1500 dedicated medical device professionals and experts makes TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

As experts in medical device testing, we offer a range of services tailored to your unique needs:



Certification

- Approval of all medical devices, systems, and components

Specific Services:

- Medical Device Regulation (MDR/IVDR)
- Quality Management System Certification
- Product Certification
- Medical Device Single Audit Program (MDSAP) certification



Post Market Surveillance (only in combination with certification)

- Support of ongoing certificate maintenance and market surveillance requirements
- Conformity of production
- Market surveillance requirements

Specific Services:

- Vigilance Reporting

