



# TÜV SÜD

# Medical Health Services

Dedicated to your success

Add value.  
Inspire trust.





# Why choose TÜV SÜD?

Dedicated to your success

















For more than three decades, TÜV SÜD has delivered certification and testing services to manufacturers and suppliers in the medical device and in vitro diagnostics industries. We are the only notified body with a scientific advisory board of top European scientists and physicians.

Our worldwide team of dedicated specialists, engineers and medical doctors deliver tailored services in multiple languages to meet global industry regulations and standards.

Our transparent communication and customer-centric approach supports efficient regulatory compliance and global market access for your innovative products. Discover how TÜV SÜD's experts can help you to manage risks and access global markets through our portfolio of technical solutions.

## Your challenges

## Our solutions

 <b>Irregular interpretation of standards &amp; requirements</b>	Assess products against regulatory standards to ensure compliance.	
 <b>Rapidly advancing technology &amp; the rise of AI</b>	Verify your regulatory compliance.	
 <b>Maintaining quality</b>	ISO 17025 accredited laboratories.	
 <b>Slow R&amp;D process</b>	Highly responsive for a predictable certification timeframe.	
 <b>Lack of reliability</b>	Manage the entire process for you.	
 <b>Unpredictable market access to EU</b>	Set clear expectations from the outset.	
 <b>Management of multiple test houses</b>	Support most testing needs on a global scale.	
 <b>Time-consuming coordination of all laboratories</b>	A dedicated project handler is your single point of contact.	

# Services for medical device manufacturers

Achieving market access for your medical devices.

TÜV SÜD's comprehensive regulatory and testing services support an efficient compliance journey and market access for your innovative medical devices. Our experts' in-depth knowledge and experience of global certification standards ensures an efficient conformity assessment for your medical device.

## Testing services

TÜV SÜD is a full-service provider with a strong focus on cardiovascular, orthopaedics, reusable products, active medical implants, and sterile medical products. From concept to market, our team is dedicated to providing you with testing services that get your innovative products to market efficiently. All our laboratories are ISO 17025 accredited, and our advanced testing facilities will help you reduce risks and optimise time to market.

Our services include:

### Physical Testing of Medical Devices and IVDs

- Electrical Safety Testing (IEC 60601-1)
- MRI Safety Testing
- Functional Safety
- EMC Testing
- Environmental Testing
- NRTL
- IECEE CB Scheme

### Chemical/Biological Testing of Medical Devices & IVDs

- Biocompatibility Testing
- Microbiology Testing
- Chemical Testing
- Chemical Characterisation
- Toxicological Risk Assessment
- Genotoxicity Assessment and Evaluation
- Sterility Assurance Testing
- Reusable Device Testing

### Cyber Security in Medical Devices

- Cyber Security Testing
- Medical Devices & IVDs Security Testing (Penetration Testing)

## Certification and regulatory services

Our experts' in-depth knowledge and experience of global certification standards supports the efficient assessment of your medical devices.

Our services include:

### Europe

- Medical Device Regulation (MDR)
- In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR)
- UKCA
- Unannounced Audits
- Restricted Hazardous Substances

### Americas

- Medical Device Single Audit Program (MDSAP)
- Medical Device Licences in Canada
- Medical Device Registration in Brazil

### Asia Pacific and Australia

- Medical Devices and Compliance with Japan's PAL Regulations
- Korea Good Manufacturing Practice Audit & Medical Device Certification
- Regulation of Medical Devices in India
- Australia Therapeutic Goods Regulations
- Medical Device Regulations Under Singapore's Health Products Act
- Registration Requirements for Medical Devices in Malaysia
- Approval of Medical Devices in Taiwan
- Approval of Medical Devices in Ukraine

# Worldwide medical device experts and laboratories

## Extensive expertise with a global reach

We are a global partner for medical device testing and certification services that optimise your access to markets worldwide.

We serve customers across the world with main offices in:

- People's Republic of China
- Germany
- India
- Italy
- Japan
- Republic of Korea
- Singapore
- United Kingdom
- USA



TÜV SÜD's certification and testing services are independent of each other and do not impact one another. Our certification services are delivered by TÜV SÜD's recognized Certification Bodies, while our testing services are conducted through TÜV SÜD Testing Labs.

## Why work with TÜV SÜD?

### Predictability, consistency and expertise

TÜV SÜD Medical Health Services optimises processes for a seamless certification and laboratory testing experience that enables global market access for your medical devices. Our transparent communication and customer-centric approach provides efficient regulatory compliance for your innovative products. For more than 30 years, TÜV SÜD's testing and certification services have supported medical device manufacturers to successfully navigate the ever-changing regulatory landscape.



#### Focused on your success.

We understand that time to market is crucial to your success. We set clear expectations from the outset and prioritise your needs to optimise turn-around times that exceed expectations.



#### Technology expertise.

We help you to verify regulatory compliance of your innovative technologies. Our due diligence services are tailored for investors acquiring medical device starts-ups.



#### Regulatory expertise.

Our regulatory experts actively participate in standards committees and have in-depth knowledge of global requirements. Our Notified Body insight helps you understand what testing and certification is required to safely bring your products to market.



#### Eliminate risks and optimise safety.

Recognised for our commitment to quality and building long term relationships of trust, we build quality into every step because patient safety depends on it.



#### Single testing solution.

Our comprehensive testing services mean that you don't have to contract and manage multiple test houses. We manage the process for you, with our dedicated project handler keeping you regularly updated.

#### Global Headquarters

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