Add value.
Inspire trust.

Accelerate your medical device entry into new markets

Unrivalled expertise from the global technology leader in medical device services.

Choose our unmatched expertise

Manufacturers in the competitive and rapidly growing global medical device industry face constant demands for product innovation. To achieve swift regulatory approval and global market access, new products must guarantee high-quality performance and complete safety for operators and patients. The experts at TÜV SÜD preside on regulatory committees and are abreast of all major global regulatory requirements. By choosing TÜV SÜD as your partner, you can be assured that you are benefiting from the premier standard of clinical assessment reports. With the highest number of medical device experts and the widest service offering of any Notified Body (NB), our team is ready to assess your innovative design. Our suite of premium services allows you to remain in line with regulations and ahead of your competition.

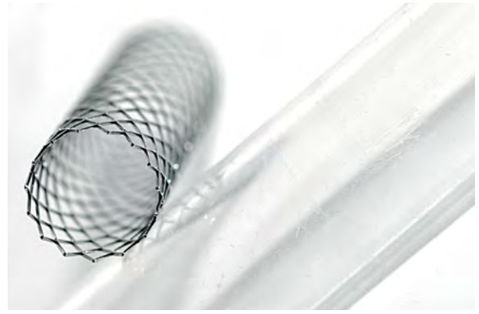
Get it right the first time with thorough assessments and timely responses by TÜV SÜD's best-in-class experts.

Align your innovations with changing regulations

Your partner for dependable, accelerated access to global markets

Healthcare improvements rely on an innovative and diverse medical device sector around the world. But as the market grows, so too does the regulatory environment and the pressure on timelines. To guarantee swift market access, manufacturers must respond quickly and effectively to regulatory changes as they happen. They need to ensure that their products meet expectations of quality, safety and performance prior to launch in order to achieve quick, cost-efficient market acceptance. To get it right the first time and remain competitive, it makes good business sense to choose an expert partner that can support your testing and certification needs in all of your intended markets globally.

With industry-leading expertise, unrivalled experience and a strong global presence, TÜV SÜD is qualified to do just that. Our team has a wide range of technical competencies to fully match all of the scientific and engineering disciplines involved in the development of your device. We tailor our services across the entire testing, assessment, auditing and approval processes to allow you to minimise risk by fulfilling all national and international medical compliance requirements. This cuts time to market and ensures consistently high-quality medical devices and smooth approval procedures. With our global network of nationally accredited laboratories and facilities, you can access assessments and testing for compliance with the most recent regulatory framework anywhere in the world.



A complete range of services that ensures quality and safety

To ensure fast, reliable market access, our multidisciplinary team brings to bear the highest levels of expertise, thought leadership and cutting-edge technology across all of our medical device services. Benefit from unrivalled knowledge and insight into the best route for assessment of clinical evaluations, quality management certification and market access. We are a one-stop solution provider for all of your testing and certification requirements.

ACTIVITIES	SERVICES ▾
AUDITING AND SYSTEM CERTIFICATION	• IN-VITRO DIAGNOSTIC DEVICE REGULATION (EU) 2017/746 • MEDICAL DEVICE REGULATION (EU) 2017/745 • ISO 9001 – QUALITY MANAGEMENT SYSTEM • ISO 13485 – QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES • ISO 14001 – ENVIRONMENTAL MANAGEMENT SYSTEM • PHARMACEUTICAL AFFAIRS LAW (PAL) FOR JAPAN • OHSAS 18001 – OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM • TAIWAN GMP
INSPECTION	• ARTIFICIAL INTELLIGENCE ASSESSMENT IN MEDICAL DEVICES • FACTORY AND SUPPLIER INSPECTIONS • FACTORY INSPECTIONS FOR INMETRO CERTIFICATION IN BRAZIL • FDA ACCREDITED PERSONS (AP) INSPECTION • FDA MOCK INSPECTIONS
TESTING AND PRODUCT CERTIFICATION	• BIOCOMPATIBILITY TESTING • CB CERTIFICATION • CHEMICAL TESTING (E.G. COMPOSITION OF MATERIALS, CHEMICAL MIGRATION) • CYBERSECURITY TESTING • DESIGN DOSSIER REVIEW • EMC TESTING • FUNCTIONAL SAFETY TESTING • IEC 60601-1 SERIES • LABORATORY TESTS FOR ERGONOMICS, ELECTRICAL/MECHANICAL/FUNCTIONAL SAFETY TESTS • NATIONALLY RECOGNIZED TESTING LABORATORY (NRTL) CERTIFICATION • PROTOTYPE TESTING • RISK MANAGEMENT REVIEWS • SOFTWARE/DATA SECURITY

Our industry accreditations

TÜV SÜD's testing and certification services meet the stringent quality requirements of the relevant international standards bodies and/or regulatory authorities. We constantly strive to ensure that our test results and certificates achieve recognition across a broad range of international and national regulatory bodies, so that you can be confident of fast and reliable customs and regulatory clearances as you export to markets around the world.

Our industry accreditations

- A2LA – Safety
- ANSI-ASQ National Accreditation Board – Quality System Registration – USA
- Conformity Assessment Body (CAB) (Hong Kong)
- Certified Authorised Body (CAB) for Good Distribution Practice for Medical Devices in Singapore (GDPMDS) Certification
- Conformity Assessment Body (CAB) under EU-AUS MRA
- Cybersecurity IEC TR 60601-4-5
- IECEE – Certification Body (CB) Test Laboratory
- In-Vitro Diagnostics Directive (IVDD)
- ISO/IEC 17021
- ISO/IEC 17025
- Medical Device Regulation (MDR)
- NVLAP – Safety and EMC
- OSHA – Nationally Recognized Test Laboratory (NRTL)
- Recognised Certification Body (RCB) by Ministry of Health, Labour and Welfare in Japan
- Standards Council of Canada (SCC) for ISO 13485 CMDCAS and CSA C22.2. 60601-1 certification
- Third Party Review of Class II Medical Devices – Korea Food and Drug Administration (KFDA)

Supporting worldwide operations

Over 1000 locations in 50 countries

Why choose TÜV SÜD?

Leading world-class expertise

We are a technology leader with 700 experts based in major markets across the globe, the most in the industry. Our world-class experts apply in-depth industry insights and experience to your local market's regulatory requirements.

Unrivalled knowledge of standards

TÜV SÜD offers comprehensive, up-to-the-minute knowledge of medical device standards. Our experts preside on numerous medical device standards committees worldwide, enabling them to offer crucial insights, unrivalled knowledge and valuable foresight.

Competence to match innovation

TÜV SÜD's wide range of competencies ensures that we can match the technical needs of any manufacturer and provides you with the greatest variety of services. Our scientific board determines the right analysis methods to aid the safety of your innovations.

A close partner throughout the value chain

We offer more than just certification, adding value throughout your product development lifecycle, including training and learning. Our best-in-class education system provides the expertise to keep you up to date with rapidly changing technology.

Independent, impartial and reliable

Choosing TÜV SÜD as a third-party assessor enhances your brand's stature as a premium quality player in the market. Our reputation for independence, impartiality and reliability instils confidence in the quality and safety of your products.

Risk management

TÜV SÜD possesses a Regulatory Foreign Affairs & Clinical Department specialising in market access and worldwide regulations, which ensures that each client's products are tested in compliance with the latest requirements.

Your business benefits

Expert partnership – As the most trusted, experienced and reliable service provider, TÜV SÜD works with 75 per cent of the world's largest medical companies. You can be certain of our in-house technological expertise in every field.

Accelerate your market access – Our flexible support gives you greater control and predictability for your conformity assessment processes.

Gain a competitive edge – Anticipate future healthcare trends and requirements, and strengthen relevant industry skills with TÜV SÜD's knowledge services and training programmes.

One-stop solution – Our expertise from initial technical meetings to market launch results in shorter certification times, more effective test procedures and swifter product launches.

Save time and money – Our comprehensive international accreditations, coupled with our extensive office and laboratory infrastructure around the globe, ensure you obtain your worldwide product and system certification efficiently.

Contact us to discuss your needs with the fastest, most reliable global partner

www.tuvsud.com/medicaldevice
medicaldevice@tuvsud.com

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. 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.

Our global offices

GLOBAL HEADQUARTERS
TÜV SÜD AG
Westendstr. 199
80686 Munich
Germany
Tel: +49 89 5791 0
Email: info@tuev-sued.de
www.tuvsud.com

PRODUCT SERVICE HEADQUARTERS
TÜV SÜD Product Service
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937
Tel: +65 6778 7777
www.tuvsud.com

AMERICA
TÜV SÜD America
10 Centennial Drive
Peabody, MA 01960
United States of America
Tel: +1 800 888 0123
Email: info@tuv-sud-america.com
www.tuvsud.com/en-us

ASEAN
TÜV SÜD PSB
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937
Tel: +65 6778 7777
Email: enquiries@tuv-sud-psb.sg
www.tuvsud.com/en-sg

BRAZIL
TÜV SÜD Brasil
Rua Girassol, 1033
São Paulo, 05433-002
Brazil
Tel: +55 11 3817-0200
Email: contato@tuv-sud.com.br
www.tuvsud.com/pt-br

CENTRAL EASTERN EUROPE
TÜV SÜD Central Eastern Europe
Novodvorská 994/138
Praha 4
14221
Czech Republic
Tel: +420 239 046 800
Email: info@tuv-sud.cz
www.tuvsud.com/cs-cz

GREATER CHINA
TÜV SÜD China
No. 88 Heng Tong Road
Shanghai 200070
P.R. China
Tel: +86 21 6141 0123
Email: info@tuv-sud.cn
www.tuvsud.cn/zh-cn

JAPAN
TÜV SÜD Japan
Sumitomo Fudosan
Nishi-Shinjuku No. 4
8F, 4-33-4, Shinjuku-ku,
Tokyo 160-0023
Japan
Tel: +81 3 3372 4821
Email: info@tuv-sud.jp
www.tuvsud.com/ja-jp

KOREA
TÜV SÜD Korea
"KLI63" Building
#60 Yoido-Dong
Youngdeungpo-Gu
Seoul 150-763
Korea
Tel: +82 2 3215 1100
Email: info@tuv-sud.kr
www.tuvsud.com/ko-kr

MIDDLE EAST
TÜV SÜD Middle East
Office 201, 2nd Floor
Ibn Battuta Gate Complex
P.O. Box 2834
Dubai
United Arab Emirates
Tel: +971 4 44 73 113
Email: info@tuvsudme.com
www.tuvsud.com/en-ae

AFRICA
TÜV SÜD South Africa
1st Floor
ExecuJet Business Centre
Tower Road
Cape Town International Airport
7525, Cape Town
South Africa
Tel: +27 21 935 7960
Email: info@tuv-sud.co.za
www.tuv-sud.co.za

SOUTH ASIA
TÜV SÜD South Asia
Solitaire, 4th Floor
ITI Road, Aundh
Pune 411007
Maharashtra
India
Tel: +91 20 66841251
Email: info@tuv-sud.in
www.tuvsud.com/en-in