One-stop Testing & Certification for Medical Products

Get Ready for the Global Market

TÜVRheinland®

One-stop Testing and Certification for Medical Products

EU Member Countries

The extended law on Medical Devices developed by the European Union (EU) regulates the free movement of medical devices. TÜV Rheinland Japan can help manufacturers meet the requirements of the EU's Medical Directives (AIMDD: 90/385/EEC, MDD: 93/42/EEC and IVDD: 98/79/EC), by assessment to the full scope of these directives.

Conformity to these directives is vital for medical device manufacturers exporting to the EU. Affixing the CE Mark to show compliance to the MDD and AIMDD is already mandatory. Compliance with the IVDD became compulsory in December 7, 2003.

EU における医療機器に関する指令

Directive	Directive on Active Implantable Medical Devices AIMDD 90/385/EEC	Medical Devices Directive MDD 93/42/EEC	Directive on In-vitro Diagnostic Medical Devices IVDD 98/79/EC
Date of Directive	Jun. 20, 1990	Jun. 14, 1993	Oct. 27, 1998
Applicable Date	Jan. 01, 1993	Jan. 01, 1995	Jun. 07, 2000
Obligatory Date	Jan. 01, 1995	Jun. 14, 1998	Dec. 07, 2003
Classification	N/A	Class I, IIa, IIb, III	List A, List B, Self-testing, Performance Evaluation, Others
Quality Management System	Quality Management System for Medical Products ISO 9001, ISO 13485		
	Annex II, III, IV, V	Annex II, III, IV, V, VI, VII	Annex III, IV, V, VI, VII
Safety Requirement	Essential Requirements (In the Directive Annex I) Risk Analysis/Assessment (ISO 14971) Clinical Evaluation/Investigation (EN 540/ISO 14155) Labelling (Annex I, EN 980, EN 1041, EN 1658) Other Applicable Standards (e.g.EN 60601-1)		
Market Information	Information Feedback System Post-Market Surveillance Customer Complaint Investigation Vigilance System Advisory Notice (Recall)		

TÜV Rheinland Product Safety

Geprüftes Medizinprodukt
Approved medical device

GM Mark

This voluntary test mark shows compliance of a medical product with the essential requirements of the Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC) and the In-vitro Diagnostic Medical Devices Directive (98/79/EC). GM is abbreviation of Geprüftes Medizinprodukt (Approved medical product).

North America (USA & Canada)
TÜV Rheinland of North America is a Nationally Recognized Testing Laboratory (NRTL) in the United States and is accredited by the Standards Council of Canada to test and certify electro-medical products to Canadian National Standards. Clients can demonstrate compliance for both U.S. and Canadian markets through a single mark – cTUVus – on their product(s) which denotes compliance to U.S. and Canadian National Standards. Including our own test laboratories throughout Asia (incl. Japan) into this scheme makes it possible to test your medical equipment outside the U.S. and Canada for your convenience.

Use of CB Scheme, Global Passport
CB is the abbreviation for "certification body". The CB scheme is based on the mutual recognition of tests and certificates among several National Certification Bodies (NCBs). The document of reference is the CB Test Certificate in conjunction with the relevant test report. The members of the CB scheme issue a CB Test Certificate in connection to the test report. Based upon this certificate and report, other CB members will issue licenses for their national level. Consequently, the complete approval test does not need to be repeated for each country. TÜV Rheinland (Cologne) was accredited as a National Certification Body (NCB) in 1994. TÜV Rheinland of North America also became an NCB in 1996. Our testing laboratories in both countries and in Japan are accredited as CB testing laboratories.
CB scheme: http://www.cbscheme.org

For details please contact our medical team.
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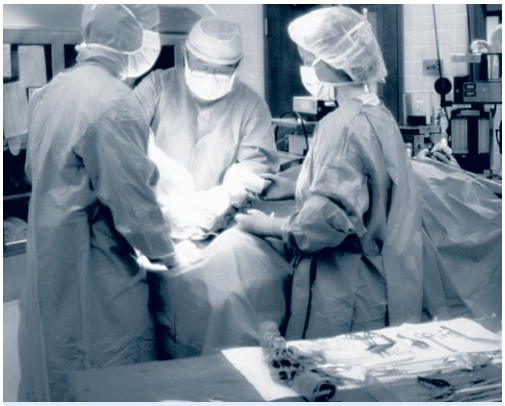

Service Scope for Medical Products

Quality Management System Certification
- ISO 9001
- ISO 13485
- CMDCAS (Canadian Medical Devices Conformity Assessment Scheme)

Medical Product Safety Testing / Certification
- CB Certification & Test Report
- GM Mark
- TÜV Mark
- CoC (Certificate of Conformity)
- cTUVus Mark
- TÜV Test Report
- JIS T 0601-1 Test Report (For Japan)

Others
- PAL (Pharmaceutical Affairs Law) Medical Product Certificate for Japan
- FDA 510(k) Third Party Review
- EMC Testing & Certification
- Ergonomics Testing & Certification
- IP Tests
- Bluetooth Testing & Certification
- Market Access Services

Other Medical Product Approvals by TÜV Rheinland

CE 0197

CE Marking (Notified body)

Certified Management System
ISO 9001, JIS Q 9001
ISO 13485

System Certification Mark

TUVdotCOM is the Internet platform for tested quality and safety. It documents all product properties, services, enterprises and systems tested and personal certifications provided by TÜV Rheinland Group. The service is available to manufacturers, purchasing, wholesalers, retailers and consumers in equal measure. That is how it establishes transparency in international trade.

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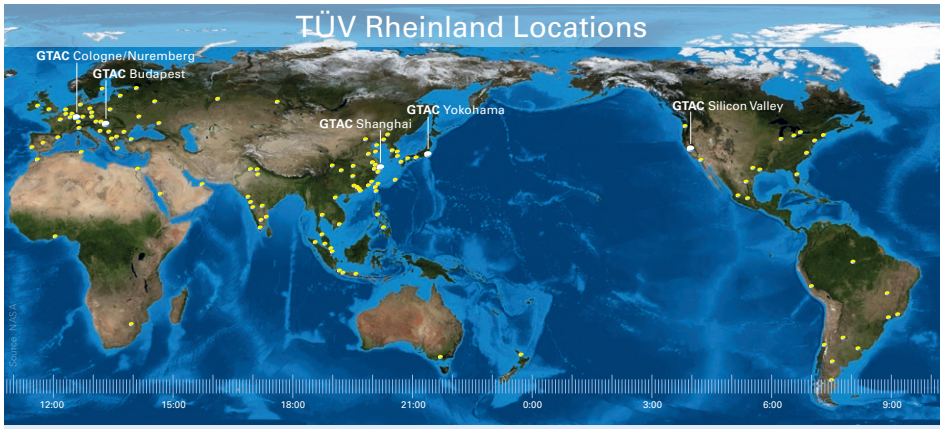

5 Global Technology Assessment Centers (GTAC)
Our network provides 24-hour access to all TÜV Rheinland Group services & capabilities

Office & Laboratory Location

- Represented worldwide with more than 12,000 employees in more than 60 countries at over 340 locations.
- Our business portfolio includes: Industrial Services, Mobility, Products, Life Care as well as Education & Consulting and Systems.
- The goal and guiding principle of the corporation – the sustainable development of safety and quality – is achieved through a strong commitment to Corporate Social Responsibility and ethical values.
- TÜV Rheinland Group has more than 130 years of experience.

For contact details please visit
www.contact.tuv.com

TÜVRheinland®
Precisely Right.