



Product Service

**Choose certainty.
Add value.**



We Ensure Your Success.

Worldwide certification of medical devices.

TÜV SÜD Product Service GmbH

TÜV®



**Global markets, short innovation cycles,
extensive test procedures.**

We will assist you.

Because quality is also a matter of trust.

As a manufacturer of medical devices, you have to deal with all kinds of challenges. The market is characterized by rapid innovation and progress. At the same time, legal regulations and requirements are particularly high. This applies not only to the domestic market but just as much to entering the international market.

As a Notified Body, we conduct the legally prescribed tests and certifications for you

throughout the world – from disposable syringes to complex products in the fields of cardio- and neurosurgery, all the way to large machines for tumor radiation – no matter what risk class your product belongs to. In addition, you can profit from our extensive expertise during all development phases. Anywhere in the world. After all, there's a reason why over 1,000 customers around the world trust our abilities and have consequently made us the market leader.

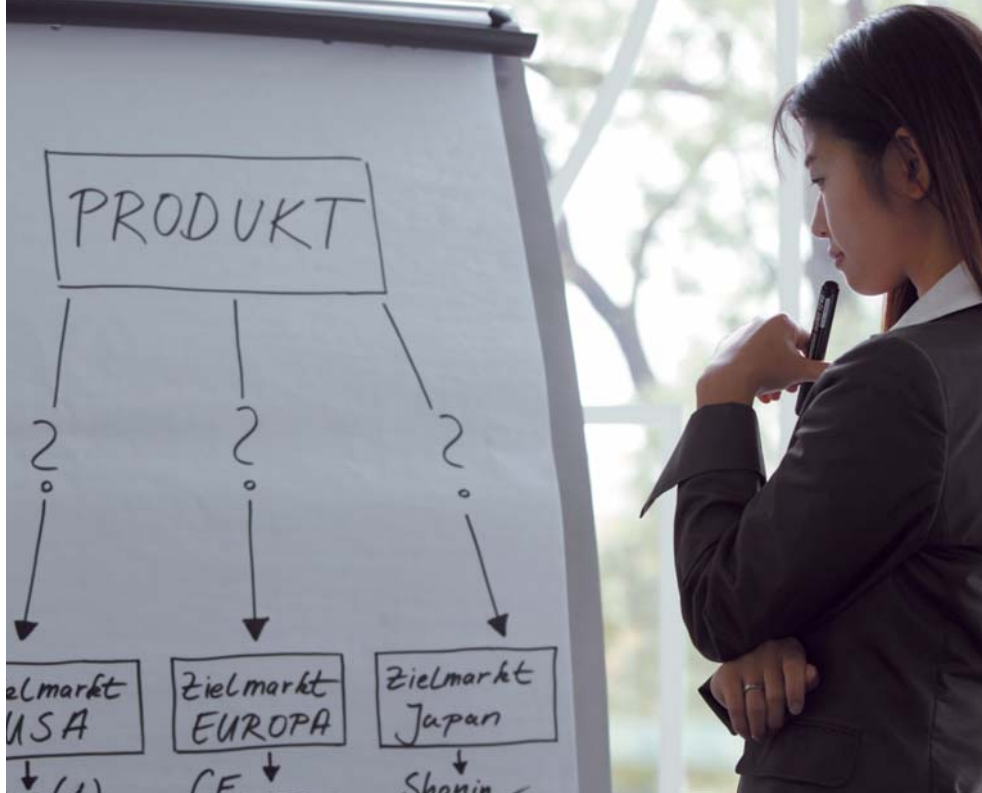
CE 0123

How you profit from us:

Reduced investment of time and money because we accompany the entire process.

Certainty thanks to specially trained doctors, scientists, and engineers.

Saving time due to our global presence in all important business centers with over 44 branches.



**Are you considering how
to bring your product to market
as quickly as possible?**

We'll help you do it.

How to ensure your success – right from the start.

We assist you during all phases of the development and production of your medical device: from the first idea to its market launch.

The result: shorter cost-intensive development times with smooth test procedures. Your product is launched quickly and safely on the market. Without detours and delays.



Our Services

Phase 1

Design & Development

Competence “in-sourcing,” taking international requirements into consideration, target-group-specific user tests, preliminary tests accompanying development

Phase 2

Pre-acceptance Technical Test / Clinical Tests

Tests for acquiring CE designation, tests and appraisals as an extended work bench, examination of clinical test plans and the data gathered by them, information on rules and guidelines

Phase 3

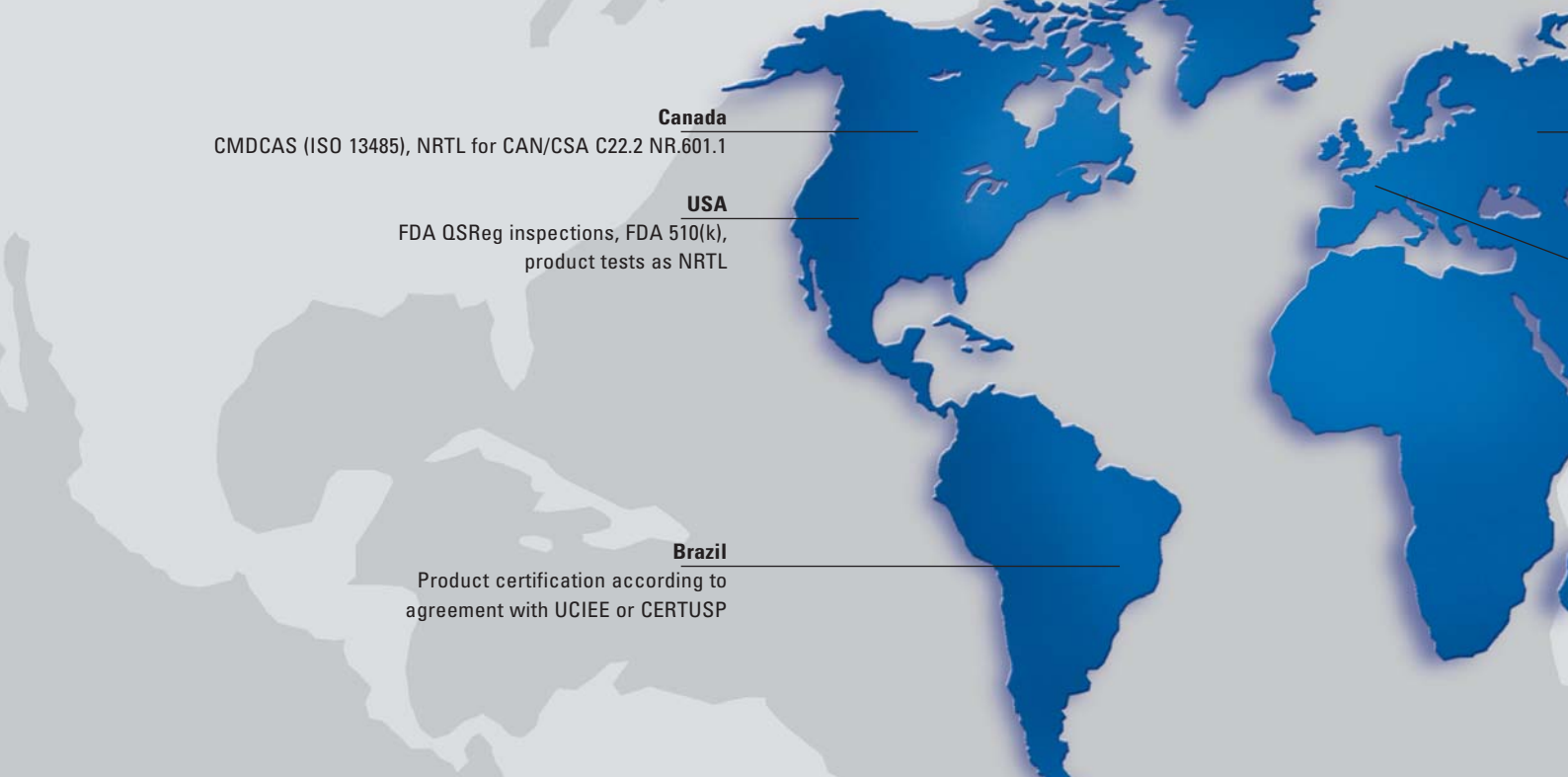
Test & Certification for International Approvals

Processing of approval procedures, conformity assessment as a Notified Body, including prototype tests, design dossier reviews, and consultation procedures, **positive marketing effects thanks to the blue TÜV SÜD octagon**

Phase 4

Production Monitoring

Appraisal, certification and monitoring of quality management systems



Canada
CMDCAS (ISO 13485), NRTL for CAN/CSA C22.2 NR.601.1

USA
FDA QSRReg inspections, FDA 510(k),
product tests as NRTL

Brazil
Product certification according to
agreement with UCIEE or CERTUSP

What we offer you. From one source.

Tests

- Product testing and certification: for all categories of medical devices according to global standards
- EC conformity procedures
- CB certification: test procedure to obtain national certification marks for your product worldwide
- EMC tests: tests for electromagnetic compatibility, i.e., assuring that the legal requirements for the mutual impact of electric devices on each other are met
- Laboratory tests for ergonomics, electrical/mechanical/functional safety, plus tests for software/data security
- DocCert: test and certification of operating instructions
- Target-group-specific user tests to check the user-friendliness of your products, for example in the field of rehabilitation

Clinical appraisal

- Clinical appraisal of medical devices and of their safety and efficiency/usability respectively
- Examination of clinical test plans

Consultation

- Consulting the drug administration in regard to medical devices/drug combinations, blood or plasma devices or medical devices with TSE-/BSE-relevant material.

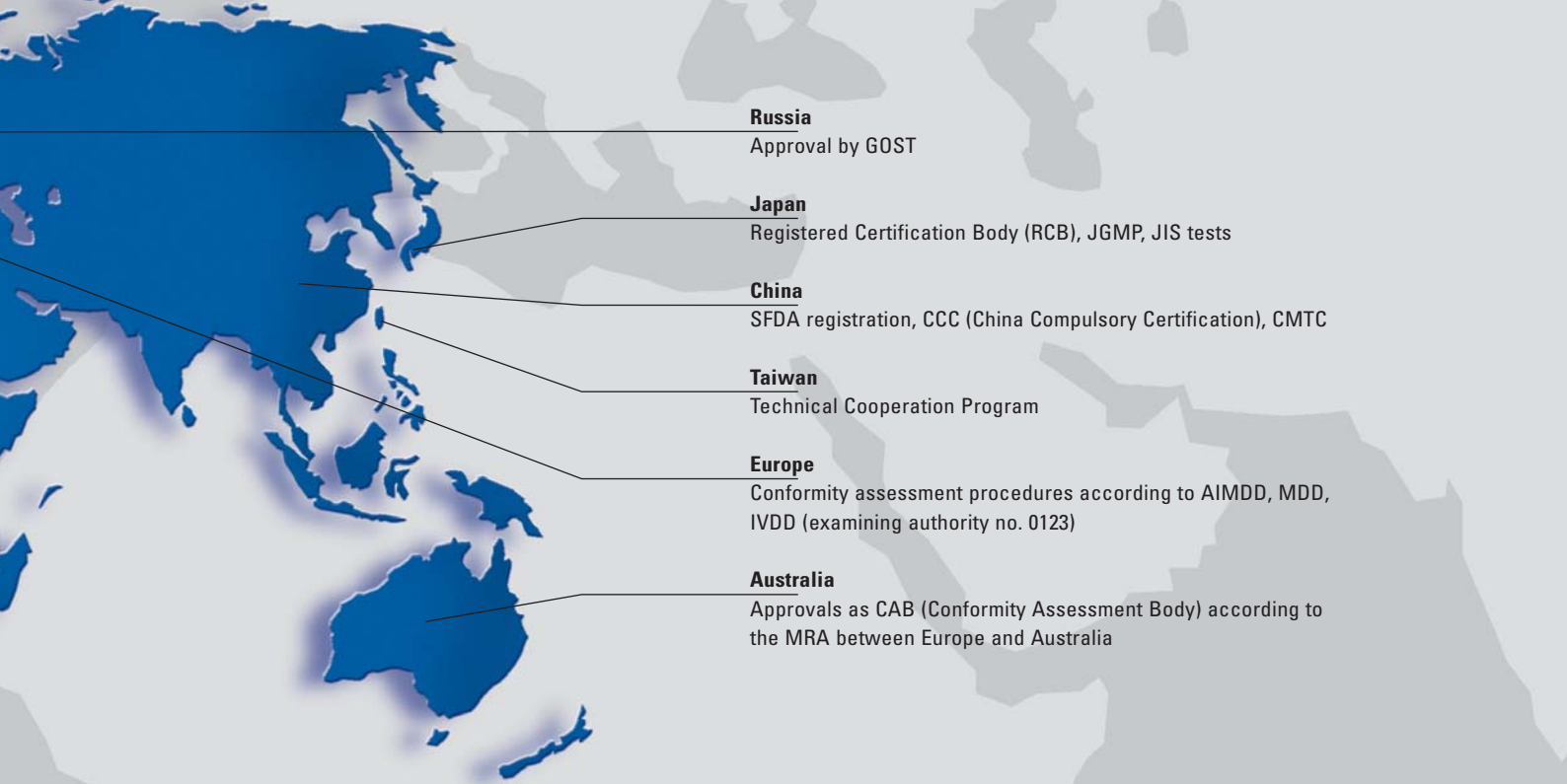
Management system certification

- Appraisal and certification of management systems according to ISO 13485, ISO 13488, ISO 9001, ISO 14001, and others
- Dialysis clinic auditing and certification

Appraisal reports for medical devices

Courses and training programs

Free sales certificates



Russia
Approval by GOST

Japan
Registered Certification Body (RCB), JGMP, JIS tests

China
SFDA registration, CCC (China Compulsory Certification), CMTC

Taiwan
Technical Cooperation Program

Europe
Conformity assessment procedures according to AIMDD, MDD, IVDD (examining authority no. 0123)

Australia
Approvals as CAB (Conformity Assessment Body) according to the MRA between Europe and Australia

How we support your success. First-hand information.

Med-Infos

Are you looking for information on new regulations in the area of medicine? "Med-Infos" from TÜV SÜD keeps you abreast of current developments. "Med-Infos" are available for downloading on the Internet at www.tuev-sued.de/medinfo.

It is a demonstration of trust in the quality of your product or the services your company provides. With a seal of safety and quality, our TÜV SÜD octagon, you create a considerable advantage for yourself on the market.

TÜV SÜD Octagon

We test your medical device according to individual criteria before it receives the blue TÜV SÜD octagon. With this quality seal, which is recognized throughout the world, you indicate that you are taking your duties as a manufacturer or dealer seriously.





Product Service

www.tuev-sued.com/mhs

Your Contacts for Medical and Health Services

Europe

Germany

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Phone +49 (0) 89 – 50 08 – 43 58

Sylvesterallee 2
22525 Hamburg
Phone +49 (0) 40 – 547 – 18 52

Masurenweg 1-3
30163 Hannover
Phone +49 (0) 511 96 63 – 866

Italy

TÜV Italy Srl
Via Isonzo, 61
40033 Casalecchio di Reno (BO)
Phone +39 (0) 051 – 298 74 11

Turkey

TÜV SÜD Teknik Güvenlik ve Kalite
Denetim
Ticaret Ltd.Sti
Yildiz Posta Caddesi No:17 Kat:5
34394 Esentepe-Istanbul
Phone +90 (0) 212 347 98 10 (262)

United Kingdom

TÜV Product Service Ltd.
Octagon House, Concorde Way
Segensworth North
Fareham – Hampshire PO15 5RL
Phone +44 (0) 1489 – 55 82 17

USA

TÜV SÜD America Inc.
5 Cherry Hill Drive
Danvers, MA 01923
Phone +1 (0) 978 – 739 – 70 00

1775 Old Highway 8 NW, Suite #104
New Brighton, MN 55112
Phone +1 (0) 651 – 631 24 87

10040 Mesa Rim Road
92121 San Diego
Phone +1 (0) 858 – 678 14 00

3170 Crow Canyon Place, Suite 150
San Ramon CA 94583
Phone +1 (0) 925 – 275 01 01

Asia-Pacific

China

TÜV SÜD China
Unit 918, Landmark Tower 2
8 North Dongsanhuan Road
Beijing 100004
Phone +86 (0) 10 65 – 90 61 – 86

16F, West Building New Hua
Lian Mansion
No. 775 Huai Hai Road
200020 Shanghai
Phone +86 (0) 21 – 61 41 01 23

Hong Kong

TÜV SÜD Hong Kong Limited
Unit 601, InnoCentre
72 Tat Chee Avenue
Kowloon Tong
Phone +852 (0) 27 76 – 13 23

India

TÜV SÜD South Asia Private Ltd.
No. 25/1, Shreekanta Mahal
First Cross, Sampige Road
Malleswaram
560003 Bangalore
Phone +91-80-23361387

Japan

TÜV SÜD Japan Ltd.
Sumitomo Fudosan 3-Bldg.
7F 4-15-3 Nishi-Shinjuku
Shinjuku-ku
160-0023 Tokyo
Phone +81 (0) 333 72 – 48 21

Korea

TÜV SÜD Korea Ltd.
12F, "KLI63" Bldg., #60
Yoido-Dong, Youngdeungpo-Gu
Seoul, 150-763
Phone +82 (0) 2 – 321 51 – 100

Philippine

TÜV SÜD Philippines Inc.
Unit 1808, The Orient Square Bldg.
F. Ortigas Jr. Ave
Ortigas Center, Pasig City
Metro Manila 1605
Phone +63 (0) 26 87 – 56 73 to 75

Singapore

TÜV SÜD PSB Pte. Ltd.
3 Science Park Drive
#03-12 The Franklin
Singapore 118223
Phone +65-6885-1270

Taiwan

TÜV SÜD Asia Limited Taiwan
7F, No. 37, Zhongyang S. Road
Beitou District
Taipei City 11270
Phone +886-2-2898-6818

Thailand

TÜV SÜD PSB (Thailand) Co. Ltd.
Thailand Science Park
111 Moo 9 Paholyothin Rd.
Klong 1, Klong Luang
Pathumthani 12120
Phone +66 2 564 8041

Vietnam

TÜV SÜD Asia Pacific Pte. Ltd.
6th Floor, Loyal Building
151 Vo Thi Sau Street, Ward 6
District 3
Ho Chi Minh City
Phone +84 8 9106431

Your contact partner at TÜV SÜD Product Service GmbH can give you further information.