Mutual Recognition Agreements (MRA) between the EU and the USA and Australia have been established to enable conformity assessment bodies of market A to approve devices for market B under the legislation of market B, and vice versa.

The Global Harmonization Task Force (GHTF) works on the effective international harmonization in the approval of medical devices. Many countries implementing new medical device regulations base their legislation on GHTF guidances.

However, all these markets still have, in addition, their specific requirements and rules. In general, approval is still very much regionalized and fragmented, although the approach got closer.

**Who is this bulletin applicable to?**
Companies manufacturing or exporting medical devices and in vitro diagnostic medical devices for the worldwide market.

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TÜV SÜD enables accelerated market entry in many countries through agreements with authorities and testing institutes.

Manufacturers benefit from being able to submit fewer documents or from the consolidation of production inspections.

**Russian Federation**
The approval of medical devices in Russia is divided into different parts: registration, GOST-R certification and Hygiene Certification (Sanitary Epidemiological Conclusion).

The “Federal Service for Control over Healthcare and Social Development” (Roszdravnadzor) is the competent authority in Russia for the registration of medical devices. The department reviews applications and decides on accepting the documents for registration. Afterwards it defines which tests (usually technical, clinical and toxicological tests) of the medical device have to be performed in accredited clinical centers and test laboratories. The last step of registration is the evaluation of the test results and issue of the registration certificate. The validity of the certificate is not limited.

The GOST-R certification is a separate procedure and starts after registration has been completed. After registration, the medical device usually has to be tested by the “Federal Agency for Technical Regulation and Metrology” (former “State Committee for Standardization”- Gosstandart) in accredited certification centers. The GOST-R certificate is limited for one or three years and can also be issued for a lot.
For medical devices and materials that have contact with the patient tissue it is necessary to obtain a hygiene certificate.

Hygienic assessment is implemented by the Department of “State Sanitary and Epidemiological Surveillance” of the Ministry of Health which reviews the results of hygienic tests. The “Sanitary Epidemiological Conclusion” (Hygiene Certificate) is the document which confirms that a product complies with Russian sanitary requirements. It is issued for the period of five years.

Most medical devices imported by Russia are VAT (18%) exempt.

TÜV SÜD and its partners can provide you with all required services including registration, GOST-R certification and hygienic certification.

USA

Class I and II medical devices requiring clearance for US market entry can only attain acceptance via a pre-market notification procedure, otherwise referred to as 510(k). The term 510(k) originates from section 510(k) of the Federal Food, Drug, and Cosmetic Act. A 510(k) submission is based on comparison of the new device with devices already legally marketed in the USA, which allows the US Food and Drug Administration (FDA) to determine whether a device is safe and effective. Medical device manufacturers are required to submit a 510(k) if they intend either to introduce a device for commercial distribution in the US for the first time, or to reintroduce a device that has been substantially modified. 510(k) was previously conducted by the FDA only. Starting in 1996, the system was revised to allow several third-party testing institutes to carry out the administrative and substantive review of the documentation on behalf of the FDA and thus to allow a faster and more efficient market access. TÜV SÜD was already authorized by the FDA in 1996 to perform third-party reviews for all eligible devices. The advantage for you is direct contact and communication throughout the review process. The timeline is 30 days for our review and another 15 days for the final FDA review. The final review is comparable to the internal procedure of the FDA. Their reviewer also has to forward a recommendation to the supervisor for final decision. The FDA fee of approx. $ 4,000 is only relevant if you submit the 510(k) directly to the FDA.

After product clearance, the FDA can carry out a production site inspection at any time. As a rule, this takes four working days and encompasses management, development, corrective and preventive action, as well as production and process control.

Under the Mutual Recognition Agreement between the EU and the USA (MRA) as well as under the FDA’s Modernization Act, manufacturers can have routine inspections done by TÜV SÜD combined with an audit under EU regulation. When the FDA announces the inspection, you may respond that you would like to participate in the Accredited Persons (AP) Program. Alternatively you can initiate an AP inspection with the FDA at any time. We also offer pre-audits (i.e. mockaudits) based on the FDA regulations.

Moreover, TÜV SÜD is a Nationally Recognized Testing Laboratory (NRTL) for the US market and offers to test your device according to e.g.
UL 60601-1. The basis for NRTL medical device certification is the testing of electrical and mechanical safety according to IEC 60601-1. You can get a complete testing package including production inspections from one partner. If you already are a customer in the context of system certification, a yearly audit can be combined easily and cost-effectively with one of these production inspections.

In addition, we will test your device according to the US-specific EMC requirements.

Canada
The Canadian Medical Devices Regulations classify medical devices similar to the EU Medical Device Directive, a main difference being that Canadian law integrates IVD products and active implants. Since 1 January 2003, Canadian law requires that manufacturers of class II, III, and IV medical devices and IVD devices have a quality management system that meets the requirements of ISO 13485 in order to obtain a license to sell their devices in Canada. Only a CMDCAS certificate issued by a SCC accredited CMDCAS registrar will be accepted. Manufacturers of medical devices licensed for sale in the Canadian market have to renew their device licenses annually until 1 November and therefore need to submit a copy of their CMDCAS certificate.

TÜV SÜD was the first registrar accredited by the Standards Council of Canada (SCC) to perform ISO 13485 CMDCAS certification.

Over 70 specially trained and authorized auditors from TÜV SÜD ensure CMDCAS certification for all clients.

We also offer to pre-review your device license application regarding compliance with the requirements of the Canadian agency TPD (Therapeutic Products Directorate).

TÜV SÜD is also authorized for the Canadian market as NRTL for the standard CAN/CSA-C22.2 No. 601.1.

Brazil
The requirements for medical device registration are harmonized with the other member states of MERCOSUR. The documentation to be submitted is to a large extent compliant with the Global Harmonization Task Force (GHTF) Guidance for Summary Technical Documentation (STED). Testing and certification by a nationally recognized certification body is required for electrical medical devices to achieve market access in Brazil. Tests performed by TÜV SÜD are fully recognized by Brazilian testing institutes we cooperate with. The related yearly production inspections can be performed by TÜV SÜD, e.g. within the framework of the EU Notified Body audits.

Japan
The revised Japanese Pharmaceutical Affairs Law (PAL) became effective on 1 April 2005. There are four classes of medical devices. The quality management system conformity criteria for manufacturing facilities of medical devices and in vitro diagnostic reagents are assessed prior to device approval and/or device certification. Not only the manufacturing facilities in Japan, but also those overseas must fulfill the GMP rule based upon ISO standard 13485:2003. Class I products are exempt from the obligation of certification. Class II medical devices are certified by Registered Certification
Bodies (RCB) as long as conformity certification criteria in form of JIS standards are assigned to the devices. Products with a higher risk potential still need approval by the Pharmaceuticals and Medical Devices Agency (PMDA).

For class II devices, a product documentation in accordance with the Global Harmonization Task Force (GHTF) Guidance for Summary Technical Documentation (STED) has to be submitted to the Japanese RCB. In addition to previous documents, detailed information on the company must also be provided.

An audit is to be carried out by the RCB in accordance with Japanese GMP requirements (ISO 13485:2003) before device certification. For products in higher classes this responsibility is handled by the PMDA. In this case, an assessment, but not inevitably an audit, is required. The extent to which GMP audits by the RCB are recognized by the PMDA for class III and IV device approval applications is not yet clear. Manufacturers of such devices have already been audited by TÜV SÜD to demonstrate compliance with GMP requirements to the PMDA.

TÜV SÜD has many years of experience and holds the deputy chair in the committee for the RCBs. Take advantage of our service as RCB.

The PMDA requires tests for class III and IV devices according to JIS standards to be performed by recognized testing laboratories such as TÜV SÜD. We also offer to test your devices according to the national EMC requirements.

**China**

There are two different schemes for approval of medical devices in China: SFDA (State Drug Administration of China) registration and CCC (China Compulsory Certification). The SFDA registration covers all kinds of medical devices marketed in China, while the CCC is only required for seven categories of medical appliances (1. Medical diagnostic X-ray equipment, 2. Haemodialysis equipment, 3. Hollow fiber dialyser, 4. Extra-corporeal blood circuit for blood purification equipment, 5. Electrocardiograph, 6. Implantable cardiac pacemaker, 7. Artificial heart-lung machine). SFDA classifies medical devices into three classes according to their risk potential. The registration of class II and III devices generally requires testing by recognized testing laboratories. In the case of class III devices, the SFDA performs a production inspection every four years. Tests carried out by TÜV SÜD are recognized if the applicant demonstrates the accreditation of the testing laboratory. TÜV SÜD is authorized to evaluate the application and to submit it to SFDA. We clarify the extent of additional testing for you and coordinate the testing by a recognized national testing institute.

The existence of a CCC mark is checked by customs at market entrance. The CCC is handled by the China Quality Certification Center (CQC), a subsidiary of the State General Administration for Quality Supervision and Inspection and Quarantine of the People’s Republic of China (AQSIQ). Tests need to be carried out in China. CQC will organize the production inspection and decides when and by whom the inspection should be performed. The manufacturer may provide a proposal for the authorized organization which performs the inspection, e.g. TÜV SÜD.
Taiwan

For registration of medical devices in Taiwan, the Pharmaceutical Affairs Law (PAL) applies. The Ministry of Health handles particular definitions and charges official organizations with implementation. Manufacturers wishing to export to Taiwan must, among other things, submit a detailed company description, a description of the production process, and a quality system documentation (QSD) including work and testing instructions. A cooperation between the EU (including Switzerland) and Taiwanese authorities exists, which facilitates accelerated market access for medical devices. In this context, TÜV SÜD played a major role in the negotiations and the implementation of a private agreement with the Taiwanese certification bodies. An audit by TÜV SÜD including the Taiwanese regulations plus certification under ISO 13485, the audit report, and a Free Sales Certificate suffice for the GMP compliance letter which is required for the registration of products in Taiwan. The GMP compliance letter from the DoH in Taiwan is valid for three years and forms one part of the records to be submitted for any medical device registration.

As a prerequisite, the devices relevant for the Taiwanese market have to be covered at the audit under ISO 13485. The quality management system must ensure that only devices registered with the Taiwanese DoH are delivered to Taiwan. There has to be an agreement with a Taiwanese distributor regarding market surveillance and bidirectional information of any complaints. Evidence regarding the handling of vigilance and distribution has to be provided, and is evaluated by the lead auditor for your company. After a successful audit, we issue an audit report confirming the compliance with Taiwanese regulations and referring to the agreement with Taiwanese certification bodies. This report replaces the submission of a QSD. Since November 2003, TÜV SÜD is authorized to perform this kind of audits.

The application for registration of the device has to be accomplished by your representative in Taiwan, not by the foreign manufacturer. TÜV SÜD can issue a confirmation letter detailing the products which are covered under the scope of a valid ISO 13485 certificate, usually required in the device registration process.

Hong Kong

The Medical Device Control Office (MDCO) regulates medical devices. On 26 November 2004, the DOH launched the Medical Device Administrative Control System (MDACS) as a regulatory framework for imported medical devices. The proposed framework is largely in line with the recommendations of the Global Harmonization Task Force (GHTF).

A Local Representative Person (LRP) is mandatory. The LRP must be either the manufacturer of the device or accredited by the manufacturer to perform the duties of the LRP. The LRP submits the application for listing medical devices and is responsible for the marketing and post-market procedures which include keeping distribution records, handling complaints, initiating product recalls, managing adverse incidents, and reporting changes.

A major component of an application is the conformity assessment. The conformity assessment covers a product’s quality management system, a post-market surveillance system, Summary Technical Documentation (STED) based on GHTF Guidance, and a Declaration of Conformity, all based on MDACS standards. The conformity assessment will not be performed by the MDCO, but by an independent Conformity Assessment Body (CAB).

TÜV SÜD has been recognized by the Department of Health as a Conformity Assessment Body (CAB) under the MDACS.
**Singapore**

In 2007, the Health Products Act was passed, allowing the Health Sciences Authority (HSA) to conduct mandatory product registration and to regulate the supply, distribution, manufacturing, import, and advertisement of health products.

There are four risk classes of medical devices in Singapore: class A, low risk; class B and C, medium risk; and class D, high risk, which are adopted from the guidance developed by the Global Harmonization Task Force. (GHTF website: www.ghtf.org).

Beginning on 1 May 2010, unlicensed manufacturing, importation and wholesaling of medical devices and supply of unregistered class B, C, and D medical devices is prohibited. From 1 May 2011, the supply of unregistered class A medical devices is also prohibited. Documentation to be submitted needs to follow the "Common Submission Design Dossier Template", CSDT, developed by the "Asian Harmonization Working Party", AHWP, which closely works together with the GHTF.

To receive the importer and wholesaler license, the organization must obtain a GDPMDS (Good Distribution Practice for Medical Devices in Singapore) certificate by a certification body.

The organization shall establish a quality management system in accordance with the requirements of GDPMDS. If the organization chooses to outsource any activities that may affect the quality of medical devices, it shall ensure control over such processes. The quality management system established should be sufficiently robust to meet external and internal factors such as changes in regulatory requirements, customer feedback, changes to key personnel, facilities etc.

TÜV SÜD has been accredited as a CB (Certification Body) to handle the GDPMDS certification for customers.

**Australia**

The amendment to the Therapeutic Goods Act and the new regulations took effect on 4 October 2002. Australia has implemented the model developed by the GHTF. The regulations and the approval process correspond substantially to the requirements within the EU. Nevertheless, for companies that do not apply the MRA between Australia and the EU, a complete registration process must be carried out. TÜV SÜD is authorized within the MRA as a conformity assessment body (CAB) and offers an abbreviated registration process at a favorable cost.

With the AUS-EU MRA certificate we offer, the Australian TGA incorporates devices into the Australian Register of Therapeutic Goods (ARTG) within five working days. For this purpose, your Australian sponsor needs to submit the MRA certificate, the application form, a copy of labeling, a copy of the Australian conformity declaration, and a copy of the EC and ISO certificates to the Therapeutic Goods Administration (TGA). Otherwise it currently takes between two months and one year for the TGA in case they decide to carry out an audit. Using the MRA for the registration process, there is no audit carried out by the TGA, no additional assessment of the technical file, no consultation with the national health authority and therefore no extra charges necessary.
The following documentation is required under the AUS-EU MRA to be reviewed prior to the issue of an AUS-EU MRA certificate:

- EC and ISO certificates for the devices concerned
- Last audit report issued by a certification body
- Test reports
- Product labeling (labels, user manual, advertisement)
- Device description (technical drawing (only overview), technical description)
- Essential requirements checklist
- Risk analysis summary
- Clinical data summary
- Declaration of conformity according to Australian regulations

**Our services with global impact**

TÜV SÜD is a National Certification Body (NCB) and, within this scope, tests medical devices in compliance with applicable IEC standards; it can issue CB reports and CB certificates. With these documents it is possible to acquire national certificates and approvals offered by certification bodies participating in the CB scheme – at present in more than 40 countries – in an abridged and therefore cost-effective and swift manner.

Further support for your export activities is available in the form of a Free Sales Certificate which is issued on request. Some non-EU countries require such documents both as a proof of compliance with national standards and as a confirmation paper for legal sales on the domestic market.

**Is there any international body working towards true harmonization of approval requirements?**

Yes. The Global Harmonization Task Force (GHTF) was set up in 1993 with the aim of achieving harmonization in medical device regulatory practices. This voluntary group has members from the EU, the USA, Canada, Japan, and Australia. The purpose of the GHTF is to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation, and facilitating international trade.

The primary way in which the GHTF works is to publish and disseminate harmonized guidance documents on basic regulatory practices. These documents, which are developed by five different GHTF study groups, can then be adopted/implemented by national regulatory authorities. TÜV SÜD also participates in various working groups of the GHTF.

**What has the GHTF harmonized to date?**

There are a number of harmonized regulatory components which together form the global regulatory model. Among these components are: essential principles for safety and performance, labeling of medical devices, the role of standards, summary of technical documentation, classification of medical devices; and a set of documents used for the vigilance reporting system. As quite a number of these harmonized documents have been derived from the European regulatory system, there is already a high congruence between the European legislation and the global regulatory model. ([www.ghtf.org](http://www.ghtf.org)).
Why TÜV SÜD?

- National Certification Body able to issue CB reports and CB certificates accepted in more than 40 countries
- Key market approvals from one partner — saving you money!
- Prompt service — saving precious time-to-market

Regardless of whether it concerns the USA, Russia, Australia, Taiwan, or another market: Detailed knowledge of market approval routes is imperative for securing speedy and cost-effective time-to-market. TÜV SÜD experts can offer the medical device manufacturer crucial support based on long-term experience and cooperation agreements in this field.

Profit from the experience of our long-time experienced experts to get the approvals for medical devices in the following countries:

- Russian Federation
- USA
- Canada
- Brazil
- Japan
- China
- Taiwan
- Hong Kong
- Singapore
- Australia

Globalization of Medical Device Approval

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

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