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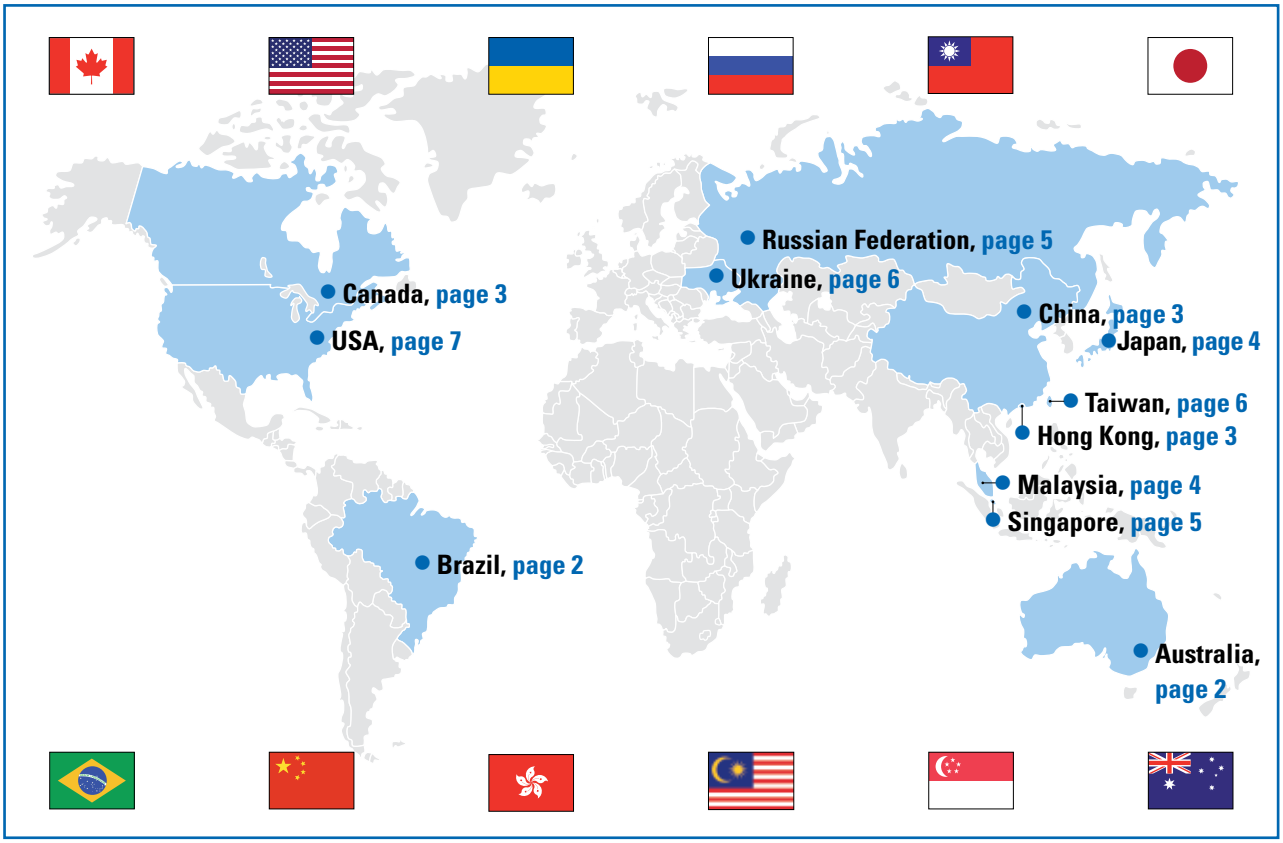
# **Med**-Info

International expert information
for the medical device industry

# Globalisation of medical device approval

**Benefit from the knowledge of our long-standing experienced experts to obtain approvals for medical devices in the following countries:**




Bringing medical devices into commercial distribution on the different markets around the globe is a complex process. In the past, efforts have been taken to harmonise the requirements in order to reduce the burden from the manufacturers, while still ensuring that the products are safe and effective.

However, all these markets still have, in addition, their specific requirements and regulations.

TÜV SÜD enables accelerated market entry in many countries through a variety of services based on agreements and authorisation by authorities.

## Australia

The amendment to the Therapeutic Goods Act and the new regulations took effect in October 2002. Australia implemented the model developed by the GHTF. The regulations correspond substantially to the requirements within the EU.

When MDSAP was initiated at IMDRF´s inaugural meeting in 2012, the Australian Therapeutic Goods Administration (TGA), which is the responsible regulatory authority for medical device registration, was one of the four developers of the Medical Device Single Audit Program (MDSAP). As such, TGA will take into account MDSAP audit reports when considering

- whether a manufacturer has demonstrated compliance with an Australian Conformity Assessment procedure or
- whether to issue or maintain a TGA Conformity Assessment Certificate.

Under some circumstances a manufacturer may avoid routine TGA inspections.

TGA recognises EU notified body CE marking as part of the registration submission. For Class III devices, this can take up to one year or even longer since a level 2 application audit is part of the registration process. Medical Class III Devices containing integral medicine or a biological component do not benefit from CE marking. For medical devices in lower risk classes, the registration can be completed within 3 months.

## Brazil

ANVISA is the national health surveillance agency linked to Brazil's Ministry of Health and is in charge of the registration of medical devices. Manufacturers without a subsidiary in Brazil, intending to place medical devices on the market there, must obtain representation by a Brazilian legal representative recognised by ANVISA.

Before they can be registered or notified with ANVISA, most electrical and some non-electrical medical devices must be certified by a certification body (CB) accredited by the Instituto Nacional de Metrologia, Qualidade e Tecnologia (INMETRO), Brazil's National Institute of Metrology, Quality and Technology. Only reports issued by testing laboratories accredited either directly by INMETRO or by a member of an international accreditation forum, such as IAAC or ILAC, are accepted for INMETRO certification. Testing carried out by TÜV SÜD is recognised by INMETRO-accredited certification bodies, as TÜV SÜD's laboratories fulfil the above criteria. Please note that all test reports must not be older than two years (4 years for large equipment) at the point in time when certification is formally requested to the CB. TÜV SÜD is accredited by INMETRO as a certification body for electrical medical devices. We can offer a complete INMETRO certification service including the initial and annual maintenance factory inspections as required under Ordinance (Portaria) no. 54/2016. You will be in contact with your regional TÜV SÜD partner throughout the complete certification process. The factory inspections can be combined with, for example, the NB audits.

Resolution RDC 185/01 sets forth the requirements regarding the content of the technical documentation to be submitted for registration with ANVISA, and the classification rules for medical devices. The content of classification largely corresponds to Annex IX of the European Directive for Medical Devices 93/42/EEC. All medical devices in Classes III and IV (comparable to Classes IIb and III in accordance with 93/42/EEC) are subject to Brazilian GMP (BGMP: Brazilian Good Manufacturing Practice) inspections carried out exclusively by ANVISA in two-year intervals. Furthermore, all Class III and Class IV medical devices have to undergo the complete ANVISA registration process. Class I and Class II medical devices can get market entry by applying for a simplified notification (cadastre) process. BGMP requirements for medical devices and IVDs are contained in RDC 16/2013. The manufacturer's legal representative is responsible for submitting the application for registration together with the technical documentation plus, if required, evidence about INMETRO certification with ANVISA. If the documentation is found to be in compliance, ANVISA will issue a device registration certificate valid for five years for Class I and Class II devices and ten years for Class III and Class IV devices. In order to avoid any delays or gaps in registration, it is recommended to initiate re-registration at least six months prior to the end of the validity period. ANVISA will accept MDSAP audit reports as a basis for issueing a BGMP certificate required for registration of Class III and Class IV medical devices.

## Canada

The Canadian medical devices regulations classify medical devices similarly 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 has required that manufacturers of Class II, III and IV medical devices as well as IVD devices have a quality management system certified to ISO 13485 CMDCAS in order to obtain a licence to sell their devices in Canada. Only an ISO 13485 CMDCAS certificate issued by a SCC-accredited and Health Canada-recognised registrar has been accepted. Manufacturers of medical devices licenced for sale in the Canadian market have to renew their device licences annually by 1 November.

End of 2015, Health Canada has announced that the CMDCAS program will be terminated and replaced by the Medical Device Single Audit Program (MDSAP). Effective with 1 January 2019, ISO 13485 CMDCAS certification will no more be accepted by Health Canada in order to obtain or renew the medical device licences required for market entry of Class II, III and IV devices in Canada.

In order to support manufacturers in their transition to MDSAP, Health Canada has published a notice which allows manufacturers to enter the program during a surveillance audit in case certain criteria are fulfilled. Further, Health Canada will not take enforcement action against manufacturers that can demonstrate that they have undergone an MDSAP audit in 2018, but have not received an MDSAP certificate by 31 December 2018.

Please note that TÜV SÜD is also accredited by the SCC to provide electrical safety certification for the Canadian market following CSA C22.2.601-1.

## China

The National Medical Products Administration (NMPA) is the authority responsible for the establishment of regulatory requirements and for registration of medical devices for commercial distribution in China. The latest version of the "Regulation for the Supervision and Administration of Medical Devices" (State Council Order No. 650, 7 March 2014) came into force on 1 June 2014. This regulation was also amended on 4 May 2017 (State Council Order No. 680).

The NMPA classifies medical devices into three categories according to their respective risk potential. Class II and III devices have to undergo an elaborate registration process while Class I devices basically have to follow a less burdensome administrative recording process at NMPA. The registration of Class II and III devices generally requires testing by recognised testing laboratories. The registration testing fee is free to start at 1 April 2017. While for Class I devices, self-test reports or test reports from certified third parties are accepted. For Class II and III devices, clinical investigations shall be conducted if the products for registration are not listed in the clinical exemption list. Class I devices are exempt from clinical trails.

The validity of the registration certificate is five years for both medical devices and IVDs. Manufacturers of a valid certificate shall apply for registration extension no later than six months prior to the expiration date of the certificate. Manufacturers must apply for a certificate change in case information on the certificate (e.g., address change) and/or the accompanying documents change. There are two kinds of change applications, namely registered item change and licence item change. Registered item changes are changes that may affect the safety and/or the effectiveness of the product and for that must be evaluated by the Center for Medical Device Evaluation (CMDE). Licence item changes are administrative changes, such as name change of the manufacturer, which do not need CMDE evaluation. It is not possible to apply for a registration extension and a certificate change in parallel.

TÜV SÜD can offer the following services to manufacturers:

- Budget and timeline service for Chinese approval
- Technical meeting service for Chinese approval

## Hong Kong

The Medical Device Control Office (MDCO) regulates medical devices. On 26 November 2004, the Department of Health (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, a 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 recognised by the Department of Health as a Conformity Assessment Body (CAB) under the MDACS.

**Japan**

The top level of regulatory document applicable for medical devices and in-vitro diagnostic reagents in Japan was known as Pharmaceutical Affairs Law (PAL). After an amendment of the law was adopted, which became effective as of 25 November 2014, the title of the revised law was changed to "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (PMD Act)".

The classification, based on GHTF documents, and the product registration scheme have not significantly changed. They include notification ("Todokede" – pre-market submission) to the Pharmaceuticals and Medical Devices Agency (PMDA) for Class I, certification ("Ninsho" – pre-market certification) by a Registered Certification Body (RCB) for Class II devices, and approval ("Shonin" – pre-market approval) for Class III and IV devices. One of the changes under the amended regulation is that RCBs such as TÜV SÜD Japan can certify Class III devices known as "me-too" devices. A significant change is the regulation of standalone software. Standalone software providing information on diagnosis, treatment and/or prevention of diseases had not previously been regulated in Japan, but has been regulated in the law since 2014. Pre-market certification or pre-market approval depend on the classification of the medical standalone software in the same way as for other medical devices. Another significant change is the streamlining of QMS audits. Japanese quality management system (J-QMS) requirements (MHLW Ordinance No. 169 from 2004) were revised and the main part of the Ordinance, chapter 2, became identical to ISO 13485:2003. Several additional requirements are defined in chapters 3 to 6. Conformity to the J-QMS Ordinance is one of the criteria of product registration. If a manufacturer is certified for ISO 13485, the certificate and audit report can be used to demonstrate the conformity to the Chapter 2 of J-QMS Ordinance. Japanese regulators (MHLW and PMDA) joined the MDSAP scheme in 2015. If a manufacturer is certified under MDSAP, in which Japanese regulation is included, the certificate and audit report can be used to demonstrate the conformity to the requirements applicable for a manufacturing site in the J-QMS Ordinance. TÜV SÜD Japan is one of the biggest RCBs, which has certified Class II medical devices and IVD reagents since 2005 as well as Class III medical devices under revised regulation paragraph.

**Malaysia**

Passed in 2012, the Medical Device Act (Act 737) and the Medical Device Authority Act (Act 738) represent the primary efforts of Malaysia to implement mandatory safety requirements for the national medical device market. As part of the device conformity assessment process, the appointed Conformity Assessment Body will assess the device based on evidence submitted in the form of technical documentation. The structure of this documentation must comply with the format known as Common Submission Dossier Template (CSDT) which is developed by the ASEAN ACCSQ. Although not identical, the CSDT format is comparable to the GHTF's STED format. As an alternative to such an assessment, a special provision known as the product verification process has been established for evaluating devices presently approved in the former GHTF members, i.e. Australia, Canada, the EU, Japan and USA.

Additionally, all manufacturers must be certified to the standard ISO 13485 while authorised representatives (of foreign manufacturers) and distributors are legally required to certify their quality management system to the Good Distribution Practice for Medical Devices 2012, known as GDPMD. Following the certification of their quality management system, these economic operators will then apply for the licences relevant to their role in the supply chain.

TÜV SÜD Malaysia is presently an appointed CAB within the purview of the Malaysian Medical Devices regulations 2012. In this capacity, our services include device assessment and certification of the quality management system of manufacturers, authorised representatives and distributors.

### Russian Federation

The approval of medical devices in Russia is divided into two steps: registration with the state authority and declaration at the accredited certification body. The Federal Service on Surveillance in Healthcare (Roszdravnadzor) is the competent authority in Russia for the registration of medical devices. Prior to submission of the technical file to the authority, the applicant should perform different technical (mechanical, electrical, EMV) and toxicological (biocompatibility) tests according to the applicable GOST-R standards in the test laboratories. The compiled technical file should be submitted to the authority, which in turn delegates the expertise of technical documents and test results to a safety experts' organisation. Based on the review result of the safety experts' organisation, the extent of clinical evaluation is defined. The last step of registration is evaluation of the clinical test results and the issue of the registration certificate. The certificate is valid for an indefinite period of time. The registration form is available in Russian in the public database on the authority's website:
**http://www.roszdravnadzor.ru/services/misearch**

The second step of approval is a registration of the declaration of conformity. This is a separate procedure and starts after registration has been completed. The GOST-R certificate has only been required for a few specified medical devices since 2011. For most medical devices the certification process has been changed and now consists of a declaration of conformity. Unlike the GOST-R certificate, the declaration of conformity may only be issued in the name of the Russian importer. The declaration of conformity should be controlled and registered by a certification body accredited by the state organisation "Rosakreditation".

For this purpose, the applicant submits all test reports according to the applicable GOST standards, which must be approved by the certification body. Like the GOST-R certificate, the declaration of conformity is valid for one to three years and can be issued for consignments.

TÜV SÜD can supply all the services you require, provided by native-speaking experts – including registration, GOST-R certification and declaration of conformity.

### 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 low-moderate risk; Class C, moderate-high risk; and Class D, high risk. This risk classification is found under HSGA GN-13.

Unlicenced manufacturing, importation and wholesaling of medical devices and supply of unregistered Class B, C and D medical devices have been prohibited since May 2010. The supply of unregistered Class A medical devices has also been prohibited since May 2011. Documentation to be submitted must follow the Common Submission Dossier Template (CSDT), developed by the Asian Harmonization Working Party (AHWP) which works closely with the GHTF. To receive the importer and wholesaler licence for Class B, C & D medical devices, the organisation must obtain a Good Distribution Practice for Medical Devices in Singapore (GDPMDS) audit by a designated Certification Assessment Body (CAB). The organisation shall establish a quality management system in accordance with the requirements of GDPMDS. If the organisation chooses to outsource any activities that may affect the quality of medical devices, it shall ensure control over these 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 PSB is accredited as a CAB to handle the GDPMDS audit and certification for customers.

For more information, please visit this website:
**www.hsa.gov.sg**

## Taiwan

The Pharmaceutical Affairs Law (PAL) applies to registration of medical devices in Taiwan. The Ministry of Health and Welfare (MOHW) handles specific definitions and charges official organisations with implementation. Manufacturers wishing to export Class II and Class III medical devices to Taiwan must, among other things, submit a detailed company description, a description of the production process, technical documentation, a clinical report and, most important, a quality system documentation (QSD) that meets Taiwan´s Good Manufacturing Practice (GMP) including work and testing instructions.

A Partnership between "R.O.C. TFDA Authorized Medical Device GMP Auditing Organizations" and "EU AIMD/MDD/IVDD Notified Body Partners" exists, facilitating accelerated market access for medical devices. In this context, TÜV SÜD played a major role in the negotiations and implementation of a private agreement with the aforementioned Taiwanese organisations.

An audit report issued by TÜV SÜD, including the Taiwanese regulations plus certification under ISO 13485 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 MOHW 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 in the audit under ISO 13485. The quality management system must ensure that only devices registered with the MOHW are delivered to Taiwan.

An agreement with a Taiwanese distributor regarding market surveillance and bidirectional information of any complaints must be in place. Evidence regarding the handling of vigilance and distribution must be provided and is evaluated by the auditor for your company. After a successful audit, we issue an audit report confirming compliance with Taiwanese regulations and referring to the agreement with Taiwanese certification bodies. This report replaces the submission of a QSD.

TÜV SÜD has been authorised to perform this type of audits since November 2003. The application for registration of the device has to be completed by your representative in Taiwan, not by the foreign manufacturer.

TÜV SÜD can issue a confirmation letter detailing the products covered under the scope of a valid ISO 13485/CE certificate, as required in the device registration process.

## Ukraine

Ukraine has introduced as effective and binding of 1 July 2015 the conformity assessment processes of medical devices according to new national regulations that are identical to the European directives for medical devices. After an initial transition period of one year, the Government of Ukraine has extended the period by one year until 1 July 2017. Against this background, TÜV SÜD offers collaboration with Ukrainian Conformity Assesment Bodies (CAB) with the intent to accelerate certification process of medical devices in the Ukraine based on a valid CE certification performed by TÜV SÜD.

Ukraine has adopted the European regulatory framework for medical devices as well as for in-vitro diagnostics and active implantable devices, transformed it into national regulations, and issued a new national conformity mark.

After 1 July 2017, all products requiring a first or renewed certification have to comply with the new regulations. Products certified according to the former national regulations are still allowed until expiry date of the certificate, but no longer than five years from the date of their placing on the market.

To facilitate new certification, Ukrainian CAB can initiate an agreement with TÜV SÜD that allows them to recognise the results of TÜV SÜD conformity assessments according to the European directives. This makes conformity assessment process much faster and easier; most of all it avoids additional audits of the medical device manufacturers to be performed by Ukrainian CAB. TÜV SÜD has signed agreements with several Ukrainian CABs and is ready to sign similar agreements with further Ukrainian Conformity Assesment Bodies in the Ukraine.

**USA**

Most Class II but also some Class I and Class III medical devices requiring clearance for US market entry can only attain acceptance via a pre-market notification 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 the 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) reviews were previously conducted by the FDA. Starting in 1996, the system was revised to allow several third-party organisations to carry out the administrative and substantive review of the documentation on behalf of the FDA.

The Accredited Persons Program requires the FDA to respond to third-party reviewed files within 30 days. The review timeline for direct 510(k) submissions to FDA is 90 days, beginning with the date of the initial submission. In case the FDA requests additional information from the applicant the review clock is on hold and the extra time needed by the applicant until submitting his additional information is added to the 90 days. The FDA fee of approximately about USD 11,000 for 2019 and about 11,600 for 2020 is only relevant if you submit the 510(k) directly to the FDA (small business fee is USD 2,728 for 2019 and USD 2,899 for 2020).

After product clearance, the FDA can carry out a production site inspection at any time in order to verify that the manufacturer is in compliance with the Quality System Regulation 21 CFR Part 820. 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 FDA's Modernization Act, manufacturers can have routine inspections performed by TÜV SÜD. 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. FDA accepts MDSAP audits as a replacement for their own routine inspections.

Moreover, TÜV SÜD is a Nationally Recognized Testing Laboratory (NRTL) for the US market and offers to test your devices according to, for example, ANSI/AAMI ES60601-1:2005/(R)2012. 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 a single partner. If you are already 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.

## Our services with global impact

TÜV SÜD is a National Certification Body (NCB) as well as a CB Testing Laboratory (CBTL) and, within this scope, tests medical devices in compliance with applicable IEC standards; it can issue CB reports and CB certificates. These documents enable national certificates and approvals offered by certification bodies participating in the CB Scheme – at present in more than 40 countries – to be obtained in an abridged and, therefore, cost-effective and swift manner.

Further support for your export activities is available in the form of confirmation letters which are issued on request. Some non-EU countries require such documents for product registration.

## 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 was founded by representatives from national medical device regulatory authorities and the medical device industry from the EU, the USA, Canada, Japan and Australia.

The purpose of the GHTF was 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 worked was to publish and disseminate harmonized guidance documents on basic regulatory practices. These documents, which were developed by five different GHTF study groups, could then be adopted and/or implemented by national regulatory authorities. TÜV SÜD also participated in various working groups of the GHTF.

There is a number of harmonized regulatory components which together form the global regulatory model. Among these components are: essential principles for safety and performance, labelling 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.

## The GHTF disbanded at the end of 2012

Its mission has been taken over by the International Medical Device Regulators Forum (IMDRF), a successor organisation with representatives from the medical device regulatory authorities – not industry – from Australia, Brazil, Canada, China, the European Union, Japan, Russia, Singapore, South Korea and the United States. Based on the strong foundational work of the GHTF, the forum continues to aim at accelerating harmonization and convergence throughout international medical device regulations (**www.imdrf.org**).

To this end, IMDRF has established several work items, such as:

- Standards – improving the quality of international medical device standards for regulatory use
- Software as a medical device
- Regulated product submission
- Medical Device Single Audit Program (MDSAP)

## Why TÜV SÜD?

- National Certification Body, able to issue CB Reports and CB certificates accepted in more than 40 countries
- Key market approvals from a single partner – saving you money!
- Prompt service – saving valuable time to market

Regardless of whether your operations concern the USA, Russia, Brazil, Japan 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 medical device manufacturers important know-how based on long-term experience and cooperation agreements in this field.

**Your contact partner at TÜV SÜD Product Service can provide further information.**

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