Electronic equipment entering the Brazilian market

New requirements for INMETRO certification for medical devices and in vitro diagnostic medical equipment in Brazil

Language skills is a benefit - Portuguese

Very often, manufacturers looking to distribute and sell electronic products in the Central and South American markets are facing the importance of language skills. In Brazil the spoken language is Portuguese and the ability to speak, read and write the local language offers a distinct advantage when reading the regulatory requirements, dealing with the approval authorities and communicating with the in-country test laboratories. As an example of this, the WEB pages of several of the governmental authorities are in Portuguese only. As a general rule, approval applications for Central and South American countries should be submitted in the local language and user guides must be provided in the local language as well.

Trade bloc and agreements with EU

Brazil is a member of the Mercosur trading bloc. As Brazil is a member of Mercosur, the process for the registration of electronic devices in Brazil has been partially harmonized, theoretically easing the process of gaining admission to the market. Mercosur was established in 1991 and encompasses Argentina, Brazil, Paraguay, Uruguay and Venezuela which officially joined in July 2012. Paraguay is temporarily suspended from Mercosur since June 2012. The EU has bilateral Partnership and Cooperation agreements with Brazil. More information about the agreements and about trading with Mercosur are to be found at the ec.europa.eu homepage.

Mercosur standards

Mercosur has its own regional standards organization Asociación MERCOSUR de Normalización (AMN) that issues and harmonizes standards. The Executive Secretariat of the Mercosur Standards Organization is located in São Paulo, Brazil. Each country in Mercosur must ratify the standards before they are adopted in each member country. A number of standards have been harmonized as Mercosur standards. Cooperation Agreement between IEC and Mercosur has been established and according to the IEC homepage: "The IEC and AMN have agreed to cooperate in a number of areas, covering especially cross representation and exchange of technical information. AMN, whenever possible, recommends to its MERCOSUR Sector..."
INMETRO certification requirements – Medical equipment

For manufacturers of medical devices seeking to sell their products in Brazil, certification from INMETRO is in many cases required in order to obtain National Health Surveillance Agency (ANVISA) registration. Historically, Normative Instruction IN-3 (RDC No. 27), published in June 2011, specified that medical devices falling under the scope of NBR IEC 60601 series must be INMETRO certified. RDC No. 27 and IN-3 were accepting 3rd edition IEC 60601-1 and it changed RCD No. 32, which omitted 3rd edition for INMETRO certification. New requirements were published 26 December 2013.

New requirements for INMETRO certification for medical devices and in vitro diagnostic medical equipment were published 26 December 2013 in the Normative Instruction 9, which adds 30 types of medical devices to the list of products requiring INMETRO certification. The trend is clear - more and more medical devices and now also in vitro diagnostic medical equipment are listed and must obtain INMETRO certification prior to ANVISA registration. Some examples:

- IEC 80601-2-30:2009 - automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 - invasive blood pressure monitoring equipment
- ABNT NBR IEC 60601-2-39:2010 - peritoneal dialysis equipment
- IEC 60601-2-49:2011 - multifunction patient monitoring equipment
- ABNT NBR IEC 60601-2-52:2013 - medical beds
- ISO 80601-2-61:2011 - pulse oximeter equipment
- IEC 61010-2-101:2002 - Safety requirements for in vitro diagnostic (IVD) medical equipment

INMETRO – National Institute of Metrology, Quality and Technology

The National Institute of Metrology, Quality and Technology (INMETRO) is the authority with jurisdiction over the general safety of products as well as EMC. INMETRO is the authority certifying ITE equipment and appliances. The certification scheme is called the Brazilian Conformity Assessment System (SBAC).

Another example falling under the requirements for INMETRO certification are syringes, needles and infusion sets (RDC Numbers 03, 04, and 05).

A complete list of products subject to mandatory INMETRO certification can be found at the INMETRO homepage; however, it is only available in Portuguese.
Test to SBAC-recognised standards
Products must be tested to SBAC-recognized standards by an INMETRO-accredited testing laboratory and a pre-license factory inspection must be fulfilled as well as a review of the user manual in Portuguese language must be conducted before an INMETRO certification can be issued. The tests can be conducted at an ILAC Member Laboratory around the world, but must be done according the INMETRO test requirements. E.g. DANAK accredited laboratories fulfills the ILAC requirement as the Danish accreditation body, DANAK, is a member of ILAC.

Certificate validation time
The certification is valid 5 years where after it must be re-certified. Even the products design is unchanged since the initial certification; a device needs to be fully re-tested by e.g. an ILAC accredited laboratory. A list of certified products (both mandatory and voluntary) in Brazil is available at the following website, however, the website is only available in Portuguese. http://www.inmetro.gov.br/prodcert/Produtos/busca.asp.

ANVISA – National Health Surveillance Agency Brazil
Agência Nacional de Vigilância Sanitária (ANVISA) regulates medical devices in Brazil. The base regulations in Brazil, as well as the medical device classification schemes, are similar to those found in the European MDD 93/42/EEC amended by 2007/47/EC.

Except for in vitro diagnostic (IVD) devices, which are covered by Resolution RDC No. 206, resolution RDC No. 185 is the primary regulation applicable to the registration of medical devices in Brazil. RDC No. 185 describes the applicable device registration procedure and it lists the requirements for documentation to legally register medical devices in Brazil.

Two ways to approval
ANVISA provides two major pathways to device approval: “Registration” is applicable to high risk devices and “Cadastro”, which is simpler and faster, is applicable to low risk devices. However, both “Cadastro” and “Registration” require formal registration and approval from ANVISA.

ANVISA performs all registration and inspection functions within the agency.

Medical classification
The first step in the process of registering a medical device in Brazil is to determine the classification of the device. Resolution RDC 185/01 Annex II lists 18 rules, which is used to determine the classification of medical devices. The classification structure corresponds to the structure used in EU Directive 93/42/EEC amended by 2007/47/EC. Generally class I/IIa/IIb/III in Europe equals class I/II/III/IV in Brazil.

Documentation needed for registration
The degree of risk associated with the use of a device determines the needed level of documentation for registration of a product at ANVISA. The registration of some class 1 and class 2 devices as well as all class 3 and 4 devices are subject to a more rigorous registration process than for low risk appliances.

Brazil Good Manufacturing Practice (GMP)
ANVISA conducts inspections of domestic and foreign medical device manufacturers to determine compliance with Brazil GMP regulations, which for medical devices is resolution RDC 16/2013. The GMP regulations are similar to US FDA 21 CFR Part 820, also known an FDA GMP. The exemption list in instruction IN-2 lists class I and II medical devices applicable for GMP registration procedure. A GMP certificate must be included in the documentation for class III and IV devices as well. The Class I and II devices not listed in the exemption list must follow the “cadastro” procedure.

Upon successful completion of an audit, ANVISA will issue the GMP certificate, which is valid for two years. The certificate must be submitted with the registration application for the above mentioned classes. ANVISA alone determines whether GMP inspections are required to revalidate or update existing registrations - or if evaluations can be completed remotely through a paperwork audit.

ANVISA Registration Holder – In-country representation required
If a medical device manufacturer, bringing medical devices to the Brazilian market, is located outside Brazil, the manufacturer must appoint a Brazilian (Medical Device) Registration Holder (BRH), which is a company holding a Company Working Allowance permit according to IN 01/94 from ANVISA. The BRH is responsible for the medical device registration in Brazil and will not only “own” the registration and the GMP certification; the BRH is the only one which can grant permission for others to import the medical device to Brazil, using the approval in their name. Once a BRH is assigned to the device, it cannot be transferred for pure commercial reasons. Be aware of, that the name of the BRH must be identified on the medical device registration certificates issued by ANVISA and the distributor will control that approval for the 5 year term of certification.

ANATEL – National Telecommunication Agency
Radio and telecom products must be certified and homologated (an administrative approval) by the National Telecom Agency (ANATEL) prior to entering the Brazilian market.

In order to obtain ANATEL product certification, it is necessary to interface with a Brazilian certification body or OCD (Designated Certification Body) accredited by ANATEL.

In-country presence required
An in-country presence is required in the form of a locally registered company (either directly or via an authorized agent) in order to apply for and hold approval in Brazil. The local company applying for approval will also be required to guarantee the supply of spareparts and maintenance for the product.
Categories of equipment to be certified
There are three categories of radio- and telecom equipment regulated by ANATEL. Category I cover terminal equipment intended for use by the general public for purposes of accessing collective interest telecommunication services. Category II cover equipment not covered by the definition of Category I products and that make use of the frequency spectrum for the transmission of signals. Examples hereof are SRD devices. Category III cover equipment not contained in the definitions of Category I and II and that will have interoperability with telecommunication network, e.g. Data network equipment.

Laws and regulations
The General Telecommunications Law (Nr. 9.472/1997) is also known as LGT. It is the legal frame for the telecom sector in Brazil. Resolution 242 from November 2000 is the general regulation regarding certification of telecommunication products. Resolution 323 from November 2002 complements resolution 242. Instrumento de Gestão 01 (IG01) defines the priority of selected test labs during the ANATEL certification process.

Product testing
Products must be tested by a laboratory accredited by INMETO per SBAC (Brazilian System of Conformity Assessment). Typically, all the tests must be performed in Brazil and all the documents must be submitted in Portuguese.

Brazilian standards
Resolution 442
EMC (reference to CISPR 22 (2005) / IEC 61000-4-X)
Resolution 529
Safety (reference to IEC 60950 (2005)
Resolution 506
RF section IX – WiFi and BlueTooth are equivalent to FCC 15.247 (2003)
Resolution 533
SAR
Resolution 481
Lithium Battery

Approval Process
The process for the radio/telecom equipment incl. power adapter:

- Test setup verification and sample shipment
- Testing (EMC + Safety + RF requirements + Functional test + SAR test)
- Creation of test reports
- Preparation of application package
- OCD reviews application package, test reports and issue
- ANATEL reviews and issue Homologation certificate
- OCD technical certification

Certificate validation time
ANATEL homologation certificates are issued by ANATEL to the local representative and they have no expiration date. OCD (Designated Certification Body) technical certificates are issued by OCD and are typically issued to the owner of design (typically the manufacturer). OCD certificates have expiration date depending on the applicable product category:
Category I approvals must be renewed every year and requires product testing and evaluation of factory quality system.
Category II approvals must be renewed every 2nd year and requires product testing.
Category III approval renewal is only required if the product is modified or if the applicable ANATEL standard is revised (if the revision requires product testing).

Renewal of certification test requirements
In-country testing is required in renewals of approvals if the product changes or there was EMC test failure in the original homologation or if the product is applicable to safety requirements (resolution 529) or in case of regulation changes.

Knowledge of legislation, registration, certification and labeling is an advantage.