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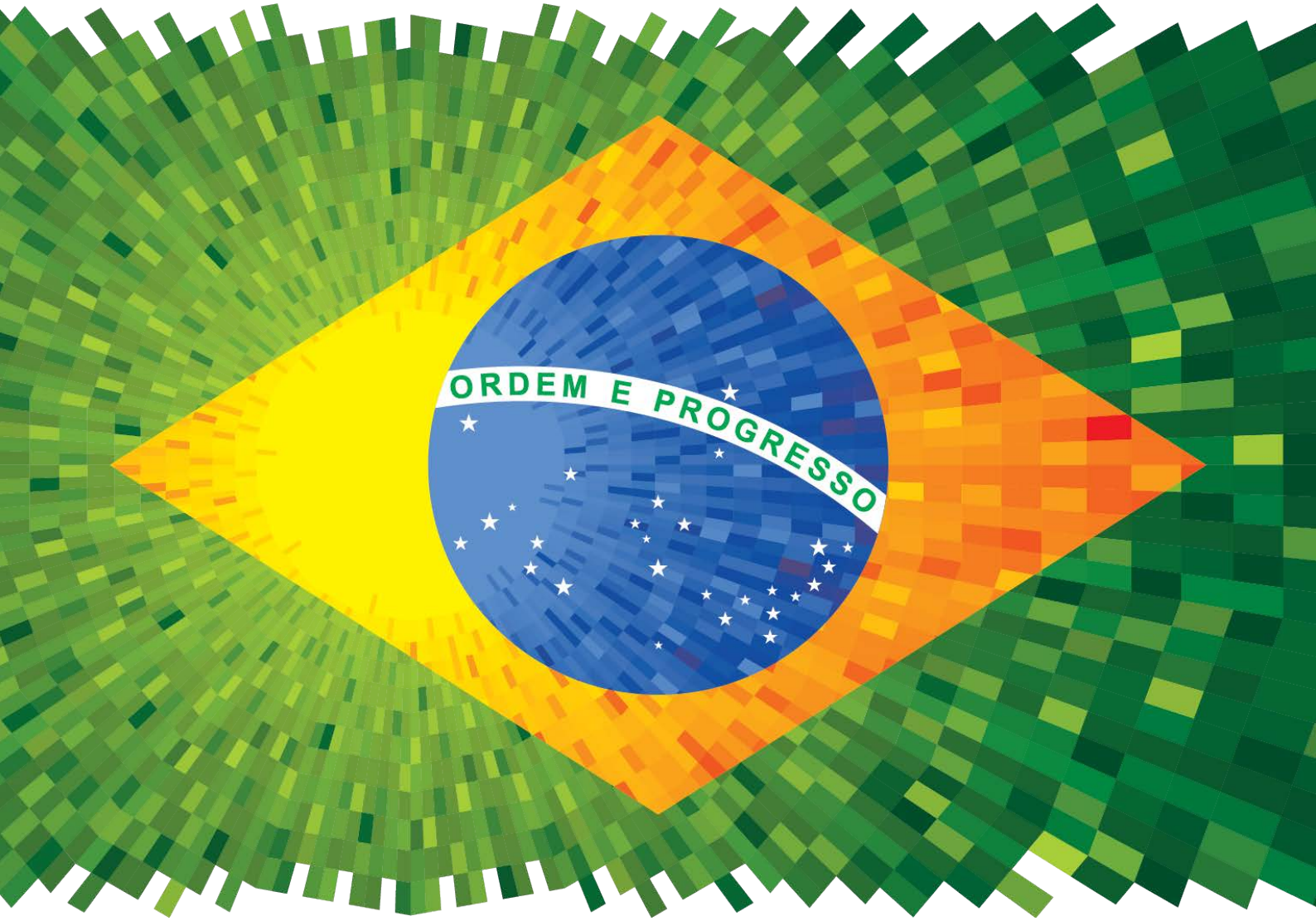
Your Guide to Brazilian Market Access



Intertek
Cleeve Road, Leatherhead, Surrey KT22 7SB UK

info.uk@intertek.com 01372 370900 www.intertek.com

Robust growth offer opportunities for increased sales

Although annual GDP growth in Brazil has averaged only three to four percent, this slower pace of growth reflects Brazil's increased economic stability, which has resulted in job growth and higher wages for Brazil's population of over 195 million.

With a population of more than 195 million people and a mature healthcare system, Brazil represents the largest medical equipment market in South America and one of the largest markets in the world. Manufacturers seeking to expand their market reach by selling medical devices in Brazil will encounter an evolving regulatory approvals system, including mandatory device registration. Because the Brazilian market represents such a great opportunity, manufacturers of medical devices can manufacture from understanding both the regulatory requirements and the registration and certification process for their products.

Why Stop at Brazil?

In addition to the current size and projected growth of the Brazilian appliances and consumer electronics market, there are also many opportunities available through Mercosur (Southern Common Market), an economic and political agreement between Argentina, Brazil, Paraguay and Uruguay which supports free trade. This union, similar to the North American Free Trade Agreement (NAFTA), greatly simplifies exporters' ability to expand into all four markets.

This agreement allows manufacturers who certify their products' compliance with Brazilian requirements to expand their foothold quickly. It also allows manufacturers to leverage their brand awareness, already garnered in the Brazilian market, across several other countries.

This union continues to expand to include more Latin American countries, allowing importers to reap sizeable benefits through interactions within this growing trading zone.

Principal Regulatory and Accreditations Bodies.

INMETRO, the National Institute of Methodology, Standardization and Industrial Quality, is the accreditation body of conformity assessment approved by the Brazilian Government. Residential appliances and Consumer Electronic products entering the Brazilian market must obtain certification by an INMETRO accredited laboratory and carry the Mark of that lab along with the mandatory INMETRO mark.

ANVISA (National Sanitary Agency), they is a Brazilian Government Agency that is responsible to define the regulation of health products (like Medical Devices and Drugs). They define the criterions of certification and register this type of products.

ANATEL (National Telecommunications Agency), it is a Brazilian Government Agency that is responsible to define the regulation of telecommunications products and services. Manufacturers of Telecommunications Equipment located in Brazil or who export to Brazil should verify if their products require mandatory certification. ANATEL provides the specific criteria, rules and standards.

Certification schemes

Mandatory certifications

The mandatory certification is required by law or regulation and gives priority to issues of safety and environment, so the products listed in the regulations may be marketed only after their certification. There are 110 different types of products under the mandatory program. See the website:
http://www.inmetro.gov.br/qualidade/prodCompulsorios.asp

Below are the main products under mandatory certification:

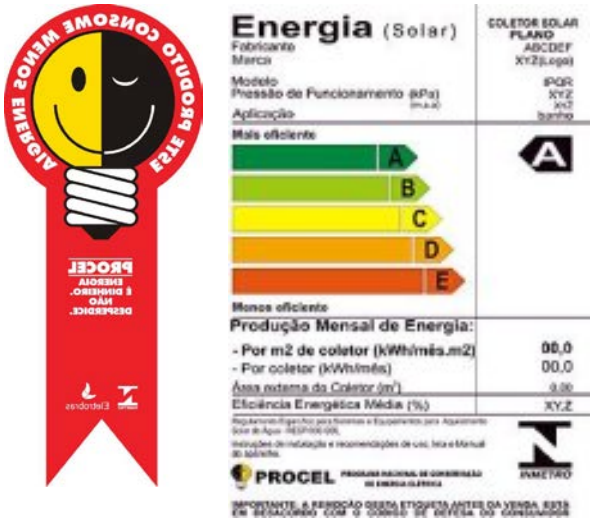
- Hazardous locations equipment
- Medical devices (Electrical medical products)
- Wire and cable
- Household Appliances
- Switches, plugs and receptacles

Voluntary certifications

Voluntary certification, although not a mandatory requirement for conformity assessment of products and services ensures a competitive advantage, besides proving that follow a standard and that have been evaluated in several items of safety and performance. There are 10 different programs under voluntary scheme where the license holder can use the Inmetro Mark, for example: Information Technology products or information technology goods, under a special ordinance (Nbr 170).

Brazilian Labelling Program

Energy Efficiency



In regards to Energy Efficiency requirements, concerning energy consumption for example, a manufacturer may choose to apply for the voluntary PROCEL program. PROCEL was developed and provided by the National Electricity Conservation and is coordinated by the Ministry of Mines and Energy (MME) in conjunction with the Brazilian Electric Power Company, Eletrobrás. PROCEL aims to guide consumers via a label indicating levels of greater energy efficiency within various categories (see the list of products under PBE – Brazilian Labelling Program below), thus providing electricity bill savings. In the process of granting PROCEL, Eletrobrás has a partnership with INMETRO.

See the web-site: http://www.inmetro.gov.br/qualidade/eficiencia.asp

Important Note: The manufacturer has to apply for testing in one of the INMETROs accredited or designated labs (In Brazil only) and then to apply to INMETRO the authorization to apply the efficiency label on the product. Foreign companies are required to have a representative (a legal representative established in Brazil) in Brazil who should apply directly to INMETRO

Program/Product	Methodology	Character
Electrical appliances for heating water (showers, taps and heaters type passage and accumulation)	Declaration	Mandatory
Gas water heaters, instant and accumulation types	Declaration	Mandatory
Centrifuge pumps	Declaration	Mandatory
Air Conditioners	Declaration	Mandatory
Commercial and public service buildings,	Inspection	Voluntary
Residential buildings	Inspection	Voluntary
Solar Water Heating Equipment (Reservoirs thermal solar collectors for pool and bath application systems coupled)	Declaration	Voluntary
Gas Stoves and Ovens	Declaration	Mandatory
Microwave Ovens	Certification	Mandatory
Commercial electric ovens	Certification	Mandatory
Incandescent lamp of domestic use	Declaration	Mandatory
Incandescent lamp of decorative use	Declaration	Voluntary
Compact fluorescent lamps with integrated reactor-based	Declaration	Mandatory
Sodium Vapor Lamps to high pressure	Declaration	Mandatory
Electromagnetic ballasts for high pressure vapor sodium lamps and Metal vapor (Halides)	Certification	Mandatory
Washing machines	Declaration	Mandatory
Electric motors three phase induction squirrel cage rotor - High yield	Declaration	Mandatory
refrigerators, freezers and their counterparts household	Declaration	Mandatory
Systems and equipment for photovoltaic energy (modules, inverters, controllers and batteries)	Declaration	Mandatory
Televisions	Declaration	Mandatory
distribution Transformers with Liquid Insulator	Declaration	Voluntary
passenger vehicles and commercial vehicles	Declaration	Voluntary
Table, Column and Air Circulators Fans	Certification	Mandatory
Ceiling Fans	Declaration	Mandatory

Note: Declaration must be conducted by the in country Supplier or Vendor

Seal Noise

A common example of mandatory compliance regards noise generation. If your product is a hair dryer, a vacuum cleaner or a blender, it is mandatory to label your product with its sound level. INMETRO and IBAMA (Brazilian Institute of Environment and Renewable Natural Resources) created the Seal Noise, part of the Silence Program, which aims to combat noise pollution by guiding the consumer to purchase quieter appliances and encouraging manufacturers to produce products with increasingly lower noise levels.

In addition to the performance aspects of a product, safety must also be considered. Important regulation changes for the appliance and electronics markets.

Note: Governmental agencies can change or modify regulations at any time. Please contact your Intertek representative for the most up to date information relative to your specific product opportunity

Getting Ready for Certification and Ordinances

How can manufacturers of household appliances, Medical Products and Consumer Electronic products actually leverage Brazil's growing market? As with many countries, regulations are constantly evolving for products that will be sold in this market. To stay compliant with these regulations, a manufacturer needs to partner with an expert certification and testing laboratory that is ready to help today. This partnership will be especially beneficial to manufacturers while navigating the certification process and when getting ready to ship to a foreign country.

Requirements: Where to Start?

First of all, it is important to understand the requirements, named "RAC" - Requirements for Conformity Assessment or Ordinances that apply to your product. Learn to differentiate between mandatory versus voluntary, and safety versus performance related regulations.

Steps of the Conformity Assessment that should include, at least, the following items:

- Definition of the Certification Model(s) used: type 1 - 9 or by batch;
- Initial Assessment;
- Certification Request;
- Analysis of Documentation Conformity and Request;
- Initial Audit of the Administration System(s) (when applicable): Most of programs require items according to NBR ISO 9001. NBR ISO 13.485 have to be used for Medical Devices;
- Initial Essay Plan;
- Handling of non-conformities in the Initial Assessment step;
- Issue of Certificate;
- Maintenance Assessment;
- Maintenance Audit (when applicable): once an year;
- Maintenance Essays Plan;
- Handling of non-conformities in the Maintenance step;
- Maintenance Confirmation;

- Recertification Evaluation;
- Handling of non-conformities in the Recertification step;
- Recertification Confirmation; VII – Handling of Claims.

Household Appliances

Household appliance and consumer electronics markets are largely due to growing consumer confidence, consistently low unemployment rates and increased disposable income, especially among lower-income consumer groups. Major appliances had record retail sales growth in 2011 while small appliances also performed well, specifically in the personal care appliances, small cooking appliances and vacuum cleaners sector.

Ordinance 371

On 29 December 2009, INMETRO, the Brazilian quality, standards and metrology bureau, issued Ordinance 371 stipulating that any electrical household appliances made in or imported to Brazil needs to pass mandatory product certification before being sold on the Brazilian market. The Ordinance's implementation was divided into three stages spanning over 2011, 2012 and 2013. On August 8, 2011, INMETRO issued Ordinance 328 as an amendment to explain, clarify and supplement parts of Ordinance 371.

In the first stage, since July 1, 2012, manufacturers or importers of electrical household appliances have been forbidden to import products without mandatory certification.

The second stage, which began on July 1, 2013, forbids manufacturers and importers to sell products to wholesalers and retailers without the mandatory certifications.

In the third stage, now due to commence on January 1, 2014, wholesalers and retailers of electrical household appliances will be forbidden from selling products without the mandatory certifications.

These dates are in fact a year later than originally planned, in order to include a series of products mentioned in Ordinance 328/2011, which supplements the product range stipulated in ordinance 371/2009. These products are: compressors, electrical stoves, electrical ovens (except those covered by IEC 60335-2-36 and IEC 60335- 2-42), commercial microwave ovens covered by IEC60335-2-90, jacuzzis, dryers, dishwashers, wine fridges, freezers, commercial refrigerators, hybrid accumulation water heaters and heat pumps.

Products Covered by Ordinance 371:

Ordinance 371 applies to most electrical household appliances included in ABNT, NBR, NM, NM National Standards or IEC 60335-2-X, except Products included in other clauses of INMETRO:

- Water dispensers (Ordinance 191)
- Gas furnaces (Ordinance 18)
- Electric heat showers (Ordinance 211)
- Refrigerator and freezers (Ordinance 20)
- Air conditioners (Ordinance 14)
- Washing machines (Ordinance 185)

Products excluded in Ordinance 328:

- Centrifuge covered by IEC 60335- 2-4
- Microwave ovens covered by IEC 60335-2-25
- Commercial electric ovens covered by IEC 60335-2- 36 and IEC 60335-2-42
- Water pumps covered by IEC 60335-2- 41
- Motor-driven pumps in IEC 60335-2-51(stationary circulation pumps for heating and service water installations)
- UV and IR radio skin exposing devices covered by IEC 60335-2-27
- Massagers covered by IEC 60335-2-32
- Projectors and similar equipment covered by IEC 60335-2-56

Main requirements of Ordinance 371:

Testing requirements: Ordinance 371 only sets requirements for safety tests, without requirements for EMC or energy efficiency testing. According to the Ordinance, all products covered should be in compliance with IEC 60335-1 and IEC 60335-2-X, as well as any Brazilian national deviations. But, at present, only electric irons covered by IEC 60335-2-3 are required to comply with the following deviation: Power cords of electric irons should be in compliance with Ordinance 286.

IMPORTANT: Electric plugs or sockets incorporated in household appliances exported to Brazil should acquire INMETRO NBR14136 (see details about the Brazilian Plug requirements below).

Test Report Requirements: To apply for the INMETRO mandatory product certification, test reports issued by ILAC labs (International Laboratory Accreditation Cooperation) can be accepted.

Importer Requirements: The Ordinance also stipulates that importers who apply for the mandatory INMETRO Mark shall establish a Customer Service Centre to provide the relevant support to Brazilian consumers.

Exporter / Factory Requirements: Ordinance 371 stipulates that regular assessments of manufacturers shall be conducted to ensure their compliance with the requirements.

As for domestic exporters of electric household appliances, because most requirements in Ordinance 371 are similar to those of CE and GS in the European Union, they can use the certification for export to Brazil if they update the product design and make timely preparations for certification.

Medical Devices, Electrical Medical Products

These Requirements for Conformity Assessment (RAC) establish the criteria for Electrical Equipment under Health Surveillance, meeting the requirements of the standards listed in Additional Documents, seeking the safety of the user. Brazil's current regulatory framework for medical devices, and the requirements for those entities seeking to manufacture, import or sell medical devices in the country. It also discusses the registration and certification process required of all device manufacturers, importers and distributors, and the steps necessary to secure and maintain approval for medical devices. This white paper includes information on requirements found in RDC 27/IN-3 and Ordinance 350, published by Brazilian regulatory authorities in June 2011.

Regulatory Background:

Resolution RDC No. 185 of October 22, 2001 is the primary regulation applicable to the registration of all medical devices, except for in vitro diagnostic (IVD) devices, which are covered by Resolution RDC No. 206 of November 2006. RDC No. 185 describes the applicable device registration protocol and lists the documents required to legally register a medical device in Brazil. Annex II of RDC No. 185 describes the classification structure applicable to medical devices, assigning medical devices to one of four distinct risk classes (I, II, III and IV) according to 18 different rules.

The classification structure for medical devices in Brazil corresponds to that used in the European Union (EU) under Council Directive 93/42/EEC concerning medical devices.

ANVISA Registration Process:

All medical devices imported into or distributed within Brazil must first be registered with the ANVISA "National Health Surveillance Agency", responsible for the regulation and oversight of medical devices and other medical products in Brazil. Specifically, ANVISA is responsible for the registration of medical devices and for the maintenance of a registered products database. Unlike the EU Notified Body system, the 510(k) system of the Food and Drug Administration (FDA) in the United States, or the Canadian Medical Device Conformity Assessment System (CMDCAS), ANVISA performs all registration and inspection functions within the agency.

Only companies based in Brazil can apply for ANVISA registration. Therefore, companies based elsewhere that do not have subsidiaries in Brazil must depend on Brazilian-based third parties, such as hosting companies, distributors and dealers, to obtain ANVISA registration for medical devices. Under such an arrangement, the local third party holds the ANVISA registration, and a manufacturer must maintain an effective commercial relationship with a third party to ensure the on-going maintenance of a registration. Otherwise, a manufacturer will need to repeat the registration process with another local third party to maintain market access.

The registration of most Class 1 and 2 devices involves a relatively simple application process – referred to as "cadastro," meaning "abbreviated registration" – based on the low to moderate risk associated with devices in these classes.

However, based on the greater degree of risk associated with their use, a more rigorous process applies to some Class 1 and Class 2 medical devices, as well as all Class 3 and Class 4 devices. In these cases, the party applying for ANVISA registration may be required to provide some or all of the following documentation with an application, depending on the device characteristics and classification:

1. Free sales certificate (it can be replaced by the INMETRO certificate when applicable);

2. Certificate of Good Manufacturing Practice (GMP);

3. Instructions manual in Portuguese;

4. Labelling and packaging;

5. Letter from the device manufacturer, authorising a Brazilian company to hold the product registration and distribute a device;

6. Clinical trials (sometimes it can be replaced by the INMETRO certification or literature proving the effectiveness of the device);

7. List of all device accessories;

8. For some devices, such as implantable medical devices, cardiovascular products, high-risk IVDs, dialysis equipment and personal hearing aid systems, an Economic Information Report;

9. INMETRO certificate, when applicable the complete set of documentation depends on the nature of the device, e.g., IVD devices, implants, electro-medical devices, etc. Defining the exact package of documentation is a complex process, and requires consulting various laws and decrees (Law 6360:1976, RDC No. 185:2001 and RDC No. 59:2000). The documentation list above applies to the majority of medical devices; in practice, however, required documentation can be much more extensive.

GMP Inspection and Certification GMP certification based on an inspection conducted by ANVISA is required for registration (RDC No. 25, May 21, 2009). The GMP certificate must be submitted with the registration application for all Class III and IV devices, as well as for Class I and II devices noted on the Exemption List (Instruction IN-2, June 6, 2011). GMP inspections are also required to revalidate or update existing registrations. The GMP certificate is valid for two years, and ANVISA alone determines whether subsequent evaluations can be completed remotely through a paperwork audit. The application for GMP should contain the following documentation:

- Device description and indication of risk class;
- Complete flow chart describing the relationship with third-party manufacturers, if any;
- Payment receipt for the GMP inspection fee;
- The GMP inspection check for compliance with RDC No. 59.

To qualify for INMETRO certification, medical device manufacturers must have their products tested to SBAC-recognized standards by an INMETRO accredited testing laboratory. Consistent with the requirements of RDC No. 27 and IN-3 published in June 2011, all medical devices sold in Brazil that fall under the scope of the following standards must be INMETRO certified:

- NBR IEC 60601 series;
- NBR ISO 6875:1998:Dental patient chair;
- NBR ISO 7785-1:1999: Dental handpieces – Part 1: High-speed air turbine handpieces;
- NBR ISO 7785-2:2004: Dental handpieces – Part 2: Straight and geared angle handpieces;
- NBR ISO 9680:2001: Dentistry - Operating lights;
- NBR ISO 9919:1997: Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use;
- NBR ISO 11195:2000: Gas mixers for medical use – Stand-alone gas mixers;
- NBR ISO 8835-2:2010: Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems;
- NBR IEC 61689:1998: Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz

About 3rd edition of IEC 60601-1

Under RDC No. 27 and Instruction IN-3, the 3rd edition of the IEC 60601-1 is now acceptable in Brazil for INMETRO certification. This is a significant change from RCD No. 32 which omitted the 3rd edition of IEC 60601-1 from the Brazilian certification scheme. But it will only be required (compulsory) from Jan/1st/2014.

Technical requirements for the evaluation of the quality system By ABNT NBR ISO 13485:2004

In the initial and maintenance evaluation of the SGQ (QMS) of the manufacturer using the ABNT NBR 13485:2004 for the products object of certification, must verify compliance with the requirements listed below:

- Control of documents
- Control of records
- Planning of product realization
- Customer communication (ref. handling customer complaints 7.2.3.c)
- Design and development validation
- Control of design and development changes
- Verification of purchased product
- Control of production and service provision
- Validation of processes for production and service provision
- Identification and traceability
- Preservation of product
- Control of monitoring and measuring devices
- Monitoring and measurement of processes
- Monitoring and measurement of product
- Control of non-conforming product
- Corrective action

New requirements for syringes, needles and infusion sets

Since June 2013 additional devices falling under the general categories of syringes, needles and infusion sets have needed to comply with a requirement for INMETRO certification. In addition to the initial factory inspection, these devices will need to undergo batch testing to NBR and ISO standards at an ILAC accredited laboratory. These test reports are then analysed by experts and if they pass, then, will issue the INMETRO certificate.

Laboratory Definition

The accredited Certification Body (CB) can use any laboratory accredited within the ILAC MLA, but the laboratory must have the correct standard in their scope by of the essays specified in the RAC or Ordinance.

In case of non-accredited laboratories, the CB should register, through corroborative documents, the reasons that resulted in selection of the laboratory, recording also the results of the evaluations carried out for its qualification effect.

For definition of the laboratories, the following items should be considered:

a) The laboratories defined should be of third parties and duly accredited by Cgcre/INMETRO;

b) Exceptionally, and as long as conditioned to evaluation and approval of CB, a non-accredited laboratory can be used for the specific scope, when one of the hypothesis configured below occurs:

i) When no accredited laboratory exist for the specific scope related to the RAC/ordinance;

ii) When only one accredited laboratory exists and the CB evidences that the price for analyses of the non-accredited laboratory plus the costs resulting from CB evaluation, in comparison with the accredited laboratory is, at least 50% lower;

iii) When the accredited laboratory(ies) within a maximum period of two months, cannot start the analyses or the essays foreseen in the Conformity Assessment Requirements - RAC;

c) When no third party accredited laboratories exist for the scope, the CB should follow the priority order mentioned below in selection of the laboratory:

- First party accredited laboratory
- Third party laboratory accredited for other scope of essays
- First party laboratory accredited for other scope of essays
- Third party non accredited laboratory
- First party non accredited laboratory

d) When INMETRO defines a non-accredited laboratory, such laboratory will have a period of time of 18 months to obtain its accreditation, without such accreditation the laboratory shall not participate in the conformity assessment program under discussion;

e) The assessment executed by the CB in the non-accredited laboratory should be executed by an CB professional having a training register, of at least 16 hours/lesson, under the ABNT NBR ISO IEC 17025 Rule in force, in addition of formal evidence of experience and specific technical knowledge, as related to the essays to be evaluated;

f) If 1st party laboratory is contracted, the CB should accompany execution of all the essays, every time that the laboratory executes this service;

g) If a non-accredited laboratory or accredited laboratories of the 1st or 3rd party are contracted for other scope of essay, CB should evaluate the requirements indicated in Attachment A of the present document;

h) For the essays carried out by foreign laboratories, as long as agreed upon by the regulator, the equivalence of the essay method and the sampling methodology established should be considered and documented. In addition, these laboratories should be accredited by Inmetro or by an OAC that is a signatory of a mutual acknowledgement agreement of which Inmetro is also a participant. These are:

- Interamerican Accreditation Cooperation – IAAC;

- International Laboratory Accreditation Cooperation – ILAC;

What About EMC?

Now, let's assume that with all of its products, your company always carries out complete EMC (electromagnetic compatibility) testing for the US and EU. Is that enough to allow you to place products everywhere in the world? Unfortunately, this is not the case. Many countries that require EMC compliance also impose additional requirements to market entry in terms of deviations to international standards, in-country testing or country presence.

In Brazil, INMETRO is again the authority with jurisdiction over the general safety of products as well as EMC. However, there are some general products that require safety for INMETRO certification and none that require EMC at this time. Only two programs include EMC tests in their programs:

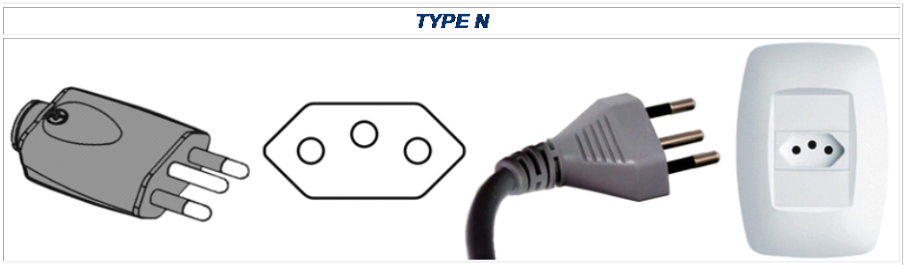
- Medical Devices : Ordinance 350 (Compulsory)
- IT Products or information technology goods: Ordinance 170 (Voluntary)

Test Reports Acceptance

Laboratory: As described above only test reports issued by an accredited lab can be accepted (see item 7.1): By Inmetro or ILAC or IAAC member

Validity: It is very important to check what the Ordinance is declaring as validity of the test reports to be used in the certification process. Examples - Medical Devices: reports with only two years of validity

Brazilian Standard of Plugs and Sockets



The above type N socket and plug are the official standard in Brazil. In order to put an end the proliferation of different types of sockets and plugs, the Brazilian Association of Technical Standards (Associação Brasileira de Normas Técnicas (ABNT)) published the standard NBR 14136 in 2001 and started implementing it in 2007. This ***Brazilian Standard NBR*** *14136, however, is not completely identical to IEC 60906-1. The biggest difference is the fact that the Brazilian standard has a pin diameter of 4mm for the 10A plug and 4.8mm for the 20A plug, while the original IEC 60906-1 standard has a single pin diameter of 4.5mm and a maximum current of 16A.*

Standard Voltage: 127 and 220 Volts / 60 Hz

How can Intertek help?

Intertek is now accredited by INMETRO as Product Certification Body – OCP for the following product categories:

- Med (IEC 60601 series)
- Household (IEC 60335 series)
- OFF / IT products (IEC 60950)

We are well-versed in the new regulations that affect all types of electrical product and can help get your product ready for Brazil. We provide:

- On-site Audit with local auditors.
- Testing to help you obtain the INMETRO Mark.
- Inspection: Intertek local auditors provide both pre-license and follow-up inspection, to ensure on-going compliance.
- Certification, such as INMETRO, as well as additional in country performance evaluations.
- Maintenance of Certificate: Intertek will verify that your product continues to comply as well as provide the Issuance of the Certificate of Compliance maintenance when is applicable.
- Fast project pick up and turn around, for faster market access

Summary

Intertek's product testing and certification specialists will provide the knowledge and guidance you need to focus on the details – numbers, timing, process – to certify your home appliances, consumer electronics and medical devices for use in the Brazilian market. Our partnerships in Brazil allow us to accelerate not only the test reports, but the entire certification process, saving you both time and money. For example, with Intertek's local auditors, you won't need to fly an auditor from Brazil (and spend the time and money to get his visa!) just because you manufacture your product in another country!

Please contact us on +44(0) 1372370900 or email us at info.uk@intertek.com, for more information on our Brazilian compliance services or to request a quotation.

For more information on specific testing and certification information, please visit our website at www.intertek.com.