SGS Helps Manufacturers Understand Brazilian Regulations for Medical Devices

SGS expert explains Brazilian regulations covering medical devices to help manufacturers access this growing market.

Brazil is currently one of the fastest growing markets for medical devices in the world. To access it, manufacturers and suppliers must test their products for quality, safety and efficacy, to ensure they meet mandatory requirements set out by the National Health Surveillance Agency – ANVISA. Certification that the product conforms to these requirements must be carried out by a certification body accredited by CGCRE – General Coordination for Accreditation of INMETRO.

Medical devices are defined by ANVISA as equipment, including parts and accessories, for medical, laboratorial or physiotherapeutic purposes. They can be used either directly or indirectly for diagnosis, treatment, rehabilitation or monitoring, and it includes equipment for beauty and aesthetic purposes. This definition comes from Resolution RDC Nr 27, issued June 21, 2011.

Stakeholders should also consider ANVISA's Normative Instruction Nr 49, which bring together all applicable standards that must be considered when determining whether a product is eligible for certification. They also include the deadline from which some standards becomes mandatory on the certification.

Products that require certification include:

- Diagnostic equipment
- Therapy equipment
- Medical-hospital support equipment
- Disposable materials and devices
- Medical-hospital support materials and devices
- Beauty and aesthetics devices
- Motorized and manual wheelchairs

Stakeholders should be aware, ANVISA makes the final decision on CGCRE certification. To gain ANVISA approval, manufacturers can either go through Notifications (simpler and faster for lower-risk devices) or Registration. Also, approval can requires a Good Manufacturing Practice (GMP) for some products. The audit is performed directly by ANVISA and it must be completed before registration submission, as certification is a pre-requisite for some products. Products must be classified before registration to determine if a GMP audit will be required.

Medical devices covered by any standard included in Normative Instruction Nr 49, considering their respective deadlines, must be certified by an Organization of Certification
of Product (OCP) and display the INMETRO mark.
This certification confirms the quality of a system, process, product or service, and is achieved through the evaluation and review of compliance with specified requirements, technical standards and technical regulations.
All processes are defined in ORD54 (INMETRO, February 1, 2016). Certificates issued in accordance with the previous instruction, ORD350, remain valid until their expiration date unless there is a significant change, in which case they must be certified to ORD54.

The evaluation process used by Product Certification Bodies (PCB) can be summarized as:

1. **Initial assessment:** formal request to the PCB of the product with the minimum documentation.

2. **Initial factory inspection:** focus ISO 13485 clauses and routine tests, according to clauses 8.6, 8.7 and 8.8 of IEC 60601-1. Conducted on 100% of products bearing INMETRO mark. There is additional request to validate the requirements of IEC 60601-1-6, IEC 60601-1-9(only clauses 4.1, 4.5.2 and 4.5.3), IEC 62304 and ISO 14971 during audits.

3. **Test reports:** issued only by laboratories accredited by members of ILAC, IAAC or EA according to all applicable IEC standards. Reports must be issued no more than 2 years ago, or 4 years ago for big size products, considering the date of initial certification process and must be redone upon renewal.

4. **Factory inspections:** must be performed every 15 months to maintain certification – four audits in five-year certification period of validity.

5. **Imported products:** Brazilian local representative inspected to check compliance with the requirements of ORD54 (customer complaints, traceability control of the products bearing the compliance seal, product preservation, etc.). Performed every 15 months.

Finally, manufacturers and suppliers need to also consider:

- **Import controls** – customs agents check medical devices at the border against ANVISA databases to ensure compliance.

- **Monitoring certification** – periodic audits performed on factories and suppliers to ensure continued compliance of product and processes, for medical electrical equipment certification. Design changes instigated during the five-year period of validity must be reported and approved in advance.

- **Local representation** –to sell in Brazil, manufacturers must have a local representative within the country who acts on behalf of the supplier in all product-related matters.

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