ELECTRICAL & ELECTRONICS
MEDICAL DEVICES - INMETRO

INMETRO
MEET REGULATORY REQUIREMENTS FOR ELECTRO-MEDICAL DEVICES
PERFORM ON THE BRAZILIAN STAGE

REGULATORY COMPLIANCE

Medical devices intended for sale in Brazil must be prior approved by the country's National Health Surveillance Agency (ANVISA). Accredited by CGCRE – General Coordination for Accreditation of INMETRO as a certification body, SGS supports medical device manufacturers bringing products to market. ANVISA has developed a set of essential requirements for medical device compliance, similar to those in the EU. There are two routes to ANVISA approval, Cadastre and Registration.

DEFINITION OF A MEDICAL DEVICE

ANVISA defines medical devices as appliances, materials or accessories whose use or application is related to safeguarding individual or collective health. This covers hygiene or cleanliness of surroundings, diagnostic and analytical purposes, cosmetics and perfumes, as well as to dietetic, optical, medical acoustic and odontology.

- Diagnostic Equipment
- Therapy Equipment
- Medical-Hospital Support Equipment
- Disposable Materials and Devices
- Implantable Materials and Devices (certification is not yet mandatory)
- Medical-Hospital Support Materials and Devices
- Beauty and Aesthetic Devices
- Motorised and manual wheelchairs

ANVISA REGISTER/CADASTRE PROCESS

STEP 1

Classify the product to determine if a Good Manufacturing Practice (GMP) audit is required. The GMP audit is conducted directly by ANVISA.

STEP 2

Electro-medical devices covered by any standard included in the Normative Instruction No 4 issued by ANVISA on September 24th of 2015 must be certified by a CGCRE – General Coordination for Accreditation of INMETRO Certification Body, like SGS, and display the INMETRO mark. This process will involve:

- Initial factory inspection against ISO 13485, plus additional requirements of ORD 350 or the new ORD 54*
- Product testing of all INMETRO marked goods conducted by accredited laboratories (accredited by a member of ILAC, IAAC or EA)
- Product test reports must be no more than two years old and must be repeated at renewal
- Annual surveillance inspections based on ISO 13485 and ORD 350 or the new ORD 54 requirements, to ensure standards continue to be met*
- Analysis of technical product documentation in compliance with the applicable standards and ORD 350 or ORD 54, as applicable

*ORD 350 will be valid for new processes only until December 2016. After this date only the ORD 54 must be considered. The process using ORD 350 must be concluded and the certificate must be issued by December 2017, otherwise the process must be cancelled and re-started according to the new requirements of ORD 54. The new ordinance has finally adapted the certification process as a whole, in the context of the 3rd edition of the IEC 60601 standards plus ISO 14971.

STEP 3

Technical documentation is submitted to ANVISA.

STEP 4

Approval achieved.

TWO ROUTES TO APPROVAL

For lower risk devices Cadastre is the simplest and quickest route to approval. Registration is more complex, but both processes require broadly similar documentation.

IMPORT CONTROLS

Medical devices transported to Brazil are checked against the ANVISA database by customs agents, to ensure they comply with registration requirements before being allowed to enter the country.

LOCAL REPRESENTATION

To sell your products in Brazil you must not only meet the ANVISA approval requirements but also have a representative within the country that can act on your behalf in all product related matters. SGS operates a national and international network of accredited laboratories. Coupled with more than 70 years working in Brazil, our expertise in electrical and electronic products classed as medical devices, makes SGS the partner to trust.

GLOBAL REACH WITH A LOCAL TOOL

With a presence in nearly every single region around the globe, our experts speak the local language, understand the culture of the local market and operate globally in a consistent, reliable and cost effective manner.

WHY CHOOSE SGS?

SGS is the world's leading inspection, verification, testing and certification company. We are recognised as the global benchmark for quality and integrity. With more than 85,000 employees, we operate a network of more than 1,800 offices and laboratories around the world.

Independent and innovative, our medical devices experts use state-of-the-art facilities and technology to deliver tailor made added value services that support improve your business.

We strive to deliver outstanding value at every step in your project by providing:

- Rapid turnaround
- Value-based pricing
- Technical assistance
- Key account management

Our expertise in compliance management will support you make the right choices for different national markets, while carrying out the necessary testing and certification quickly and professionally.

CONTACT US

For further information, please contact your local SGS representative or email the global team at br.eecomercial@sgs.com

WWW.SGS.COM/EE

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WHEN YOU NEED TO BE SURE

SGS