

CONSUMER TESTING SERVICES  
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 helps medical device manufacturers bring 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, to personal hygiene or cleanliness of surroundings, or to diagnostic and analytical purposes, to cosmetics and perfumes, as well as to dietetic, optical, medical acoustic, odontology and veterinary products.

- 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
- In-vitro Diagnostic Products (certification is not yet mandatory)
- Beauty and Aesthetic Devices

## 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.

## ANVISA REGISTER/CADASTRE PROCESS

### STEP 1

Classify the product to determine if a Good Manufacturing Practice (GMP) audit is required. A GMP certificate is a prerequisite for Class III and IV products as well as some Class I and II product (in accordance with Brazilian regulations). The GMP audit is conducted directly by ANVISA.

### STEP 2

Electro-medical devices covered by any standard included in the Normative Instruction No. 3 issued by ANVISA 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.
- Product testing of all INMETRO marked goods conducted by IEC accredited laboratories (accredited by a member of ILAC, IAAC or EA).
- Product test reports must be no more than two years old and repeated at renewal, if at the time of renewal there are no test reports available from within the last 5 years.
- Annual surveillance inspections based on ISO 13485 and ORD 350 requirements, to ensure standards continue to be met.

### STEP 3

Technical documentation is submitted to ANVISA.

### STEP 4

Approval achieved.

## 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 7 years working in Brazil, our expertise in electrical and electronic products classed as medical devices, makes SGS the partner to trust.

## WHY CHOOSE SGS?

SGS is the world's leading inspection, verification, testing and certification company. We are recognized as the global benchmark for quality and integrity. With more than 75,000 employees, we operate a network of more than 1,500 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 help 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 help you make the right choices for different national markets, while carrying out the necessary testing and certification quickly and professionally.



## 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.

## CONTACT US

To learn more about SGS's INMETRO certification services contact your local SGS representative, or contact our global team at [ee.global@sgs.com](mailto:ee.global@sgs.com).

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