

Medical
Device
Certification
in Brazil



Expertise and experience

Electro-medical device product certification in Brazil

bsi.

...making excellence a habit.™

Brazil is one of the most interesting new export markets for medical device manufacturers in North America, Europe and Asia. As one the BRIC economies (Brazil, Russia, India and China) it represents significant market growth opportunities. In surveys, over the last three years, Brazil has been consistently identified by medical device manufacturers as a top new market to consider for their medical devices.

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations, and certifications.

Brazilian Medical Device Regulations

All medical devices in Brazil are regulated by the Brazilian Health Surveillance Agency (ANVISA), medical devices are classified according to their risk, Class I (low risk) to Class IV (high risk). Non-Brazilian manufacturers need a local Brazilian Registration Holder (BRH) based in Brazil.

ANVISA requires that all devices must complete a device registration process, this includes submitting a technical file to ANVISA through your BRH. All of your manufacturing locations must comply with Brazilian GMP (RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC Nº16, Brazilian regulations similar to ISO 13485).

BSI will soon qualify to conduct Brazilian GMP inspections under the Medical Device Single Audit Program (MDSAP) initiative.

ANVISA conducts the technical file review and issues the registration.

Electro-Medical Devices

IEC 60601 is the international standard for safety of electro-medical devices. Electro-medical devices entering Brazil require a mandatory INMETRO* IEC 60601 product certification, this must be completed before applying for ANVISA registration. BSI Brazil is accredited by INMETRO to issue IEC 60601 Product Certification.

All electro-medical manufacturers must have a local representative that will apply for product certification. Medical devices must be tested to IEC 60601 and the relevant parts of the standard, manufacturers will audited by the INMETRO Product Certification Body or their approved agent, product certification is issued for up to five years.

* INMETRO is the national accreditation body for testing, certification and system assessment.

BSI INMETRO IEC 60601 Product Certification Process

The table shows the overview of the certification process, for full details, please contact BSI via the details on the back page

| | Phase | Objective | Responsible | |
|---------------------|-------|---|--|---|
| Certification steps | 1 | Quotation proposal request | Collect basic client and product data | BSI Sales |
| | 2 | Initial review | Confirm certification viability and review audit days | BSI Brazil Reviewer |
| | 3 | Quotation and Certification Agreement | Establish a contract. Collect product tests data | BSI Sales |
| | 4 | Initial product review and Factory Audit planning | Complete Product Test Records Review; plan Factory Audit | BSI Brazil Reviewer (stage 1) |
| | 5 | Conduct factory audits | Review QMS, routine tests, product/process verification | BSI Auditor (stage 2 and CAVs) |
| | 6 | Final product and Factory review | Perform certification | BSI Brazil Reviewer makes recommendation to BSI Certification Committee |

Product Documentation

Product documentation required at Stage 1 includes:

1. The applicable quality management system documents, such as quality manual;
2. Confirmation of the **Routine Tests** applied to the product, see below;
3. The **Type Tests Report** performed on the latest version of the product, by a valid Accredited Laboratory, within the last 2 years.

Routine Tests

Ongoing tests performed on each produced unit, during or after manufacturing, normally within the manufacturers facility, to confirm compliance with the minimum test requirements defined in IEC 60601-1: 2005, including:

- a Equipment Operation;
- b Protective earthing, functional earthing and potential equalization (see IEC 60601-1: 2005 clause 8.6)
- c Leakage Currents and Patient Auxillary Currents (see IEC 60601-1: 2005 clause 8.7)
- d Insulation, Dielectric Strength (see IEC 60601-1: 2005 clause 8.8.3)

Valid laboratory accreditations for Type Testing Report

- a INMETRO Laboratory accreditation (preferable);
- b IAAC – Inter-American Accreditation Co-operation;
- c EA – European Accreditation for Co-operation;
- d ILAC – International Laboratory Accreditation Co-operation.

Audit of Manufacturer, Stage II

Predictable, reliable service consistent with other BSI Healthcare services (CE and ISO 13485)

- Assessment of the quality management system in accordance with ISO 13485 requirements, particularly in relationship to the product(s) undergoing product certification.
- Confirmation that the agreed Routine Tests are performed in 100% of the manufactured units.
- Product and process audit, related to the certification scope, of the manufacturing processes to confirm effective methods, controls, infrastructure, verifications, people, etc are in accordance with the declared and planned arrangements.
- Verification that Design Historical Record and Device Master Record are in-place, maintained and in use.
- As appropriate review of previous quality management system audit records performed by a Product Certification Body or Regulatory Agencies (such as ANVISA), and the corrective actions records for nonconformities identified.
- The product sampling and selection criteria, if type tests have not yet been performed.

'Out of the **25** global medical device manufacturers, **23** organizations selected BSI as their trusted partner for CE marking certification against the EU directives.'

What this means for You

For the evaluation of the quality management system in accordance with ISO 13485 requirements, if you have a current ISO 13485 certified under Cgcre/INMETRO accreditation (or other IAF accreditation), or ANVISA RDC 16, BSI may waive the necessity to repeat the management system verification in each Factory Audit if:

- The management system certification scope covers all products applied for IEC 60601 product certification
- The last management system audit indicates that all ISO 13485 requirements related were covered into the audit.

CAV duration may change from time to time based on the change of manufacturing site size, product design changes and technology changes of production process. Extraordinary audits may be required if technical circumstances justify. For CAVs, the Audit shall include the verification of the usage of the BSI Assurance Mark.

Why talk to BSI?

- Predictable, reliable service consistent with other BSI Healthcare services (CE and ISO 13485)
- Knowledgeable product and certification local experts within BSI Brazil
- Single point of contact with a BSI local account manager for quotations and managing applications
- Possibility to roll/combine annual INMETRO Product Certification audits into regular ISO 13485 / CE Marking audits
- Efficient/timely BSI Brazil certification
- Global recognition and confidence in BSI provides confidence in the manufacturer and their device
- BSI will be conducting MDSAP audits in the future that will be recognized by ANVISA.

BSI as the industry thought leader

Here to help you:

- We have 2,900 members of staff,
- 65 BSI offices around the world,
- 70,000 clients operating in 150 countries,
- Together our clients account for 54% of the FTSE 100, 40% of the Fortune 500 and 24% of the Nikkei listed companies,
- We are one of the world's largest independent certification bodies for management systems, with over 90,000 registered sites across the globe.

BSI Medical Devices - Interfacing with the Regulatory Authorities and Lobbying

- BSI have representations on the following world leading associations
- NB-Med Notified Body Forum,
- Team-NB
- Regulatory Affairs Professionals Society (RAPS)
- The Organisation Professional Regulatory Affairs,

Three unique reasons to let BSI help you

Experience:

We have a wealth of experience in helping medical device manufacturers achieve their Global access goals, with a specialist local presence you can rely on.

Expertise:

Local experts to deal directly with ANVISA and INMETRO, keeping you closer to the market and decisions.

Market Access:

At BSI we understand the importance for companies wishing to sell into new markets. Our Brazilian focus will help you to stay ahead of the competition.

Your partner in worldwide compliance: Call BSI today on 11 2148-9600 or visit medicaldevices.bsigroup.com – to start your partnership



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