Medical device registration process in Brazil

Steps to gaining market authorization from ANVISA

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Executive Summary

Medical devices are governed by ANVISA, the Agência Nacional de Vigilância Sanitária or National Health Surveillance Agency, under the Brazilian Ministry of Health. ANVISA is an autonomous arm of the government and is responsible for the protection of public health. As part of that role, ANVISA oversees the production and marketing of medical devices, including the review, approval, and post-market monitoring of healthcare products.

ANVISA's overarching regulatory framework is based on Law 6360/1976, which makes provisions for health surveillance, and Decree 8077/2013, which regulates the registration, control, and monitoring of the products addressed by Law 6360/1976. Decree 8077/20136 also outlines the operating conditions for companies such as manufacturers, distributors, and importers subject to licensing within the scope of health surveillance in Brazil.

All medical devices imported into or distributed within Brazil must first undergo notification or registration with ANVISA. The primary registration requirements are set forth in Resolutions RDC 185/2001, RDC 40/2015, RDC 270/2019, and RDC 423/2020, although a variety of guidance documents and ancillary regulations also exist. Once ANVISA makes its final decision on registration applications, the result is published in Brazil's Official Diary. Approved devices are then listed on ANVISA's public registration database. For Class I and II devices not requiring registration, ANVISA will issue a notification number upon submission of the required documents.

Aside from ANVISA notification or registration, some products require additional certifications in Brazil. For example, many electro-medical devices require electrical safety certification through Brazil's National Institute of Metrology, Standardization and Industrial Quality (INMETRO), and this certificate must be appended to the ANVISA device application.

Brazil in-country representation

Certain functions require formal licensing by ANVISA, including manufacturing, distribution or importation of medical products. Further, ANVISA will only issue these licenses to local companies, i.e., only a Brazilian company may apply to ANVISA for the manufacture or distribution of medical devices; foreign companies cannot. Therefore, foreign manufacturers must appoint a licensed importer in Brazil to submit their notifications or registrations.

ANVISA does not define the role of an independent representative like the Medical Devices Regulation in Europe defines an Authorized Representative. Instead, technically an importer should submit registrations for foreign companies. However, considering the size and volatility of the Brazilian market, having a distributor hold registrations becomes impractical for many manufacturers. As a result, foreign companies who wish to maintain control over their product registrations typically follow one of three routes:

1. Set up their own licensed entity in Brazil, which requires maintaining or contracting with a warehouse, implementing the relevant sections of Brazilian Good Manufacturing Practices (B-GMP) quality system requirements, and hiring the minimum required staff.

2. Outsource the registration to a licensed consulting firm, often referred to as a hosting company or a Brazil Registration Holder (BRH). The BRH submits registrations on behalf of the manufacturer and issues Letters of Importation per shipment, authorizing importers/distributors to buy and receive the product. Resolution RDC 81/2008 allows BRHs to grant permission to other companies to import using a registration granted under its name. The BRH remains primarily responsible for the product, including reporting and traceability.

3. Obtain multiple registrations for the same device, through various importers. Each importer must separately pay ANVISA registration fees, as well as fees for any adjunct certifications required, such as INMETRO or B-GMP. Certificates and fees cannot be shared between importers. Further, ANVISA will review each application independently without taking into consideration that the device may have been approved in the past. Therefore, this option tends to be more viable for lower risk devices that only need approval by ANVISA and do not require B-GMP certification.

ANVISA defines a medical device in Annex I, section 13, of Resolution 185/2001:

"Medical Device: Health product, such as equipment, apparatus, material, item or system with a medical, dental, or laboratory use or application for prevention, diagnosis, treatment, rehabilitation and that does not use contraception and pharmacological, immunological or metabolic means to perform the main function in humans but can be assisted in its functions by such means."

Classification and grouping criteria

Medical devices in Brazil are classified using a four-tiered scheme based on risk to the human body. Increasing risk is assigned to Classes I, II, III, and IV, respectively. Annex II of RDC No. 185/2001 describes the 18 classification rules, which are largely similar to the 18 rules outlined in the European Medical Devices Directive (MDD) 93/42/EEC.

Medical devices are further categorized as:

- **Material** (definition according to ANVISA website): Non-active health product, whose operation does not depend on a power source or any other distinct power source generated by the human body or gravity and which works by converting this energy.
- **Equipment** (definition according to ANVISA's equipment manual): All health equipment used for medical, dental, laboratory and physiotherapy purposes, directly or indirectly used for diagnosis, therapy, rehabilitation and monitoring of humans and for beautification and aesthetic purposes.

ANVISA allows products of similar materials and/or indications to be grouped together in a single registration, if all the criteria for grouping are satisfied.

In Brazil, there are two types of grouping rules:

- **General grouping rules:** Grouping rules applicable to most devices; the grouping regulation depends on the device type (i.e., material, equipment, orthopedic implant).
- **Specific grouping rules:** Grouping rules applicable to specific types of products, for which an individual grouping Normative Instruction applies. These include specific grouping rules for materials and orthopedic implants.

Companies should consult the applicable grouping rules, as ANVISA is less flexible than some other regulators regarding which products can be grouped into a family. For example, products bundled into a single US FDA 510(k) or European Technical File may require separate registrations in Brazil.

Grouping rules	Material
1-4	Non-invasive medical devices
5-8	Invasive medical devices
9-12	Active medical devices
13-18	Special rules

Source: Emergo by UL

Type of grouping rules	Material	Equipment	Orthopedic implants
General	RDC 14/2011	RDC 97/2000	RDC 59/2008
Specific	Normative Instruction 06/2011	N/A	Normative Instruction 01/2009

Source: Emergo by UL

Device registration pathways

In Brazil, medical devices can be approved through two alternative pathways — *notificação* or *registro* — depending on device classification.

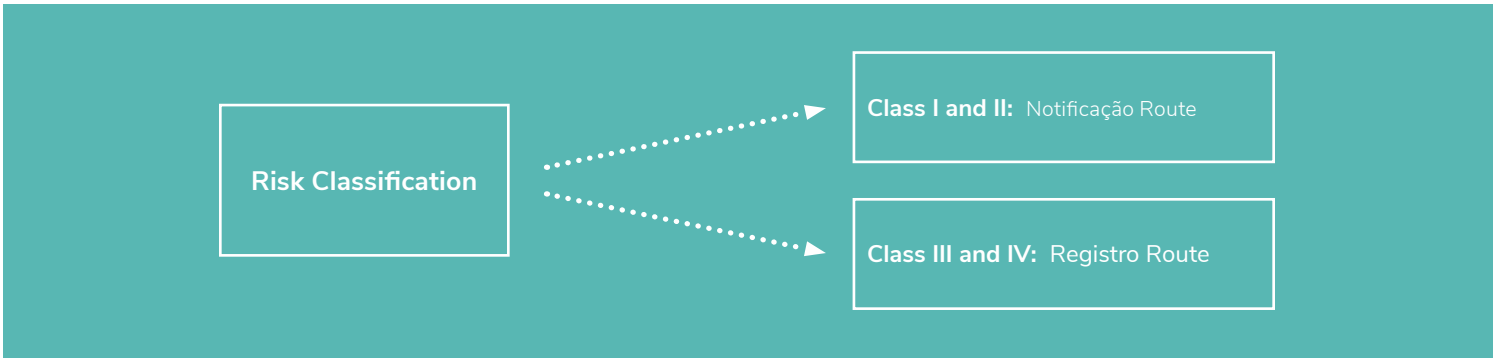
Notificação route

Resolutions 270/2019 and RDC 423/2020 govern the notification process, which applies to all Class I and II medical devices. Essentially, notification is a simplified form of registration that calls for less preparation of technical data and does not require B-GMP certification or ANVISA review prior to approval. These applications require a specific form based on the type of product (e.g., material, equipment, software), as well as other items such as a Letter of Authorization from the foreign manufacturer appointing their Brazil Registration Holder, and any additional Brazilian certifications required for that product.

Aside from outlining the registration requirements, RDC 40/2015 requires that BRHs or domestic manufacturers prepare and maintain a Technical Dossier for all Class I and II devices. This requirement became effective in 2015 when ANVISA released Resolution RDC 40/2015.

A Technical Dossier is a comprehensive collection of technical data, and includes items such as: global marketing history; risk management file or summary; Essential Principles checklist; usability and human factors studies; and more. Technical Dossier requirements are based on the International Medical Device Regulators Forum's (IMDRF) Non-IVD Table of Contents, of which Brazil is a member. ANVISA also published a guidance document, Guia no. 06/2016, to clarify the level of information required per section. The Technical Dossier does not need to be submitted with the notification application. Instead, the BRH or domestic manufacturer must keep a current version on file. Technical Dossiers are also subject to review during ANVISA inspection of BRHs and domestic manufacturers.

Class I and II notifications do not expire and will remain valid for as long as the device is on the Brazilian market. However, changes to the device, such as to materials, shelf-life, or additional models, must be provided to ANVISA. After submitting the modification to ANVISA, implementation proceeds immediately.



Source: Emergo by UL

Registro route

Resolution RDC 185/2001 defines the registro route, which applies to all Class III and IV devices. The registro process requires a comprehensive level of technical and clinical information provided for ANVISA review, as outlined in Annexes IIIa, IIIb, and IIIc of the Resolution. Satisfactory evidence must be provided to validate the product's safety and efficacy. For some products, such as drug eluting stents, such evidence may need to stem from results of pivotal clinical studies performed for the subject device.

Prior to approval of registro applications, proof of compliance with B-GMP is also required. While companies may submit registro applications without proof of B-GMP compliance, the application will not be approved until a B-GMP certificate has been obtained for all applicable manufacturing facilities.

Once approved, Class III and IV registrations are valid for ten years. Renewal applications must be submitted at least 180 days (six months) prior to the expiration date.

GMP inspection

Brazil has its own Good Manufacturing Practices requirements, outlined in Resolution RDC 16/2013. RDC 16/2013 is similar, but not analogous, to ISO 13485 and US FDA current Good Manufacturing Practices.

B-GMP certification must be obtained for all applicable manufacturing sites, which ANVISA outlines in RDC 183/2017. RDC 183/2017 covers various manufacturing activities, such as design, production, assembly, labeling, etc., and identifies which of those stages require inspection and certification.

As with device registration, foreign manufacturers cannot submit a B-GMP application to ANVISA directly. The request must be made by their BRHs.

B-GMP certificates are further tied to the specific manufacturing facility, production line (e.g., medical device versus *in vitro* diagnostic product), and product classification, as noted in Resolution RDC 39/2013. In other words, a B-GMP certificate would be issued to a BRH, for a legal manufacturer, of inspection conducted at a contract manufacturer's facility, and is applicable only for Class III and/or IV medical devices. If any of those elements changes, a new B-GMP certificate must be obtained.

Foreign facilities are inspected by ANVISA (federal level) auditors, while domestic manufacturers are inspected by VISA (local level) auditors located in their state.

RAMS Smart Builders

Emergo by UL's digital RA/QA platform, RAMS, now offers support for preparing Material and Equipment documentation for the Registro pathway. These tools allow you to complete forms in English and accommodate submitting your technical file documentation in Portuguese (translation support is available). They also make it simple to generate your Letter of Authorization and include helpful explanations throughout to streamline the process. Visit **EmergobyUL.com/RAMS** for more information and to sign up for your free account.

Costs and timeframes

The B-GMP fee for foreign manufacturing sites is R$72,806 per facility. **Domestic and Mercosur country** manufacturers pay a lower inspection fee.

The official B-GMP inspection timeframe is 90 days. However, since ANVISA made B-GMP compliance mandatory in May 2010, inspections have been in a continual backlog. At its worst point, inspections were delayed by five or more years.

In response, industry groups such as the Brazilian Association of Industry of High Technology Medical and Hospital Equipment, Products and Suppliers (Abimed, of which Emergo by UL is a member) have filed and won joint lawsuits requiring ANVISA to approve Class III and IV applications prior to issuing B-GMP certificates.

Over time, ANVISA has put some measures in place to alleviate the inspection delays. For example, previously B-GMP compliance was mandatory for many Class I and II devices, such as for electro-medical devices or any formulated device, irrespective of how low a risk it posed to the user. However, ANVISA gradually lifted B-GMP certification requirements for all Class I and II devices. Nevertheless, B-GMP inspection delays continue, with years of backlog still in ANVISA's queue.

In a further effort to resolve the B-GMP backlog, and the flood of industry and individual lawsuits filed against ANVISA as a result, ANVISA joined the IMDRF's pilot Medical Device Single Audit Program (MDSAP) in January 2014. The program was created to allow MDSAP-recognized auditing organizations (e.g., BSI, DEKRA, TÜV SÜD) to conduct a single audit that would satisfy requirements for Australia, Brazil, Canada, Japan, and the USA.

While the MDSAP certificate would not replace the B-GMP certificate, the MDSAP audit results could be used to obtain B-GMP certification. In this scenario, a company could obtain an MDSAP certificate from an auditing organization recognized by ANVISA, supply that to ANVISA, and obtain a B-GMP certificate.

Recently, ANVISA published RDC 217/2018 and added the risk-based approach to the B-GMP inspection process. With this change, ANVISA has the option to issue a B-GMP certificate without performing an on-site inspection, or by performing an inspection with a reduced audit scope or leveraging based on the MDSAP audit report/certificate.

GMP certificates are valid for two years, and renewals must be submitted between 270 and 180 days prior to expiration, in accordance with Chapter V, Article 42 of RDC 39/2013.

INMETRO certification

An additional safety certification from Brazil's INMETRO is required for some products. INMETRO certification is conducted by a Product Certification Body or OCP (e.g., SGS, TÜV Rheinland, UL). This body will review any previous audits performed to standards such as MDSAP or ISO 13485. They will then decide whether to perform an on-site inspection, or if a desktop audit will be sufficient. Further, as with device registration, INMETRO certificates require a licensed BRH. Foreign manufacturers cannot obtain INMETRO certification on their own without a local Brazilian representative.

As part of the device registration, all applicable products must provide a copy of their INMETRO certificates with their notificação or registro applications. The current regulation is Ordinance 384/2020, which eased some of the requirements contained in Ordinance 54/2016, notably eliminating the expiration of INMETRO certificates after five years. INMETRO certification is required for all electro-medical devices identified in Normative Instruction IN 45/2019, and is based on international test standards, e.g., IEC 60601 series testing and ISO 14457:2012 Dental Handpieces. In general, most electro-medical products require INMETRO certification.

If manufacturers have conducted testing through an International Laboratory Accreditation Cooperation (ILAC) laboratory and the test report reflects the current version of the device under review, further testing of the product is not needed to obtain INMETRO certification. Instead, the OCP will review and leverage the existing test reports during their review. Registrants should discuss this issue in detail with their OCPs.

Other products also require INMETRO certification, such as:

- Hypodermic needles
- Breast implants
- Surgical/examination gloves
- Syringes

These products are typically certified through an on-site audit or batch testing. Manufacturers should discuss the pros and cons of each option with the OCP.

INMETRO certificates issued under Ordinance 384/2020 do not expire, assuming manufacturers continue maintenance efforts, including audits conducted by the OCP every 15 months or at least annually. Certification bodies must review and revise certificates issued under Ordinance 54/2016 when performing the next maintenance audit.

Additional Certifications

INCQS certification

Certain medical devices require certification by the National Institute of Quality Control in Health (INCQS), such as:

- Blood bags
- Certain IVD reagents, such as dengue, syphilis, HIV

As part the certification process, the manufacturer must ship devices to Brazil, where they undergo testing by INCQS.

ANATEL certification

As per Federal Law 9472/97, telecommunications products must have a Certificate of Conformity issued by a Designated Certification Body (OCD), indicating that they comply with applicable Brazilian regulatory requirements. This certificate must also be approved or homologated by ANATEL, the National Telecommunications Agency in Brazil.

The certification process involves review of product documentation and product testing conducted by the OCD in Brazil. The certificate expiration varies depending on the product category. If applicable, the ANATEL certificate or test report issued during the certification process is required for the device application to ANVISA.

MTE certification

Certain medical devices intended to protect the user of the device (as opposed to the patient) require certification by the Ministry of Labor and Employment (MTE). For some medical devices such as surgical gloves, MTE certification is required as part of the INMETRO certification process. However, most MTE products do not require certification prior to submitting notificação or registro applications.

To obtain MTE Certification, products will require testing by a laboratory accredited by the Department of Safety and Health at Work (DSST) in Brazil. Testing will be completed according to the standards set forth by the Brazilian National System of Metrology, Standardization, and Industrial Quality (SINMETRO).

If there are no certified testing laboratories in Brazil able to perform the specific testing required, foreign test reports may be accepted. Once the testing is complete, the test reports along with the required product documentation will be sent to the MTE for review and approval. The MTE also requires certain inscriptions (such as the approval number) to be added to the certified device prior to commercialization in Brazil.

Economic monitoring of medical devices

Due to their importance to the Brazilian national health system, certain medical devices must provide information about pricing, distribution margins, and related data known as Economic Information Reports (EIR) to ANVISA.

The itemized list of products requiring an EIR is defined in IN 85/2021, and the list of information required in the EIR is outlined in RDC 478/2021. The scope of products requiring an EIR has been reduced to the following types of products for cardiovascular procedures:

- Implantable double-chamber defibrillator
- Implantable single-chamber defibrillator
- Implantable defibrillator for cardiac resynchronization therapy
- Biological heart valve prosthesis
- Mechanical heart valve prosthesis
- Pharmacological stent for coronary arteries
- Stent for coronary arteries
- Pacemaker heart chamber, implantable dual with frequency response
- Pacemaker heart chamber, implantable dual, demand
- Pacemaker, implantable heart rate fixed single camera and demand
- Cardiac pacemaker, single chamber implantable with frequency response
- Pacemaker for implantable resynchronization therapy heart
- Pacemaker, intracardiac

BRHs must submit EIRs to ANVISA within 60 days of a device's registration being published in the Official Diary.

Modifications to approved registrations

Modifications to active device registrations require careful analysis because ANVISA may require a modification application, depending on the change. Where applicable, modified products can only be placed onto the market after ANVISA's approval of the changes.

For lower-risk notification products, import and commercialization of the old version is allowed until the end of the product's shelf-life.

Summary + Conclusion

The complexity and costs associated with the medical device registration in Brazil depends on classification of the device, as well as whether any additional certifications are required, such as INMETRO, ANATEL, or INCQS. Through the lifetime of the registration, it is important to maintain strong change control processes and keep your registration information up to date. This is particularly critical to avoid problems during the importation process, as the shipped product must match the product that was approved by ANVISA, including each individual model number. Furthermore, registrants must stay informed of regulatory changes as ANVISA constantly reviews and updates regulations.

Learn more

Need help with ANVISA compliance? Emergo helps medical device companies with regulatory compliance and market access in Brazil and other markets worldwide. Here's how we can help:

- Medical device and IVD classification and assessment
- ANVISA technical file preparation and submission
- Brazil Registration Holder for companies with no local office

Learn more about how we can help you with European medical device compliance at **EmergobyUL.com**.

About the author

Luiz Levy Cruz Martins is the Quality Assurance Manager for Emergo's office in Brasília. With more than 10 years of experience in medical device regulatory and quality affairs, his expertise includes ANVISA registration submissions and quality management system implementation and audits to RDC 16/13, ISO 13485, ISO 9001, FDA QSR, and other QMS standards. Luiz holds Lead Auditor certification from BSI and completed a bachelor's degree in pharmacy, as well as post-graduate courses in industrial management and quality management systems in Brazil.

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