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White Paper

MEDICAL DEVICES REGULATIONS IN BRAZIL

Understanding ANVISA Regulatory Procedures

INDEX

1 Introduction

Medical devices are of utmost significance in Brazil's healthcare industry and the rapidly evolving technological innovations have further added a gigantic positive influence. With over 211 million population, Brazil is the largest country in South America/Latin America and there is a dire need to cater right healthcare needs of the people. In Latin America, Brazil stands as the largest medical device market in terms of revenue, manufacturing output and imports. In recent times, the Brazilian medical device sector is witnessing substantial growth and offering opportunities, globally. However, gaining access to the Brazilian market is prone to significant hurdles with the complex and dynamic Regulatory approval system. This whitepaper focuses on the Brazilian market growth and throws light on the current medical device regulations in Brazil, which could help to overcome the Regulatory and market-entry bottlenecks.

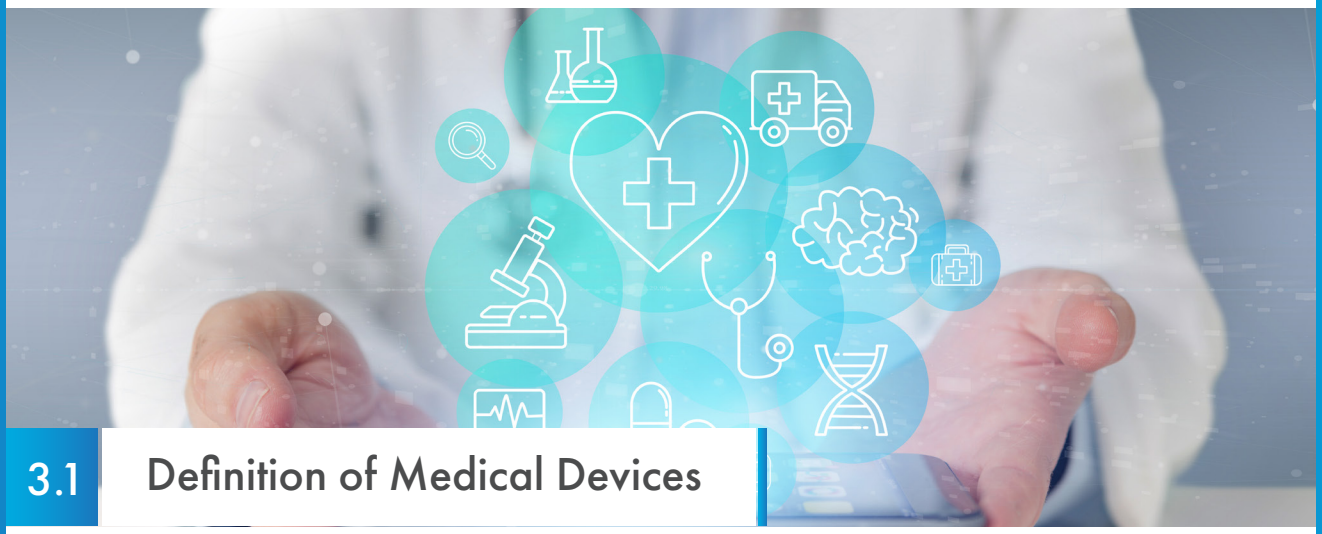
2 | Brazil Medical Devices Market Dynamics

According to Medgadget research, throughout the forecast period (2017-2023), Brazil medical device market is expected to reach USD 1.8 billion with a growing CAGR of 9%. The market growth is triggered by several factors, such as an increase in public health expenditure, usage of revolutionizing innovation and technologies in state-of-the-art medical devices, growth in healthcare infrastructure in the country, growing healthcare mobile applications, the emergence of stronger biocompatible materials, cloud integration and a rise in the elderly population.

Besides, high growth potential for the import of medical devices, the falling cost of production, the rising manufacturing capacities in the electronic industry, the demand for early detection and non-invasive therapies for chronic diseases will propel the Brazilian medical devices market growth. On the other hand, the factors which impede the Brazilian market growth are, high cost of imported medical devices, high sales tariffs, low penetration of medical devices and fluctuating connectivity among inaccessible regions of Brazil. However, some major factors, like spreading awareness, demand to curtail rising healthcare costs and the development of user-friendly devices are expected to support the growth of the market over the assessment period.

3 Medical Devices Regulations in Brazil

Since 1993, the National Health Surveillance Agency or ANVISA (Agência Nacional de Vigilância Sanitária) has been regulating the registration and commercialization of medical devices in Brazil. ANVISA is a self-funded agency under the Brazilian Ministry of Health, which carries out all the registration and inspection processes within the agency, unlike the European Union (EU), United States (US), or Canada Regulatory bodies. ANVISA works with a mission, "to protect and promote the health of the population, intervening the risk associated with production and use of products and services subject to health regulation, in a coordinated and integrated action within the Unified Health System (SUS - Sistema Único de Saúde)". Medical device manufacturers willing to legally sell their products in Brazil, must comply with the medical device regulations set forth by ANVISA for classification, registration and authorization procedures.



3.1 Definition of Medical Devices

As per Annex I of RDC 185/2001, ANVISA defines medical devices as, "Health products, such as equipment, devices, materials, articles or systems for medical, odontological, or laboratory use or application, intended for prevention, diagnosis, treatment, rehabilitation, or anti-conception and that does not use pharmacological, immunological or metabolic means to fulfil its main function in humans beings, but have its functions assisted by such means."

3.2 Classification and Grouping of Medical Devices

As the approval process in Brazil is time taking, it is advised to adhere to the correct medical device classification and grouping, before the registration process. Improper classification can significantly impact the Regulatory approval process and associated costs. Therefore, the initial step to comply with Brazilian regulations is to ascertain the classification of medical devices.

To determine the classification of medical devices, ANVISA has published the rules as found in Annex II of RDC 185/2001. In accordance, medical devices are classified into four classes (Class I-IV) based on their risks to users. Class I and II devices are considered as low-risk and Class III and IV devices as high-risk. Medical devices also follow the 18 classification rules, which are largely similar to the 18 rules outlined in the European Medical Devices Directive (MDD) 93/42/EEC. Accordingly, the manufacturers who want to register a medical device in Brazil must determine its risk class. The below tables depict the classification and grouping of medical devices in Brazil.

Risk Level	Classification
Low Risk	Class I
Medium Risk	Class II
High Risk	Class III
Very High Risk	Class IV

Grouping Rules	Material
1-4	Non-invasive Medical Devices
5-8	Invasive Medical Devices
9-12	Active Medical Devices
13-18	Special Rules

3.3 Registration Pathways for Medical Devices

After determining the correct classification of a medical device, manufacturers can proceed to registration procedures. In Brazil, depending on the risk classification, medical devices can be registered through two pathways, namely, Notificação Pathway and Registro Pathway. To obtain ANVISA registration for medical devices, only companies based in Brazil are applicable and those based elsewhere must rely on Brazilian-based third parties, such as, host companies, distributors and dealers. The lower-risk Class I and II devices will follow the Notificação registration process, which includes a simplified application and the higher-risk Class III and IV devices will follow the rigorous Registro registration process.

Notificação Pathway

- Applicable to all Class I and II medical devices
- Before the market-entry, these class of medical devices only require a formal notification and no longer need approval by ANVISA
- Unlike the old registration pathway (Cadastro), this new notification pathway does not require any comprehensive submissions, like technical dossiers, labeling materials and proposed Indications for Use (IFU) documents. However, the manufacturers are expected to have all these documentations available upon request (in case of an inspection by ANVISA)
- A re-validation is not required for Class II devices that are already registered in ANVISA, except if changes are requested. However, manufacturers must be compliant with GMP requirements and any other applicable technical standards and regulations. The initial registration number could be used as a notification number and the additional notification is not required, except for the cases, when certain changes have been made to the devices
- For entities responsible for the medical device changes, it shall be sufficient to submit the appropriate notification containing the description of the changes made to the device. The applicant should duly prepare and keep any additional information and provide it upon request. The related notification form could be downloaded from the official ANVISA`s website

- The device's labeling information and IFU should meet the general requirements applicable for the appropriate type of device class, under the risk-based classification of medical devices. The labeling of a medical device under the notification procedure should contain the ANVISA notification number and should be in Portuguese or in a form of the appropriate symbols
- Medical devices under the notification procedure are also exempted from the obligation to provide a free sale certificate issued in the country of origin. While this same rule applies to the certificate of conformity, the absence of this document, should not prevent the marketing of the device, providing that the appropriate notification has been duly filed to ANVISA
- The applicant should provide the certificate within 180 days from the date, the appropriate request becomes valid. Failing to do so will result in the cancellation of the notification. A consolidated report issued by the testing laboratories can be provided by the applicant, in case, if for some reason, the requested certificate could not be issued
- During the period of validity of notification, if the validity of the certificate of conformity expires, the applicant can provide a new certificate within 90 days and failing to comply with this requirement, could lead to cancellation of the notification
- In case, if during the audit or inspection, ANVISA would identify non-compliances or irregularities, it is entitled to cancel the notification. In case, if any notification of changes contains any incorrect data, the same rule should be applied. The notification could also be canceled upon request submitted by the applicant itself, in case, if they no longer intend to market the medical device in Brazil

Registro Pathway

- Applicable to all Class III and Class IV medical devices
- It is mandatory to pay the application fees, before registration
- A licensed third-party company is required to be your Brazilian Registration Holder (BRH), if your company is not present in Brazil. This company will oversee the registration procedures of your device and will hold the title of your registration certificate
- This registration process requires a comprehensive level of documentation for ANVISA review, like a letter of authorization from the foreign manufacturer to a local representative in Brazil, a BGMP (Brazil Good Manufacturing Practices) compliance certificate and an INMETRO certificate
- As outlined in RDC 16/2013, manufacturers will be audited by ANVISA for BGMP compliance. All manufacturing facilities must have proof of BGMP certificate, prior to approval of Registro applications, without which the application will not be approved. Fees for these audits are due every two years and this audit is done to investigate the product's safety
- An INMETRO (The National Institute of Metrology, Standardization and Industrial Quality) certificate is required for all electro-medical devices. This certification is valid for five years and requires annual audits and payment of fees

- In compliance with RDC 185/2001, a technical file, including clinical studies and device information should be compiled
- All files relevant to ANVISA submissions must be in Brazilian Portuguese
- A notification number will be issued within 30 days after applying and the registration timeline is between 8-15 months
- ANVISA provides a DOU (Diário Oficial da União) registration number to the approved devices and this registration is valid for 10 years
- For renewal, applications must be submitted at least 180 days (6 months) prior to the expiration date
- You may begin marketing your device after you have a designated and approved distributor to bring your product into Brazil

4 | UDI Requirements for High-risk Devices

ANVISA's new RDC 232/2018 listed out the below mentioned UDI requirements for high-risk devices:

- The device traceability labels will have to feature bar codes with information including, device identifier, expiration date and a lot of serial numbers
- The registrants will have to provide three copies of traceability labels to ANVISA for use in medical records, patient documents and financial documents
- Bar codes will have to meet GS1 and Health Industry Business Communications standards in order to be accepted by ANVISA
- The regulator has to set up a UDI database, the RNI system, to store and manage UDI information

5 | Authorizing Medical Devices in Brazil

Before the medical devices are authorized by ANVISA, certain devices must comply with the BGMP inspection standards and have an INMETRO certification, to confirm the device's compliance with the Brazilian standards and requirements.

5.1 BGMP Inspection

Brazil has its GMP requirements as outlined in Resolution RDC 16/2013 and it is similar to ISO 13485:2016 and the US FDA current GMP. A BGMP certification based on an inspection conducted by ANVISA is required for registration. This certificate is applicable to Class III and Class IV devices and must be submitted with all the registration applications. BGMP inspections are also required to revalidate or update existing registrations and ANVISA alone determines whether subsequent evaluations can be completed remotely through a paperwork audit. The process involves:

- BGMP certification must be obtained for all applicable manufacturing sites such as design, production, assembly, labeling, and are issued to a BRH and is applicable only for Class III and/or IV medical devices
- The application includes the following documents like device description and an indication of risk class, a complete flowchart describing the relationship with the third-party manufacturers, if any, payment receipt of inspection fee and an inspection check for compliance with RDC No. 59
- Foreign facilities are inspected by ANVISA (federal level) auditors, while domestic manufacturers are inspected by VISA (local level) auditors located in their state
- MDSAP (Medical Device Single Audit Program) certificate would not replace the BGMP certificate, however, MDSAP audit results could be used to obtain BGMP certification
- BGMP certificates, whether issued via an onsite inspection conducted by ANVISA or by leveraging MDSAP, are valid for two years
- Renewals must be submitted between 270 and 180 days prior to the expiration

5.2 INMETRO Certification

To successfully register with ANVISA, most electrical medical devices and some non-electrical medical devices must achieve an additional safety certification from the Brazilian accreditation body - INMETRO or through an INMETRO accredited certification body. An INMETRO certificate will be issued for approved devices, which are authorized to display the INMETRO certification mark. Prior to INMETRO certification, a factory inspection is also required, in order to maintain the INMETRO certification. This certification is valid for 5 years and a re-certification has to be performed after the expiry date. The process involves:

- INMETRO certification is conducted by a Product Certification Body or OCP and requires an onsite audit of the manufacturing facility, for both the initial certification and annual surveillance audits
- As with device registration, INMETRO certificates require a licensed BRH
- Without a local Brazilian representative, foreign manufacturers cannot obtain INMETRO certification on their own
- As part of the device registration, all applicable products must provide a notarized copy of their INMETRO certificates with their Notificação or Registro applications
- All electro-medical devices identified in Normative Instruction IN 04/2015 require INMETRO certification and are based on international test standards, e.g., IEC 60601 series testing, ISO 14457:2012 dental handpieces. Other products such as hypodermic needles, breast implants, surgical/examination gloves, syringes also require INMETRO certification
- If manufacturers have already conducted testing through an International Laboratory Accreditation Cooperation (ILAC) laboratory and if the test report is less than two years old, there is no need for INMETRO certification
- The OCP will review and leverage the existing test reports during their review
- INMETRO certificates are valid for five years assuming manufacturers continue maintenance efforts, including annual onsite audits by the OCP of the manufacturing facility

6 | Conclusion

In Brazil, the medical devices sector is gaining ground with positive indicators like on-demand healthcare, increasing mobile healthcare applications, favorable demographic conditions, increase in elderly population and affordable government initiatives. To align with these positive growth factors, ANVISA has also announced several Regulatory priorities for medical devices in 2020, like, working on the regulations of SaMD in Brazil, implementing a UDI system, updates to Normative instructions on electromagnetic compliance certification, launching a new product labeling and IFU uploading system and revisions to INMETRO ordinance. However, manufacturers willing to expand their market reach will encounter challenges, while navigating through the evolving and complex Brazilian Regulatory process. Though ANVISA has devised key regulations to address the increasing demand for medical devices in Brazil, the manufacturers must ensure to understand the Regulatory procedures, adhere to the complaint standards and develop applicable strategies to maintain continuous market access. Furthermore, registrants must stay abreast of the anticipated ANVISA's Regulatory changes and work with Regulatory experts, to mitigate setbacks from unforeseen challenges and simplify the access to the Brazilian market.

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medicaldevices.freyrsolutions.com

+1 908 483 7958 | sales@freyrsolutions.com | www.freyrsolutions.com

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