MarcM Consulting Canada
is founded on the principle that
good regulatory management is the key
to success in business relations between
local and foreign partners and governments.

Brazil-Canada Chamber of Commerce, Healthcare Forum
December 7th, 2017

Medical Devices in Brazil: A Regulatory Overview

With a surging economy ranked in the top ten globally and with its mature industrial base, Brazil annually attracts billions of dollars in foreign investment.

Covering almost half of South America, Portuguese-speaking Brazil shares its border with every country on the continent except Chile and Ecuador. Its expanse is the fifth largest globally, exceeded only by that of Russia, Canada, China and the United States. The 26 states and national capital area of the Federative Republic of Brazil house a combined population of approximately 200 million people, mainly in major cities on or near its Atlantic shoreline.

Scenic Rio de Janeiro and business-oriented São Paulo dominate the country's south while further north Salvador retains its centuries-old colonial charm and Fortaleza boasts spectacular multi-coloured sand beaches. Ecologically, the vast Amazon rainforest and river basin give Brazil a level of biodiversity no longer found in many other parts of the world. Brazil is about more than regulations!

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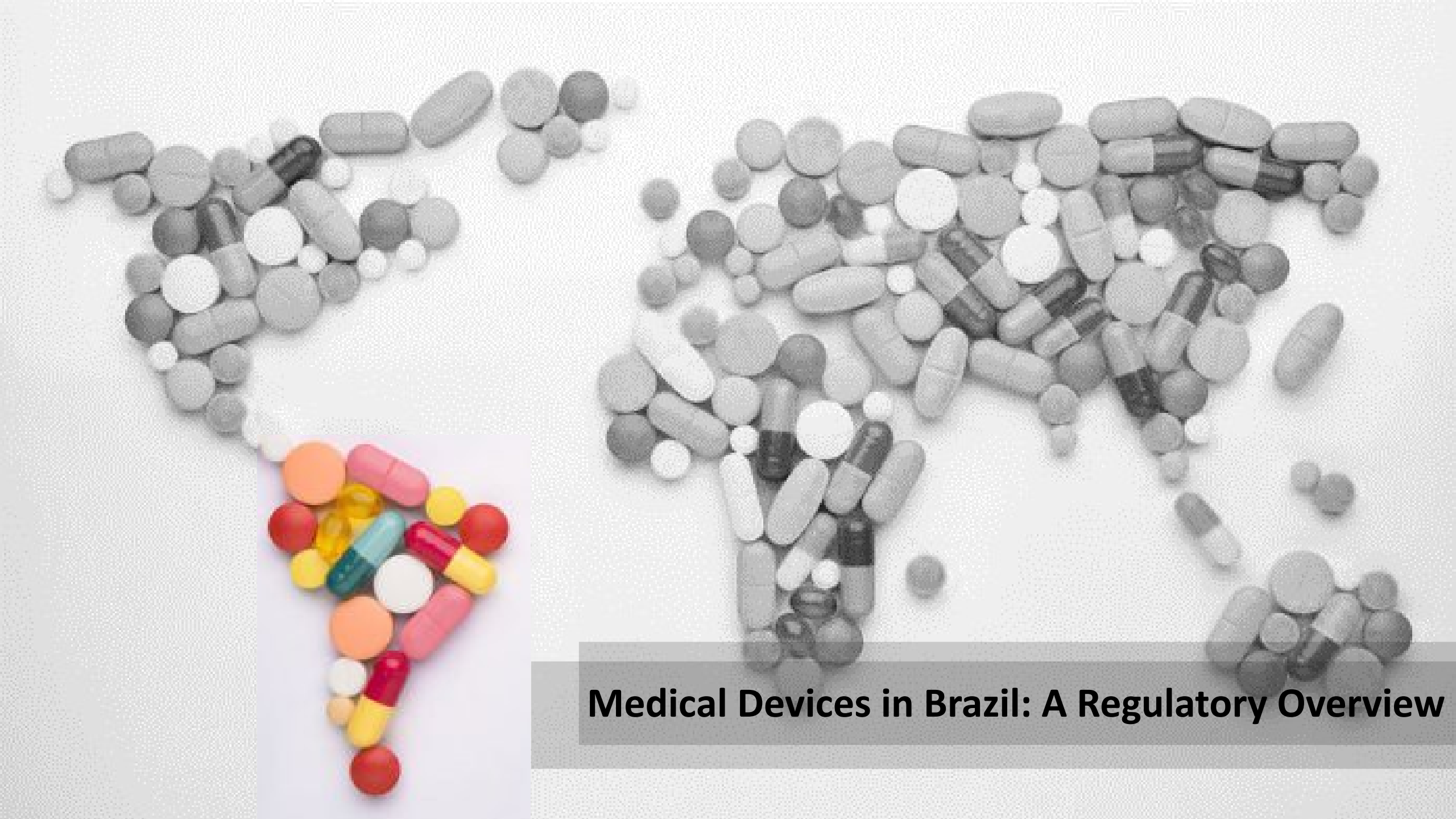
"Bringing the Americas Closer Together"



Medical Devices in Brazil: A Regulatory Overview


Roraima
Amapá
Amazonas
Pará
Maranhão
Ceará
Rio Grande do Norte
Paraíba
Piauí
Pernambuco
Alagoas
Sergipe
Acre
Rondônia
Tocantins
Bahia
Mato Grosso
Federal District
Goiás
Minas Gerais
Mato Grosso do Sul
Espírito Santo
São Paulo
Rio de Janeiro
Paraná
Santa Catarina
Rio Grande do Sul
North Region
Northeast Region
Central-West Region
Southeast Region
South Region

Brazil – Medical Devices Regulatory Overview

TOPICS FOR INITIAL CONSIDERATION - COMPANY REQUIREMENTS

- Have a local representation/Agent (subsidiary, partnership with local established company)
- Local representation/Agent must have a legal representative person, a technical representative professional (usually Pharmacists or Engineers) and hold Federal/ANVISA and State or Municipal Medical Devices Establishment Licences.
- Lay-out and facility must be approved by local sanitary surveillance government body, including warehouse/storage area, administrative area, changing rooms, toilets, etc
- Device type and classification based on risk level. Class I, II, III, IV
- Mandatory Good Manufacturing Practices Certification issued by ANVISA and/or MDSAP Certification for Class III and IV. Class I and II, facility can be audited at any time by ANVISA

Brazil – Medical Devices Regulatory Overview

TYPES OF MEDICAL DEVICES

Non IVD:
Equipment
Software
Articles and
Materials

Comply with RDC 185/01

IVDs:
Reagents
Kits
Calibrators
Standards and
Controls

Comply with RDC 36/15

They have different and specific requirements and classification systems.

Brazil – Medical Devices Regulatory Overview

TYPES OF MEDICAL DEVICE APPLICATIONS

Notification: Class I & II
Simplified/Expedited Process

Comply with RDC 40/15 (Non IVD) & RDC 36/15 (IVD)

Registration: Class III & IV

Comply with RDC 185/01 (NonIVD) & RDC 36/15 (IVD)

i. In both cases Marketing Authorization numbers are issued by ANVISA

ii. Except in the case of notifications, approvals are valid for 5 years and must be renewed in the last year of expiration

iii. One application can cover single product or a family of products.

Brazil – Medical Devices Regulatory Overview

TOPICS FOR INITIAL CONSIDERATION FOR EQUIPMENT, ARTICLES & SOFTWARE

- Product tests maybe required.
- INMETRO seal is the assurance of compliance, a sample is required for testing
- OCD (Organismo de Certificação Designado)/ Certifier body authorized by INMETRO to issue Certificate of Conformity.
- OCD (Organismo de Certificação Designado)/Certifier body: request ANATEL approval for devices – ANATEL seal to be part of the labelling. This applies for medical devices that make use of the radio-electrical spectrum for signal transmission
- Other specific documents.

Main Regulatory Requirements - ANVISA

1

Information of product commercial name (whether translated in to Brazilian Portuguese, or not).

This name has to be exactly the same at (i) the ANVISA application, (ii)labels and IFUs of the product in Brazil, (iii) approval in the country of origin.

If grouping is applicable: must choose a common name for all products part of the family, even though parts may be named differently. If the commercial name or commercial model is different from Health Canada's approval, a justification letter will need to be prepared (preferably in Portuguese)

2

List of all Models / System components, indicating their Part Numbers

For systems, it is necessary to provide information about all possible commercial configurations (including part numbers, etc).

3

List of all accessories, when applicable, including:

- catalogue number/product code,
- indication of use,
- information on which accessories are optional and which are included in the product's packaging.

Main Regulatory Requirements - ANVISA

4

Information on whether the device has an internal power supply:

- type;
- autonomy;
- change period;
- time necessary to reach the maximum charge.

5

For registration of a family of products, a list/table listing the differences between the commercial models of this product, if applicable .

6

Detailed information about packaging materials. Such as: packaging composition, carton grammage and package dimensions. Images of the device in its primary and secondary packaging, as it applies.

For example:
Acceptable: One unit of the product comes wrapped in a linear low density polyethylene bag manufacturer with high density polyetilene fiber bags (30x20x15mm). Five units of the product are in a secondary package made of white corrugated card box 32ECT, 180g/m³ (150x100x75mm).

NOT acceptable: One unit of the product comes wrapped in a plastic inside a Tyvek bag. Five units of the product packed on the plastic bag are on a card box.

Note: products can only be shipped with the packaging specifications provided and approved by ANVISA. Any changes may require post-market change/amendment of ANVISA's approval.

Main Regulatory Requirements - ANVISA

7

Detailed information about packaging including quantity of products, accessories, informing as well what is included in the primary and in the secondary packaging. The packaging configuration must also be described.

. *Comply with RDC 185/01 (Non IVD) & RDC 36/15 (IVD)*

8

Detailed description of product´s Indication and instructions of use.

In case the device will be used together with other devices and/or accessories, assembly instructions must be provided.

Note: In addition to the general indications/ instructions of use, specific information about the length of time that the equipment remains in contact with the human body, the specific location of its use, as well as information regarding how invasive it is and who is the target audience (stakeholders) for which the device is intended, must be provided.

9

Detailed description of the device's Mechanism of Action principle, including:

- The description of the physical, chemical and biological fundamentals of the equipment technology.
- The length of contact time that may exist between the health-related equipment and the patient.

Main Regulatory Requirements - ANVISA

10

Information about the product and accessory raw materials that come into contact with the human body. Graphical information including: technical drawings, pictures or photos enabling the visualization of material(s), components, parts or spare parts and accessories, if applicable.

Describe the raw material with its respective technical specifications, including physical, chemical, physico- chemical, organoleptic, mechanical and other applicable specifications, correlating with each part, component or material. It must be informed, if applicable, the reference technical standard for the raw material used in the manufacturing.

Example: Stainless Steel Alloy F139 - according to ASTM F139, 100% polypropylene - according to ASTM 2859.

11

Dimensions/sizes of each model and its accessories

12

Information regarding the sterility of the product, if applicable. In cases where the product is provided sterile, please indicate in detail the method of sterilization.

Note: The validation report must be provided.

13

Expiration/Validity (shelf life) and stability studies, if applicable.

14

Information on re-use, cleaning or sterilization for re- use, if applicable
Note: if it is the case, you need to indicate who is the party responsible for these activities.

Main Regulatory Requirements - ANVISA

15 Information about how to discard the device.

17 Special requirements for handling the product, when applicable.

For example:

- The device should only be operated by health professionals
- The device must be handled at “this” specific environmental conditions, etc.

16 It is mandatory to indicate conditions (temperature, humidity and atmospheric pressure values, and all necessary parameters), according to stability studies, for:

- Transport;
- Storage;
- Handling.

For example:

- Transportation must be performed in temperatures from 15ºC to 45ºC and humidity from 0% to 90%, without conditioning.
- Avoid collision during transportation: the product may be damaged.
- Product must be stored in temperature conditions from 20ºC to 35ºC and humidity from 10% to 70%, without conditioning.
- Keep away from direct sun light.

If the storage condition is room temperature, specify the range.

Main Regulatory Requirements - ANVISA

18 Information regarding all warnings and precautions.

19 List of all contraindications, considering the clinical and scientific evidence.

20 List of all adverse effects, if any.

21 The name and address of the legal manufacturer – Same as the one listed on the Health Canada's approval and Certificate of Free Sale.

For medical device produced by more than one manufacturer a declaration including all manufacturers needs to be provided. Additional documentation from each facility should be determined and required.

22 Are there any outsourced manufacturing step?

If so, provide details of each outsourced/ contracted manufacturers, such as: Company name, address and manufacturing step performed by each of them.

Main Regulatory Requirements - ANVISA

23 List of all manufacturing sites and international distributors (corporate name and address) from where the product will be shipped to Brazil.

24 Photos, pictures and engineering drawings of the product and also of the accessories.

25 Provide Information about any existing toxic or flammable component.

26 Information regarding interference with electrical, electromagnetic or radiation equipment.

For example:
- Electrostatic discharge, pressure and change pressure, acceleration and thermal ignition source.

27 Compatibility with other devices, if applicable.

Main Regulatory Requirements - ANVISA

28 Provide a manufacturing flowchart describing the different steps of the manufacturing process and a detailed written description of each stage.

The manufacturing flowchart must display all manufacturing steps of the product, from raw material procurement to the shipment of the finished product. Additionally, there are some important aspects to be considered in relation to the flowchart.

Note:
There is no need to send copies of the company's procedures and work instructions. They will be reviewed during the audit.

29 Studies related to the use/ application of the product, (it is mandatory for innovative products that the studies are directly related to the product).
Journal articles, publications, clinical studies of the product to which the submission is being prepared.
A critical evaluation of this bibliography needs also to be provided.

For established products: scientific studies that support product technology and intended use is sufficient

Main Regulatory Requirements - ANVISA

30 Description of safety and efficacy of the product (clinical trials and all risk management files).

Clinical trials must comply with RDC 10/15.

Clinical trials conducted in Brazil, must be first approved by ANVISA.

Current GCP requirement adopts ISO 14155:2011

31 Report of tests demonstrating cytotoxicity, irritation, biocompatibility, sensitization, according to ISO 10993, where applicable.

Note: If any ISO 10993-Series standard is not applicable, provide a justification with a rationale for such decision.

This item is applicable for all parts of the device that is in contact with the user, patient, etc.

32 Tests reports:

- All tests listed in the INMETRO Certificate
- Usability tests (IEC 62366)
- Additional test and validation reports performed for design approval.

Main Regulatory Requirements - ANVISA

33 Software documentation:

- System architecture documentation according to IEC 62304
- Software version

34 All Instructions for Use/ Manuals (translated to Brazilian Portuguese).

For example: user manual, service instructions manual, quick reference guide, administration manual, installation guide, etc.

In case the product will be used with other products, provide also assembly instructions

35

Certificate of Conformity issued by a Certifier Body approved by INMETRO.

This certification is based on the results of specific test reports.
If ANATEL certification is necessary, the Certifier Body is also responsible to get ANATEL clearance.

Main Regulatory Requirements - ANVISA

Official Documentation Required - Translated, Legalized and Consularized

1. Certificate of Free Sale (CFS) from the country of origin or equivalent*

2. Copy of ISO Certificate (MDSAP)* or Good Manufacturing Practices Certificate issued by ANVISA. *Comply with RDC 183/17*

3. Letter of authorization of the manufacturer to the holder of the product licence approval to represent and market the product in Brazil. Only the Portuguese version should be legalized by the Brazilian Consulate. (follow specific template)

4. In case of any outsourced manufacturing step, a letter explaining the relationship between companies. Only the Portuguese version should be legalized by the Brazilian Consulate. (follow specific template)

* The original must be legalized by the Brazilian Consulate before sending it to Brazil. Then, a “sworn” translation by an authorized translator needs to be done**
** If agreed, MarcM offers to take care of the necessary sworn translations that are to be performed in Brazil.

THANK YOU.

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