



# BRAZIL MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Brazilian market.

## START HERE: WHAT IS THE PRODUCT IN BRAZIL?

### 1 Confirm the Brazilian regulatory identity

Define the intended purpose, technology and claims.  
Determine whether the product is active, software, implantable, sterile, measuring, or electrical.  
This drives classification and the regulatory route under ANVISA.



Intended purpose



Technology &amp; claims



Device attributes



Classification driver

### 2 Choose the regulatory route

#### CLASS I



Low risk

Low individual and public health risk.  
Often eligible for a lighter notification / listing route.

#### CLASS II



Moderate risk

Moderate individual and public health risk.  
Typically requires full registration.

#### CLASS III



High risk

High individual and public health risk.  
Requires full registration with robust technical and clinical evidence.

#### CLASS IV



Highest risk

Very high individual and public health risk.  
Requires full registration with the most stringent evidence expectations.

Lower-risk products may use a notification / listing route.  
Higher-risk products require full registration with ANVISA.

### 3 Build the Brazilian market-access infrastructure



#### ANVISA framework

Understand ANVISA requirements, RDCs/instructions, classification rules, standards (ABNT/ISO/IEC), and the registration process.



#### Brazilian Registration Holder / local representative

Appoint a Brazilian Registration Holder (BRH) responsible for product registration, vigilance, and regulatory communications.



#### GMP / inspection and local technical requirements

Ensure QMS compliance (e.g., ISO 13485), ANVISA inspections readiness, and compliance with Brazil-specific technical requirements.



#### Submission / registration setup

Establish e-Services access, submission strategy, document structure, and post-market obligations (vigilance, licensing, renewals, changes).

### 4 Build the evidence stack



**Administrative**  
Device description, intended use, indications, market claims, and regulatory history.



**Quality / QMS**  
QMS aligned with ISO 13485 and ANVISA expectations; stability and shelf-life evidence.



**Safety & performance**  
Bench, biocompatibility, sterilization, EMC / electrical safety, and performance data per ABNT standards.



**Clinical evidence**  
Clinical performance evidence per ANVISA expectations, including local data when required.



**Labeling / Portuguese readiness**  
Portuguese labeling and IFU compliant with ANVISA and consumer communication rules.



#### RA TRAP TO AVOID

Local representation, Portuguese materials, electrical or special local requirements, and post-approval change control can significantly alter timelines.



#### STRATEGIC INSIGHT

Early route selection, aligned BRH, and a Brazil-ready dossier reduce review cycles, queries, and downstream delays.



## BRAZIL MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

### A Program flow

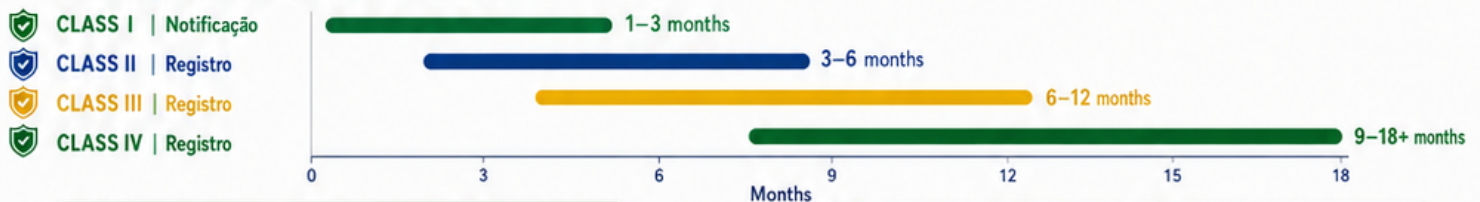


### B What gets heavier as the class rises?

| Signal                     | CLASS I                      | CLASS II             | CLASS III        | CLASS IV          |
|----------------------------|------------------------------|----------------------|------------------|-------------------|
| <b>Pathway intensity</b>   | Lowest ● ● ● ●               | Low–moderate ● ● ● ● | High ● ● ● ●     | Very high ● ● ● ● |
| <b>Evidence intensity</b>  | Basic ● ● ● ●                | Moderate ● ● ● ●     | High ● ● ● ●     | Very high ● ● ● ● |
| <b>Clinical support</b>    | Not usually required ● ● ● ● | Limited ● ● ● ●      | Moderate ● ● ● ● | Extensive ● ● ● ● |
| <b>QMS readiness</b>       | Basic ● ● ● ●                | Moderate ● ● ● ●     | High ● ● ● ●     | Very high ● ● ● ● |
| <b>Post-market control</b> | Lower ● ● ● ●                | Moderate ● ● ● ●     | Higher ● ● ● ●   | Highest ● ● ● ●   |

### C Indicative route-based planning ranges

*Hopestone planning estimates for timing only — actual timing depends on device complexity, evidence quality, application completeness, and ANVISA workload.*



**i** Notificação (Class I) devices are not full registrations but must comply with all applicable ANVISA requirements.

**L** These are Hopestone planning estimates. ANVISA review times vary.

### D Labeling & language essentials

**Portuguese labeling**  
All labeling and IFU must be in Portuguese (Brazilian Portuguese) and accurate.

**IFU readiness**  
Clear IFU in Portuguese with intended use, indications, use, limits, and step-by-step instructions.

**Claims control**  
Claims must be supported by evidence and consistent with intended use.

**BRH / importer info**  
Include Brazil Responsible Holder (BRH) and importer details on labeling as required.

**Vigilance / complaints**  
Provide contact for technical assistance and reportable events / complaints.

### E High-impact Brazilian decision points

**Risk class drives the pathway**  
Lower-risk (Class I) may use Notificação. Higher-risk (Class II–IV) require full registration.

**Electrical & local requirements**  
Devices with electrical components may require INMETRO conformity as applicable.

**Implantable / high-risk**  
Higher classes expect strong clinical evidence, biocompatibility, and performance data.

**Post-approval changes**  
Changes to design, labeling, or IFU may need prior ANVISA approval and renewals are required.

### F Primary resources used for this training aid

- ANVISA — Medical Devices (Dispositivos Médicos)  
<https://www.gov.br/anvisa/pt-br/assuntos/dispositivos-medicos>
- ANVISA — Medical Device Registration (Registro de Dispositivos Médicos)  
<https://www.gov.br/anvisa/pt-br/assuntos/registro-de-produtos/registro-de-dispositivos-medicos>
- ANVISA — Peticionamento Eletrônico  
<https://www.gov.br/anvisa/pt-br/assuntos/peticionamento-eletronico>
- Hopestone Capital & Consulting — [hopenstonecapital.com](https://hopenstonecapital.com)



#### IMPORTANT

**Product-specific Brazilian requirements and current ANVISA guidance govern.**

Confirm classification, evidence, labeling, and submission obligations before execution.