BRAZIL IVD REGULATORY MAP

A practical orientation for global RA teams entering Brazil

START HERE: WHAT IS THE PRODUCT IN BRAZIL?

1 Confirm Brazilian regulatory identity

Confirm the intended use, product family, and IVD category under ANVISA. Classification and regulatory route depend on intended use, risk, and ANVISA's current IVD framework (RDC 830/2023).

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS I	CLASS II	CLASS III	CLASS IV
Low risk	Low-to-moderate risk	Moderate-to-high risk	Highest risk
Notification route under ANVISA. Often for non-invasive devices with low potential risk.	**Notification route** under ANVISA. Moderate risk devices; non-invasive or minimally invasive.	**Registration (*registro*) route** under ANVISA. Higher risk devices requiring comprehensive evaluation.	**Registration (*registro*) route** under ANVISA. Highest risk devices requiring the most stringent review.

Classes **I–II** generally follow the **Notification** route. Classes **III–IV** generally follow the **Registro (Registration)** route under ANVISA's current IVD framework.

3 Build the Brazil market-access infrastructure

ANVISA framework
Understand RDC 830/2023, INs, guides, and Good Regulatory Practices (RDC 16). Know classification rules and requirements.

Brazilian Registration Holder / local setup
Appoint a Brazilian Registration Holder and ensure local technical and regulatory responsibilities.

GMP / technical dossier readiness
Ensure manufacturing site compliance (Brazil or abroad), Brazilian GMP expectations, and a complete technical dossier.

Portuguese labeling / commercialization readiness
Prepare Portuguese labeling, IFU, claims and instructions, and confirm compliance with Brazilian requirements.

4 Build the evidence stack

Administrative
Device description, intended use, target population, risk classification, and market history.

Quality / QMS
QMS aligned with ISO 13485 and ANVISA expectations (RDC 665/2022 / RDC 16).

Analytical performance
Method performance, precision, accuracy, reportable range, interference, and comparability.

Clinical / scientific performance
Clinical performance or scientific evidence supporting intended use and risk profile.

Labeling & IFU
Portuguese labeling and IFU including symbols, warnings, claims, and user instructions.

RA TRAP TO AVOID

Do **not** start by asking the timeline — start with classification → Brazilian Registration Holder → evidence → GMP → and the correct route (notification vs registro).

STRATEGIC INSIGHT

Notification vs registro, and having the right Brazilian local infrastructure, are major drivers of approval timelines. Plan early to reduce delays and rework.

BRAZIL IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

1. **Scope** — Define intended use and product family
2. **Classify** — Apply Brazil IVD risk classification (Class I–IV)
3. **Local holder setup** — Appoint Brazilian legal representative (detentor) and establish QMS
4. **GMP / dossier planning** — Plan GMP compliance and dossier content per ANVISA requirements
5. **Evidence** — Generate and review performance, analytical, and clinical evidence
6. **Submit to ANVISA** — Submit electronic dossier via system and pay applicable fees
7. **Launch / maintain** — Market authorization, post-market controls, changes, vigilance, and renewals

B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III	CLASS IV
Pathway intensity	Notification (simpler)	Notification (moderate)	Registro (complete dossier)	Registro (most complex)
Analytical performance	Basic ●●○○	Moderate ●●○○	High ●●●○	Very high ●●●●
Clinical / scientific support	Not usually required ●○○○	Limited / targeted ●○○	Moderate ●●●○	Extensive ●●●●
Manufacturing / QMS readiness	Basic ●○○○	Moderate ●●○○	High ●●●○	Very high ●●●●
Post-market control	Lower ●○○○	Moderate ●●○○	Higher ●●●○	Highest ●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on dossier quality, ANVISA review, and inspections. Health Canada review timelines, and other factors.

Notification routes (Class I & II) are generally faster with lighter dossier and lower review intensity.

Registro routes (Class III & IV) require complete technical dossier, GMP compliance, and ANVISA review.

D Labeling & language essentials

Portuguese-language support
All labeling and instructions must be in Portuguese. Other languages may be included as needed.

Product labeling
Labeling must include intended use, risks, precautions, lot/serial, validity, storage, and ANVISA holder details.

Instructions for use
Provide clear IFU in Portuguese with intended use, step-by-step instructions, limitations, and performance claims.

Claims control
Claims must be supported by evidence and consistent with intended use per ANVISA rules.

Product identifier / traceability documentation
Include UDI (DI & PI), lot/serial, and traceability records as required (RDC 751/2022).

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- ANVISA – Medical Devices Area: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos-e-produtos/saude/medicamentos-e-produtos/tecnovigilancia
- ANVISA – IVD (In Vitro Diagnostics) Information: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos-e-produtos/diagnosticos-para-saude
- RDC 751/2022 – In Vitro Diagnostics: https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-751-de-15-de-setembro-de-2022-431602122
- RDC 185/2001 – Generic Requirements: https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-185-de-22-de-outubro-de-2001-31747891
- Hopestone Capital & Consulting: https://hopestonecapital.com

IMPORTANT

Product-specific Brazilian requirements, current ANVISA guidance, applicable RDCs, and recent regulatory updates govern. Confirm current requirements before execution.