MEDBRIDGE

REGULATORY PATHWAY GUIDE · ANVISA

Bringing a Class I medical-device SaaS to Brazil

A step-by-step guide to ANVISA notification for a foreign manufacturer of a low-risk medtech software product with an electrical component, already cleared by the FDA and CE-marked.

- Foreign manufacturer
- Risk Class I (low risk)
- FDA cleared · CE marked
- Software as a Service (SaMD)
- Electrical device component
- Paperwork by MED BRIDGE

Prepared by MED BRIDGE · September 2026 · Based on ANVISA regulations in force at publication

AT A GLANCE

A notification, not a registration.

PATHWAY

Notificação

Class I and II devices are notified, not registered (RDC 751/2022, Art. 6).

ANVISA REVIEW

No prior technical analysis

Notification is processed routinely within 30 days of filing (Art. 10 §5–6).

GMP CERTIFICATE

Not required

Brazilian GMP certification (CBPF) applies to Classes III–IV only. The manufacturer declares compliance with RDC 665/2022.

VALIDITY

No expiry

Notified products are exempt from revalidation (Art. 28). Keep the dossier current.

LOCAL HOLDER

Brazilian company

A Brazilian legal entity with an ANVISA company authorization (AFE) must hold the notification.

ELECTRICAL HARDWARE

INMETRO certificate

Required for equipment under RDC 549/2021, even for notifications. Not required for standalone software.

The one question that shapes the route

Is the medical function delivered by the SaaS alone, or does it depend on electrical medical hardware? Standalone software (SaMD, explicitly including "Software as a Service") is notified with ANVISA's **software form** under RDC 657/2022. Software embedded in, or controlling, a medical device is regularized **together with that equipment** (RDC 657/2022, Art. 3), which brings INMETRO certification into play. The flowchart on the next page shows both branches.

THE PATHWAY

From classification to **market launch**

HOLDER MED BRIDGE / Brazilian holder · MANUFACTURER · OCP INMETRO-accredited body · ANVISA

1 Confirm class & regime
Standalone SaMD with no diagnostic/monitoring decision role → Rule 11, Class I. Active hardware → Rule 13. If in doubt, file ANVISA's software classification form (RDC 657, Art. 19).
HOLDER · MANUFACTURER

2 Brazilian holder in place
Brazilian legal entity with ANVISA company authorization (AFE) for medical devices and a technical responsible (RT). Register the company and its size (*porte*) in ANVISA's systems.
HOLDER

3 Manufacturer declaration
Legal manufacturer authorizes the holder to represent and sell in Brazil and affirms GMP compliance with RDC 665/2022. Apostilled; EN/ES/PT; ≤ 2 years old.
MANUFACTURER

4 Dossier & Portuguese labeling
Build the Class I technical dossier from the FDA/CE technical file (kept on file, not submitted). Labels and instructions for use in Portuguese.
HOLDER · MANUFACTURER

Does the product include electrical medical hardware?

NO

5 Software (SaMD) notification form
RDC 657/2022, Art. 10. No INMETRO. Menus preferably in Portuguese (Art. 6); label and instructions may live inside the software (Art. 8); version ID replaces lot/serial number.
HOLDER · SaaS-only branch

YES

5 INMETRO certification (SBAC)
Certify with an INMETRO-accredited body (OCP) to the standards listed by ANVISA (IN 283/2024 — e.g. IEC 60601 family). IEC test reports from ILAC-accredited labs can support it. The certificate replaces the Free Sale Certificate (RDC 549, Art. 3 §1).
MANUFACTURER · OCP

6 Equipment notification form
Software regularized with the equipment. Add the ANATEL homologation certificate if the device has Wi-Fi/Bluetooth/RF (RDC 546/2021).

7 Pay fee & file petition
Generate the GRU and pay the TFVS fee (set by company size). File the form + manufacturer declaration (+ INMETRO/ANATEL certificates) electronically. Incomplete files are summarily rejected (Art. 10 §4).
HOLDER

8 Notification number published
No prior technical analysis. Processed routinely within 30 days (Art. 10 §6) and published in the Diário Oficial (DOU). Sell or import only after publication (Art. 60 §1).
ANVISA · ≤ 30 days

9 Upload instructions for use
Upload the Portuguese IFU to ANVISA's Medical Device Document Repository within 30 days of DOU publication (Art. 33 §5). Mandatory, even for software.
HOLDER · ≤ 30 days

10 Launch & stay compliant
Commercial launch. Keep the dossier current, report adverse events (tecnovigilância), file changes per RDC 340/2020, keep INMETRO valid. No revalidation needed.
HOLDER · MANUFACTURER

STEP BY STEP

What happens, **who does it,** and on what basis

	STEP	WHAT TO DO	WHO	LEGAL BASIS	TIMING
1	**Confirm classification & route**	Apply ANVISA's risk rules to the intended purpose. Standalone SaMD that is not used for diagnostic/therapeutic decisions or physiological monitoring is Class I (Rule 11); other active devices default to Class I (Rule 13). Decide which branch applies: standalone SaaS or equipment with software.	HOLDER MFR	RDC 751/2022, Arts. 5–8, Annex I (Rules 11, 13); RDC 657/2022, Arts. 1, 3, 19	**1–2 weeks** est.
2	**Brazilian holder ready**	The notification holder must be a Brazilian legal entity responsible for the device in Brazil, with ANVISA company authorization (AFE) for medical devices, a local sanitary licence and a technical responsible (RT). Register the company and its size (*porte*) in ANVISA's systems — the size sets the fee.	HOLDER	RDC 751/2022, Art. 4 (VIII, XXXVIII); RDC 16/2014 (AFE)	**Immediate if AFE exists; months if new** est.
3	**Manufacturer declaration**	Declaration from the legal manufacturer with both companies' names and addresses, express authorization to represent and sell in Brazil, and a statement of knowledge of and compliance with Brazilian GMP (RDC 665/2022). Apostilled or consularized; in PT/EN/ES (or sworn translation); issued within 2 years.	MFR	RDC 751/2022, Art. 13 (II) & sole paragraph	**2–4 weeks** est.
4	**Technical dossier & labeling**	Assemble the Class I dossier (structure per Annex II / RDC 657 Art. 11) largely from the FDA/CE technical file. It is **not** submitted but must exist before filing and be kept up to date. Translate labels and instructions for use into Portuguese; add the holder's name and address as "detentor da notificação".	HOLDER MFR	RDC 751/2022, Arts. 10 §9, 46–48, 56–57, Annex II; Q&A RDC 751, Q47	**4–8 weeks** est.
5	**Branch A — SaaS only**	Use ANVISA's software notification form. No INMETRO. Menus preferably in Portuguese (English allowed for professional-only use if meanings are explained in Portuguese). Label/IFU can be shown inside the software; the version ID provides traceability.	HOLDER	RDC 657/2022, Arts. 6–8, 10–11	—
5–6	**Branch B — with electrical hardware**	Obtain the INMETRO certificate of conformity from an accredited OCP against the standards listed by ANVISA (IN 283/2024), then use the equipment notification form. Add ANATEL homologation if the device transmits by radio (Wi-Fi, Bluetooth). With the INMETRO certificate, no Free Sale Certificate is needed.	MFR OCP	RDC 549/2021, Arts. 2–4, 7; RDC 751 Art. 13 (III–IV); Q&A Q10, Q19–20	**2–4 months** est.
7	**Pay fee & file**	Generate the GRU and pay the sanitary surveillance fee (TFVS; amount by subject code and company size). File the electronic form, manufacturer declaration and, if applicable, certificates. Missing or illegible documents lead to summary rejection with no chance to correct.	HOLDER	RDC 751/2022, Arts. 10 §4, 13, 45; Portaria Interministerial 701/2015	**1 week** est.
8	**Publication in the DOU**	No prior technical review. ANVISA triages and may audit at any time. The notification number is published in the Diário Oficial da União; only then may the product be imported, sold or delivered.	ANVISA	RDC 751/2022, Arts. 10 §5–6, 37, 60 §1	**≤ 30 days**
9	**Upload IFU**	Petition "Disponibilização de Instruções de Uso no Portal da Anvisa" and upload the Portuguese IFU (or label model, if there is no IFU) to the Medical Device Document Repository.	HOLDER	RDC 751/2022, Arts. 33–34	**≤ 30 days after DOU**
10	**Launch & maintain**	Launch commercially. Notification does not expire. Class I changes are filed as "immediate implementation" petitions; bug fixes and minor changes are non-reportable but must be controlled by the quality system. Respond to any ANVISA audit request within 30 days.	HOLDER MFR	RDC 751/2022, Arts. 16, 28, 38; RDC 657 Art. 16; RDC 340/2020; IN 74/2020	**Ongoing**

DOCUMENTS

What to file, what to keep, **what to reuse**

FDA/CE marks items that can usually be adapted from the existing FDA or CE technical documentation.

A Filed with ANVISA

Submitted electronically with the notification petition (RDC 751, Art. 13).

- [ ] **Notification form**: software form (SaaS) or equipment form (hardware), completed in Portuguese.
- [ ] **Manufacturer declaration**: authorization to represent and sell in Brazil and GMP statement (RDC 665/2022); apostilled; ≤ 2 years.
- [ ] **INMETRO certificate of conformity**: only for equipment covered by RDC 549/2021.
- [ ] **ANATEL homologation certificate**: only if the device uses radio communication.
- [ ] **Proof of payment**: TFVS fee via GRU.

NOT REQUIRED FOR CLASS I NOTIFICATION

- [ ] Free Sale Certificate or FDA/CE certificate (registration only, Art. 14)
- [ ] ANVISA GMP certificate (CBPF), which applies to Classes III–IV only

B Technical dossier, kept on file

Must exist before filing, stay updated, and be produced if ANVISA audits (RDC 751 Art. 56; RDC 657 Art. 11 for SaMD). Items marked for Class I:

- [ ] **Administrative & technical info**; list of models / versions
- [ ] **Intended purpose**, user, indications, use environment, contraindications FDA/CE
- [ ] **List of technical standards** applied FDA/CE
- [ ] **Compatibility & interoperability tests** FDA/CE
- [ ] **Revision history** of changes
- [ ] **Electrical safety & EMC** (hardware; IEC 60601) FDA/CE
- [ ] **Labeling & IFU** in Portuguese
- [ ] **Detailed description** & principles of operation FDA/CE
- [ ] **Risk management** (ISO 14971) FDA/CE
- [ ] **Software architecture**, firmware and version descriptions FDA/CE
- [ ] **Residual anomalies** list with risk analysis FDA/CE
- [ ] **Usability / human factors** (IEC 62366-1) FDA/CE
- [ ] **Clinical evidence summary**, where applicable FDA/CE
- [ ] **Manufacturing sites**, process flowchart, design & development info FDA/CE

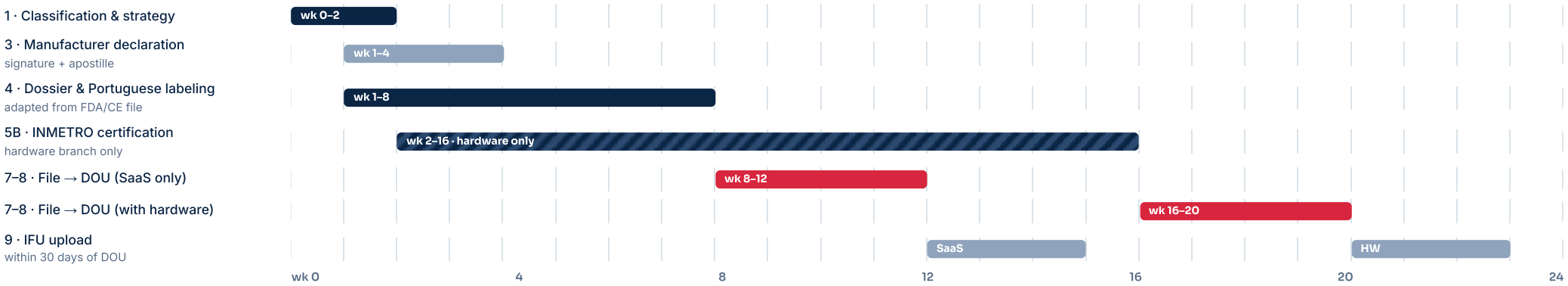
C Labeling & in-software content

Portuguese is mandatory for forms, labels and IFU (RDC 751, Art. 10 §9; Art. 46).

- [ ] **Legal manufacturer** and **notification holder** names and addresses
- [ ] **ANVISA notification number** (added after publication)
- [ ] **Product & version ID** for traceability (SaMD: replaces lot/serial)
- [ ] **Warnings, precautions** and operating instructions
- [ ] SaMD extras: **update procedure**, **minimum hardware/software**, **operating principle**, **interoperability**, **cybersecurity information** (RDC 657, Art. 7)
- [ ] **Hardware**: indelible label with name, model, manufacturer, ANVISA number and serial (RDC 751, Art. 49)
- [ ] **Electronic IFU** allowed with version correlation and free printed copy on request (Arts. 50–53); not allowed alone for lay/home-use equipment (Art. 54)

TIMELINE

Indicative plan, **assuming the Brazilian holder already has its AFE**



SAAS ONLY

≈ 3 months

From kickoff to published notification est.

WITH ELECTRICAL HARDWARE

≈ 5 months

INMETRO certification is the critical path est.

WHAT ADDS TIME

- Holder without AFE (new AFE, sanitary licence and inspection)
- ANATEL homologation for radio devices
- Classification doubts requiring an ANVISA opinion
- Summary rejection for incomplete files (restart)

Post-market vigilance

Report adverse events and technical complaints and run field actions through ANVISA's channels (tecnovigilância).

RDC 657 Art. 24; RDC 67/2009; RDC 551/2021

Changes & new versions

New features, new indications or major UI changes need a petition; bug fixes and security patches do not.

RDC 657 Art. 16; RDC 751 Art. 16 §4; RDC 340/2020

Keep it valid

INMETRO certificate valid at all times (90 days to replace if it lapses). UDI for Class I is due 6 years after ANVISA's UDI database rule takes effect.

RDC 549 Art. 7; RDC 591/2021

SOURCES (ANVISA, OFFICIAL)

1. **RDC 751/2022** — risk classification, notification/registration, labeling & IFU (in force 1 Mar 2023)
2. **RDC 657/2022** — regularization of Software as a Medical Device (SaMD), incl. SaaS
3. **RDC 549/2021** — compulsory INMETRO (SBAC) certification of equipment; **IN 283/2024** — applicable standards
4. **RDC 665/2022** — Brazilian GMP; **RDC 546/2021** — essential safety & performance requirements
5. **RDC 340/2020** & **IN 74/2020** — post-market changes; **RDC 591/2021** — UDI; **RDC 16/2014** — AFE
6. ANVISA, *Perguntas & Respostas RDC 751/2022*, 2nd ed. (Mar 2023); ANVISA "Notificação de produtos para saúde" and "Medical devices" (English) pages

Important. This guide summarizes ANVISA regulations in force at publication (September 2026) for the scenario described. It is not a legal opinion. Classification depends on the exact intended purpose and should be confirmed case by case. Durations marked "est." are MED BRIDGE estimates, not ANVISA deadlines. Always check the current checklist for the ANVISA subject code before filing.