



IMDRF International Medical Device
Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026



Regulatory Updates - BRAZIL

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Brazilian Health Regulatory Agency - ANVISA



Brazilian Health Regulatory Agency - ANVISA



Brasilia, Federal District



Anvisa's Headquarter



Anvisa's Regional Offices (44)



Border Control

(Borders, Ports and Airports)

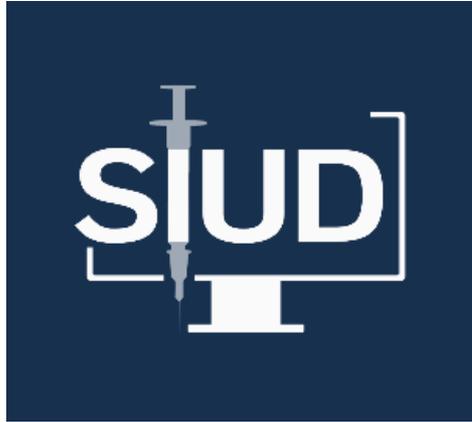


Brasília – Unesco World Cultural Heritage *(designers: Lúcio Costa and Oscar Niemeyer)*

Founded: April 21, 1960



New Regulations



Normative Instruction n. 426/2026.

- Published in February 2026.
- Officially launched the Brazilian UDI Database (SIUD).
- Effective March 1st (voluntary submissions).
 - Compulsory submissions:
 - Class IV → Sep/29
 - Class III → Mar/30
 - Class II → Mar/31
 - Class I → Mar/32



Request made to IMDRF Members regarding UDI



UDI assignment to medical devices manufactured by pharmaceutical industries

- UDI requirements apply when the product falls under the medical device definition of the relevant jurisdiction.
- Some exemptions that may vary across jurisdictions, such as for Class I devices and commonly exempt categories like custom-made devices.
- There are also specific requirements for particular categories of devices, such as combination products.



MD Market Authorization per year in Brazil

Type	Risk Class	2022	2023	2024	2025
Notification	Class I	2718	2711	2797	2725
	Class II	3751	4162	4205	4769
Registration	Class III	1014	718	921	1158
	Class IV	328	300	393	472
Total	All classes	7811	7891	8320	9124

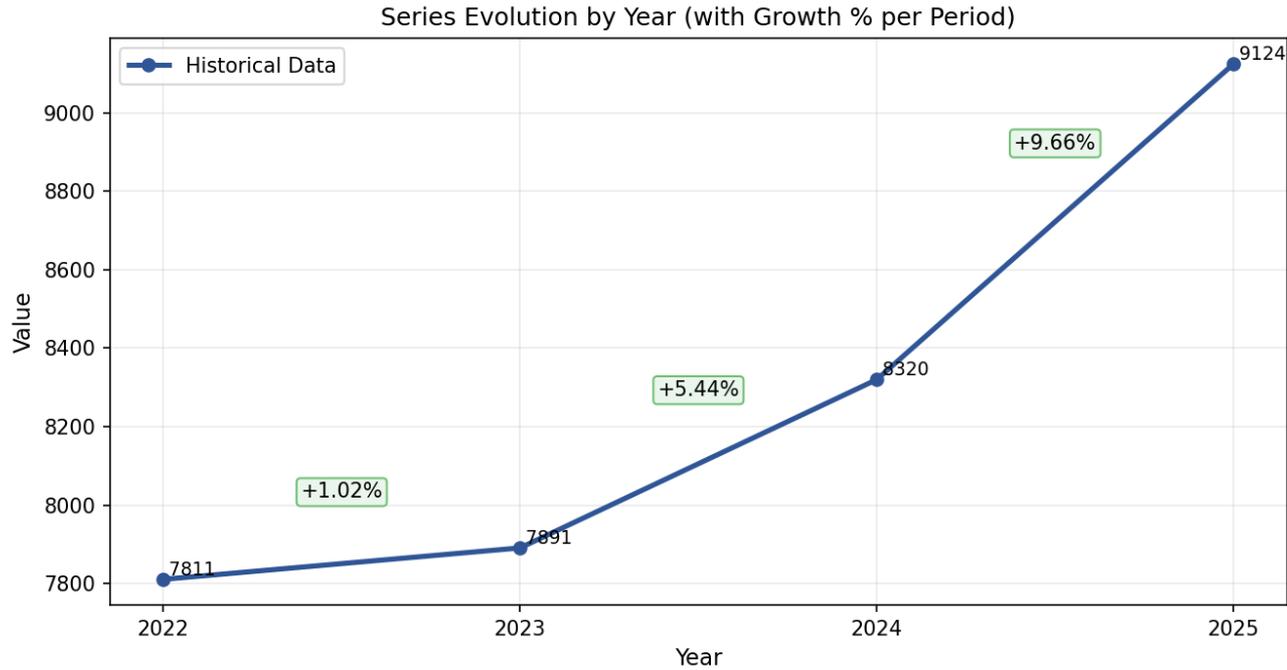

 ≅ 17 %

Active MD
 Authorizations
96.961
 (Feb 2, 2026)

- Average of Annual Increase: 5,37%



MD Market Authorization: 2022 – 2025 (Evolution by Year)



MD Market Authorizations in Brazil - Origins



	Country	Products
	Brazil	31,4%
	China	19,15%
	USA	16,02%
	Germany	8,5%
	Italy	2,41%
	France	2,1%
	India	2,02%
	Korea	1,94%
	Switzerland	1,68%
	UK	1,45%
	Japan	1,30%
	All other countries	12,08%



Reliance Mechanism for Premarket Authorization

IN 290/2024 - effective since Jun / 2024

- Product Registration Certificates from **Equivalent Foreign Regulatory Authorities** used for market authorization in Brazil
- Official Member Authorities of **MDSAP (AUS, CAN, JAP, USA)**



Reliance Data	Results*
Requests	485
Concluded	275
Approved	258
Not approved	17
Percentage of total requests	14,1%

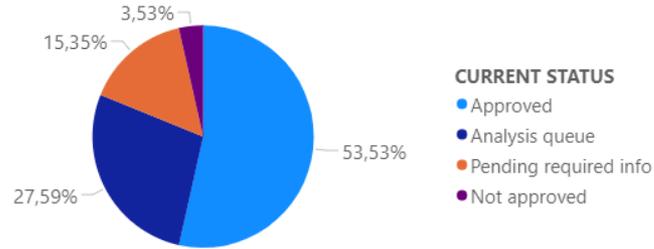
* Feb/2026



Reliance Mechanism for Premarket Authorization

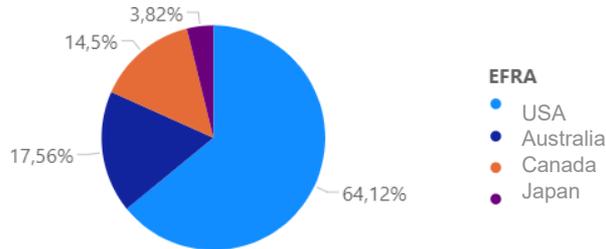
PERIOD **SUBMISSION RESULTS** **TOTAL COUNT**

Starting June, 2024 -
updated daily

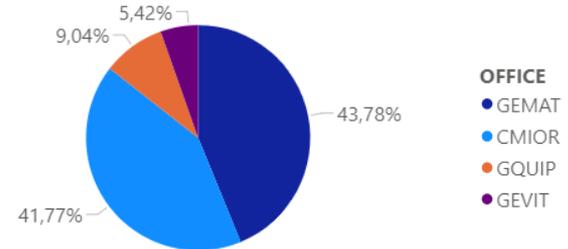


485

AUTHORIZATION ORIGINS



SPECIFIC FIELD



U₁

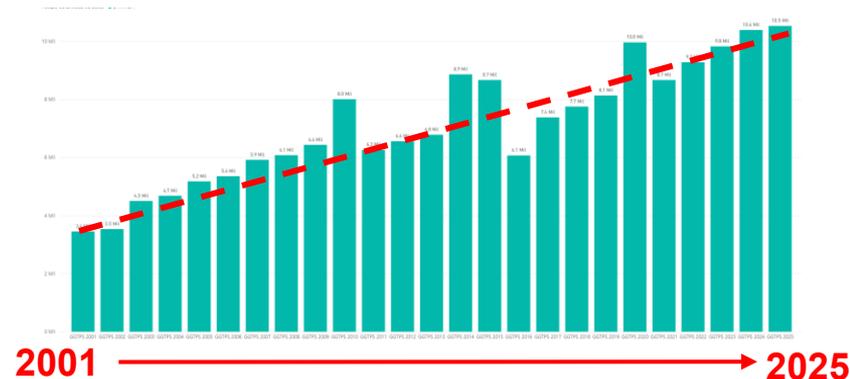


Action Plan to Optimize Premarket Review Process

- **Scenario:**
 - Increase in incoming submission every year ($\cong 6\%/year$);
 - No corresponding increase in Human Resources — in fact, there was a reduction;
 - Increase in technology complexity.
- The time required to review the submission increased.
- As a result, the submission backlog and the waiting time also increased.



MD Premarket Approval (all classes) Incoming Submission (Anvisa 2001-2025)



- Started in October 2025.

Main objectives:

- Optimize time and resources;
- Reduce time required to bring the product to Market;
- Accelerate access to medical technology.



Action Plan to Optimize Premarket Review Process

- Changed the **chronological approach** to reviewing submissions to a **grouped approach** by manufacturer and/or category of devices. **(SINGLE REVIEW PROGRAM)**
 - **Identify similarities** (same documents/reports, equivalent deficiencies to be clarified, etc.) across different submissions from the same manufacturer.
 - Instead of sending a formal “**letter requesting clarification**”, schedule a **teleconference** with the company to discuss a set of similar submissions and clarify specific points of interest.
 - **Grouping submission by devices category** accelerates the review process by keeping the reviewer focused on the same technology.



Action Plan to Optimize Premarket Review Process



- **Some additional actions (planned):**
 - Expansion of the **reliance mechanism** to include additional Regulatory Authorities.
 - Definition of a new internal model for submission document management (**MD Master File**).
 - Implementation of tools to identify new submissions for **devices already approved** by Anvisa.



Use of MDSAP by Anvisa

Year	# GMP Certificates Issued Based on MDSAP Reports (% of total)
2018	107 (19.3%)
2019	374 (48.7%)
2020	544 (49.1%)
2021	529 (51.4%)
2022	621 (59.7%)
2023	659 (59.1%)
2024	708 (61.2%)
2025	659 (59.25%)
**2026	41 (59.09%)*



 ≅ **561%**

** Until Jan 31, 2026

Validity of GMP Certificate

RDC 850/2024 – Validity of Anvisa GMP certificates issued through MDSAP extended from 2 to 4 years.

* The new 4-year certificate validity will reduce the number of certificates due for renewal in 2026.



MDSAP & Anvisa

It was approved to assess the feasibility of making MDSAP mandatory in Brazil.

- Included in Anvisa's Regulatory Agenda 2026-2027;

Current status:

- Regulatory Impact Assessment (RIA) scheduled to start in 2026.

MDSAP



Thank You!

