Medical Technology Sector Map - Brazil and the Americas

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Brazilian Alliance for Innovative Healthcare Industry

ABIIS – Brazilian Alliance for Innovative Healthcare Industry

Is an alliance of entities in the medical device sector, composed by the Brazilian Association of Importers and Distributors of Healthcare Products (**ABRAIDI**), the Brazilian Chamber of Laboratory Diagnostics (**CBDL)**, and the Advanced Medical Technology Association (**AdvaMed).**

Contextualization of the problem

Rationale for the Study – Anvisa (early 2025)

Motivation

The motivation for this study stems from the widening gap between the rapid expansion of the global medical technology market and the institutional capacity of regulatory authorities to keep pace with this evolution.

Scope

Maps economic, productive and regulatory information on the medical technology sector across:

Brazil	Argentina
Canada	Colombia
Mexico	United States

Study period: July 2024 – June 2025

Contextualization of the Problem

Brazilian scenario

- Population aging: projected increase of **92.7%** in the population aged 60+ by 2050.
- Higher incidence of chronic diseases.
- Growth of the national market – 2024 reached around **US$15.4 billion**, growing **11.5%** — a pace higher than the global average.

GGTPS

General Management of Health Products Technology

- Growing demand for product regularization
- Greater complexity of devices
- Continuous advancement of new technologies
- Workforce stagnation

! **THE REGULATORY STRUCTURE HAS NOT GROWN AT THE SAME RATE**

Indicators

Country	Population (2023)	Income Level (World Bank)	Health Spending (% of GDP) (2021)	Regulatory Authority
United States	343,477,335	High Income	17.36%	USFDA
Brazil	211,140,729	Upper Middle Income	9.89%	ANVISA
Mexico	129,739,759	Upper Middle Income	6.08%	COFEPRIS
Colombia	52,321,152	Upper Middle Income	9.02%	INVIMA*
Argentina	45,538,401	Upper Middle Income	9.71%	ANMAT
Canada	39,299,155	High Income	12.33%	HEALTH CANADA

*Health Authority

Regulatory Convergence

Regulatory/ Health Authority	IMDRF	IMDRF Document Implementation Report (Total 34 documents) Sep 25 % Fully or Partially Incorporated	MDSAP
ANVISA	Founding Member Member of the Management Committee	79.3%	Founding Member Member of the Board of Authorities Regulators
HEALTH CANADA	Founding Member Member of the Management Committee	86.2%	Founding Member Member of the Council of Regulatory Authorities
USFDA	Founding Member Member of the Management Committee	100%	Founding Member Member of the Council of Regulatory Authorities
ANMAT	Official Committee Observer Manager	41.4%	Affiliate Member
COFEPRIS	Affiliate Member	-	Affiliate Member
INVIMA	Affiliate Member	-	-

Human Resources

NRA	Nº of Professionals MD Life Cycle (approx.)	Context
ANMAT	100	They work with MDs in different areas of INPM
ANVISA	113	According to data from the transparency portal, GGTPS had 48 professionals in July of 2025, just one more than in 2015. A structural deficit that compromises agility and predictability regulatory.
HEALTH CANADA	165	Unofficial data – Number of professionals allocated to the Directorate of Medical Devices, responsible for licensing products
INVIMA	65	The Directorate of Medical Devices and Other Technologies is responsible for the control of MDs (including MD IVDs), Anatomical Components (fluids, cells, tissues, among others) and in vitro Reagents (in vitro reagents of analytical grade, specific analyte and general laboratory use)
USFDA	2.260	Information obtained in July 2025.
COFEPRIS	42	Unofficial data

Risk Classification

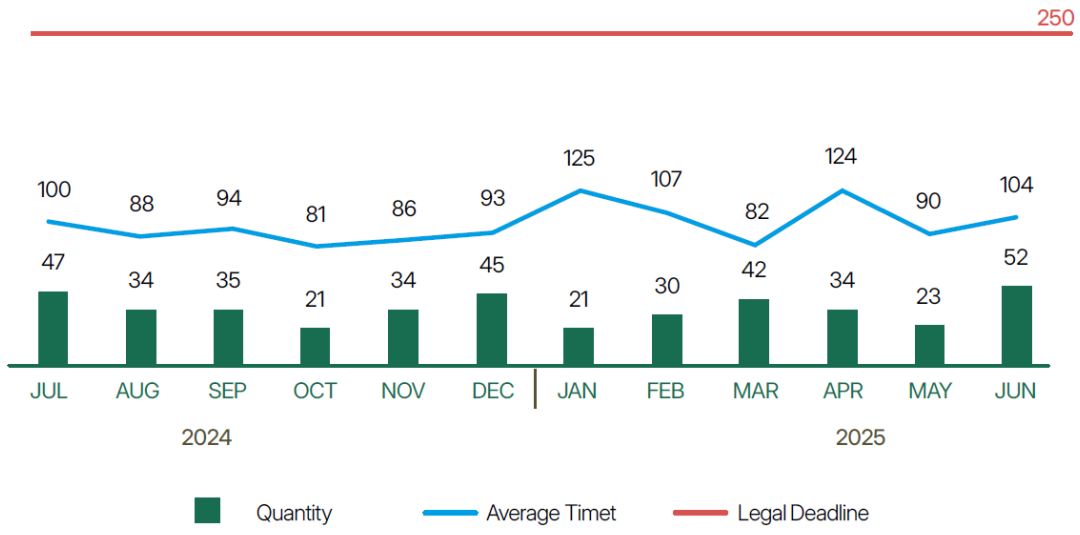
NRA	Regulation		Risk Class	Alignment
ANMAT	MD	Provision No. 64/2025	I, II, III and IV	Harmonized Mercosur – Reference: Regulation European Union 745/2017
	MD IVD	Provision No. 2198/2022	A, B, C and D	Harmonized Mercosur – Reference: Regulation European Union 746/2017
ANVISA	MD	RDC nº 751/2022	I, II, III and IV	Harmonized Mercosur – Reference: Regulation European Union 745/2017
	MD IVD	RDC nº 830/2023	I, II, III and IV	Harmonized Mercosur – Reference: Regulation European Union 746/2017
HEALTH CANADA	MD	Medical Device Regulations (SOR/98-282)	I, II, III and IV	Directive 93/42/EEC (European Union)
	MD IVD		I, II, III and IV	--
INVIMA	MD	Decree No. 4725/2005	I, IIA, IIB and III	Directive 93/42/EEC (European Union)
	MD IVD	Decree No. 3770/2004	I, II and III	--
USFDA	MD (including MD IVD)	21 Code of Federal Regulations (CFR) Parts 800 - 1050	I, II and III	They do not adopt classification rules. Database with 1,700 generic types classified and grouped into 16 medical specialities.
COFEPRIS	MD (incl. MD IVD)	Appendix II to the MD Supplement to the Pharmacopeia of the United Mexican States	Class I – Low risk (Regulatory Agreement of July 7, 2025) Classes I, II and III	Unable to evaluate - Available from the Pharmacopoeia of the United Mexican States upon purchase

Legal Deadline for Regularization

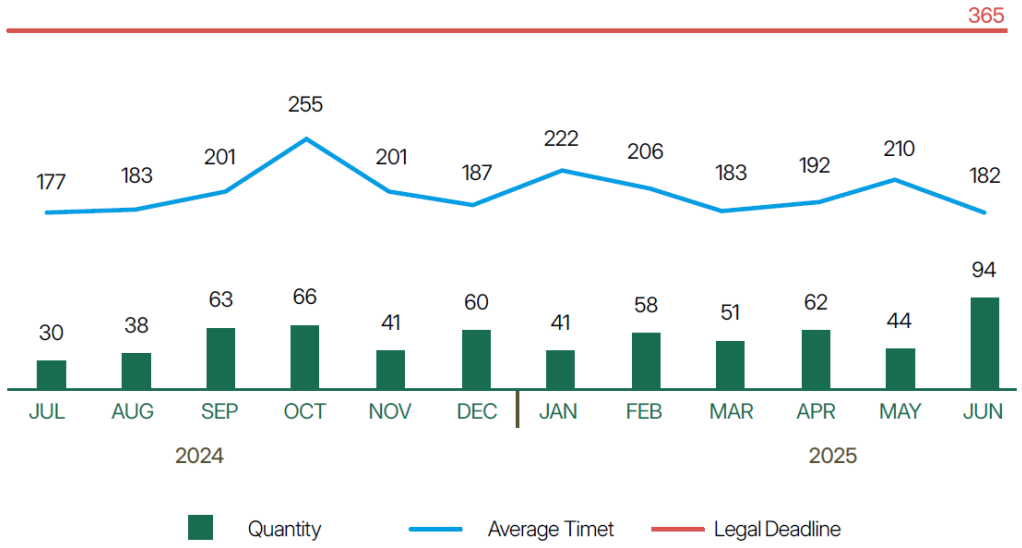
NRA	Regulation	Term	
ANMAT	Disp. No. 9688/2019	**I and II** - 15 working days	**III and IV** - 110 working days
	Disp. No. 9688/2019	**A and B** - 15 working days	**C and D** - 110 working days
ANVISA	RDC nº 743/2022	**I and II** - 30 days	**III and IV** Equipment - 250 days Materials - 320 days MD DIV 365 days
HEALTH CANADA	Health Canada Website – Review Process	**I** - License Exempt	**II** - 15 days
		III - 75 days	**IV** - 90 days
INVIMA	Decree No. 582/2017	**I and IIa** - 2 working days	**IIb and III** - 90 days
	Decree No. 581/2017	**I and II** - 2 business days	**III** - 90 days
US FDA	MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027	**I and II** non-exempt 510(k) 124 days (2024) 112 days (2025)	**III** 290 days (2024) 285 days (2025)
COFEPRIS	Agreements: 07/11 and 08/22 - Process Simplification 07/18/2025 - Abbreviated Way	**I** - 20 to 30 business days*	**II** – 25 to 30 business days *
		III – 30 to 35 business days*	* depending on the route chosen (abbreviated or simplified)

ANVISA

Registration – Medical Equipment



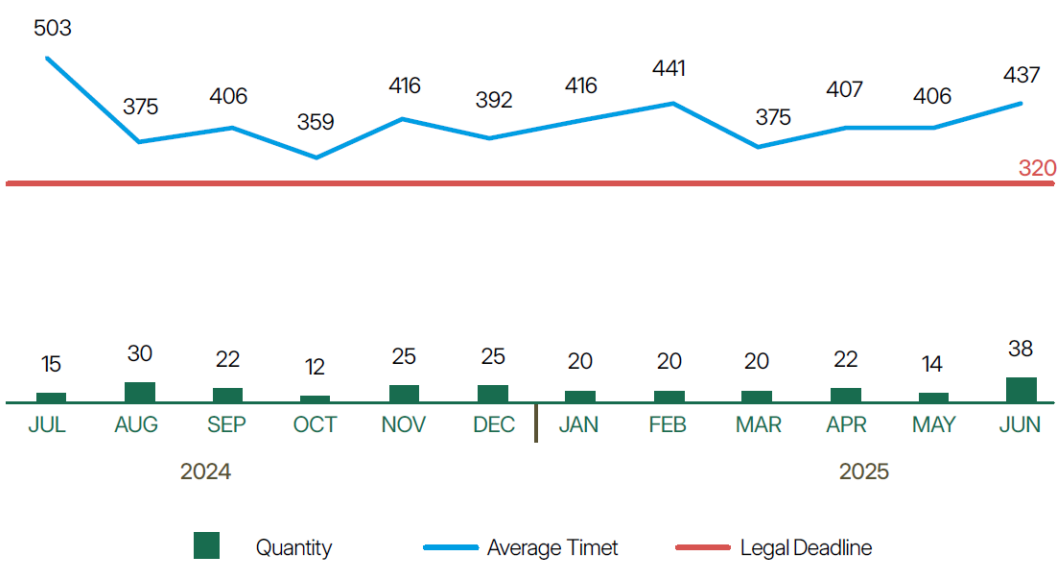
Registration – Medical Device for in vitro Diagnostics



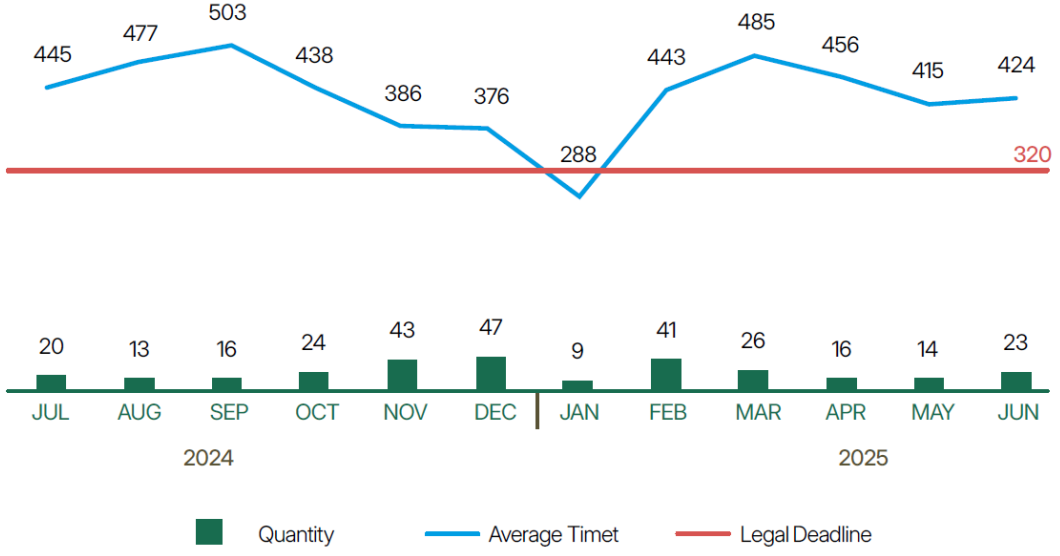
Submission Type	Area	Legal Deadline
Registration Class III and IV	Equipment	250 days
	IVDs	365 dasy

ANVISA

Registration – Material for Health Use (except implantable orthopedics)



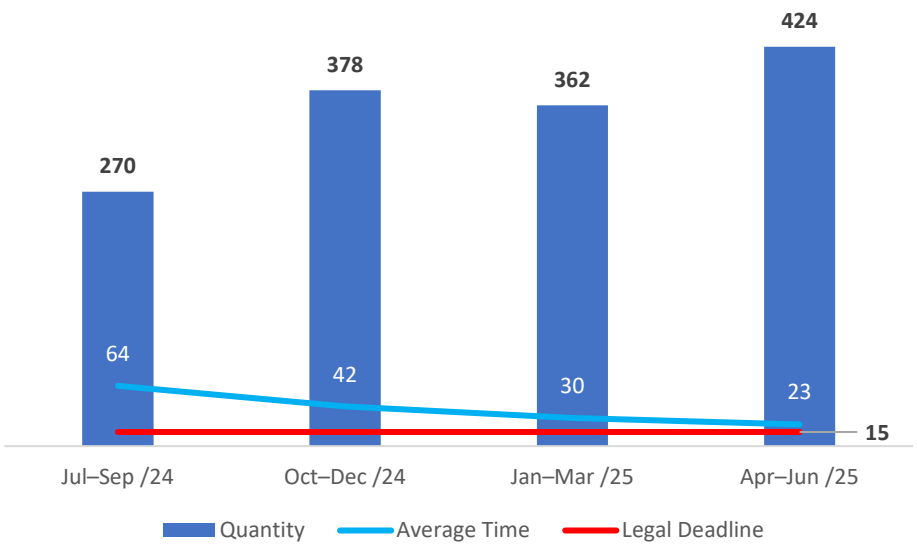
Registration – Orthopedic Materials Implantable



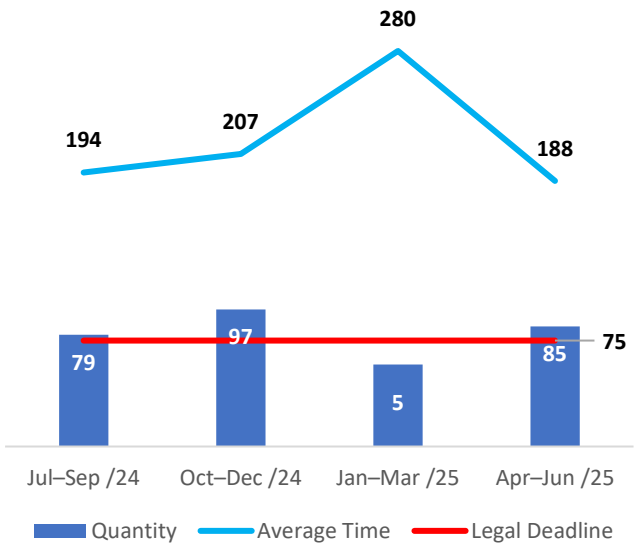
Submission Type	Area	Legal Deadline
Registration Class III and IV	Materails	320 days

HEALTH CANADA

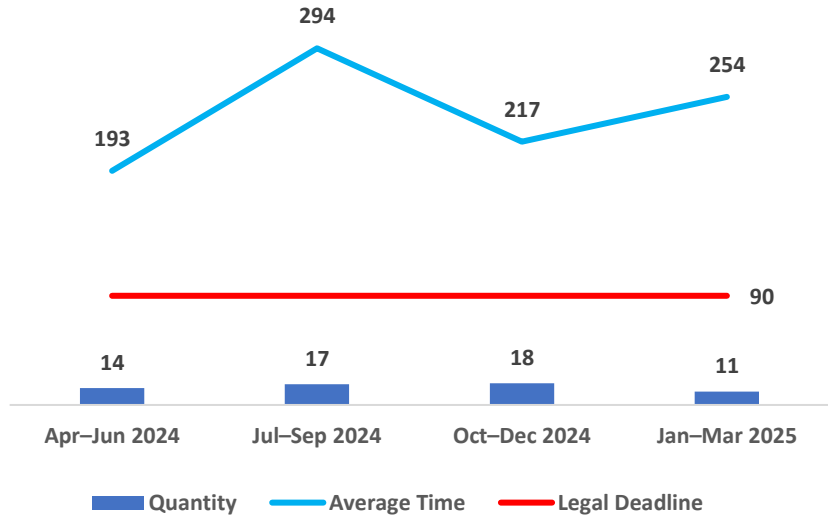
Class II Licensing



Class II Licensing

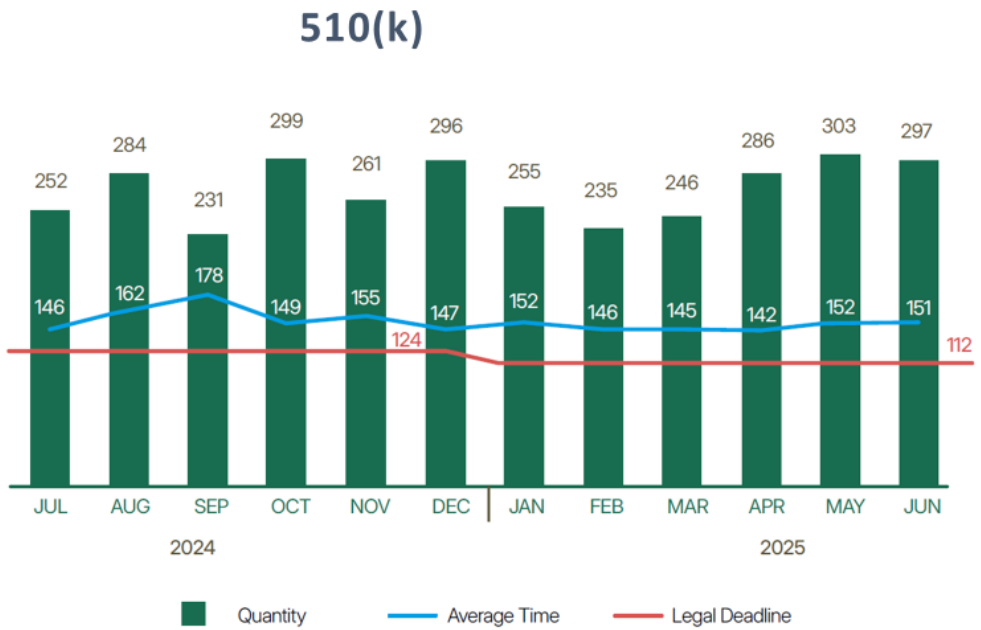


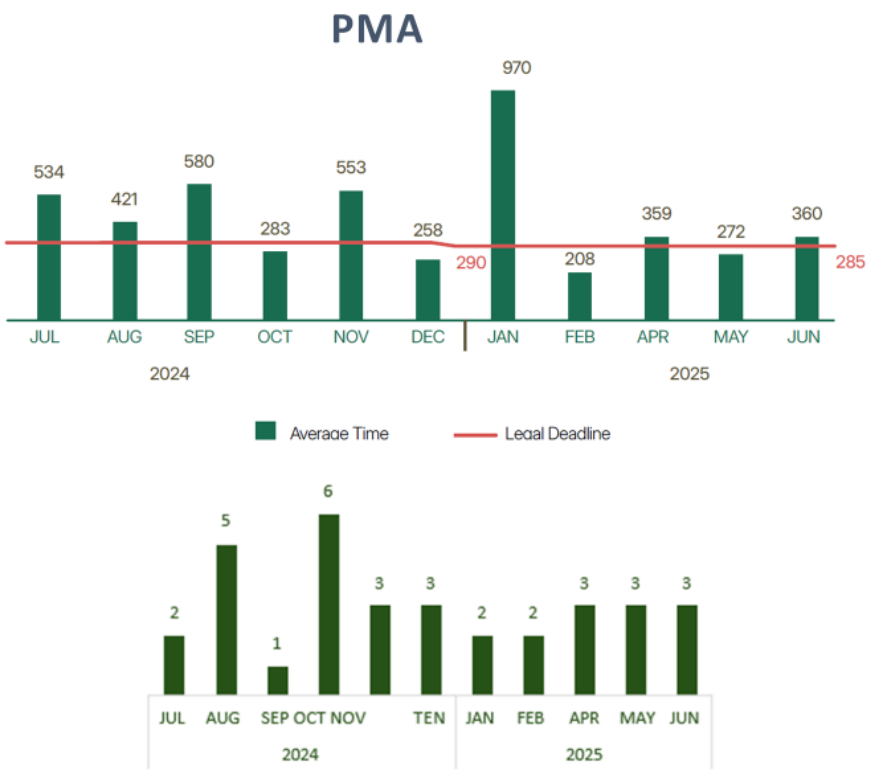
Class IV Licensing



Class I	Exempt
Class II	15
Class III	75
Class IV	90

UNITED STATES





Class	Average - Decision time (MDUFA)
510(k)	2024 - 124 days
	2025 - 112 days
PMA	2024 - 290 days
	2015 - 285 days

Regularization Fees

ANMAT		ANVISA		HEALTH CANADA		INVIMA		US FDA		COFEPRIS	
Provision no. 4058/2025		RDC nº 857/2024		Website Health Canada		Resolution no. 202457944/2024		Medical Device User Fee Amendments (MDUFA)User Fees for FY 2025		Rates – Website	
MD - I and II	$166.57	I and II	$653.57	II	$ 450.39	MD I and IIA	$ 956.74	510(k)	$ 24,335 .0	I	$846.36
MD - III and IV	$ 274.72	III and IV	$ 8,949.84	III	$ 9.924.46	MD IIB and III	$1082.91	PMA	$540,783.00	II	$1,246.64
MD IVD - A and B	$ 148.43			III (MD DIV Next to Patient)	$21.140.25	MD IVD I and II	$ 630.88	510(k) Small companies	$ 6,084.00	III	$1,612.22
MD IVD - C and D	$187.87			IV	$21.521.52	MD IVD III	$ 841.16	PMA Small Businesses	$ 135,196.00		

Access to the publication

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Thank you

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