MEDICAL TECHNOLOGY SECTOR MAP

BRAZIL AND AMERICAS

2026

ABIIS | Aliança Brasileira da Indústria Inovadora em Saúde

Credits

Brazilian Innovative Health Industry Alliance

PRODUCTION

Dr. Leticia Seixas Prata da Fonseca – Vitros Regulatory Affairs

Dr. Marina Amaral Egydio de Carvalho – Egydio de Carvalho Individual Law Firm

COLABORAÇÃO

DocPress Comunicação

Laika Design

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Members of the ABIIS Board of Directors.

We would like to extend our special thanks to the representatives of the Brazilian Health Regulatory Agency (ANVISA) and the entire regulated sector, whose technical expertise, availability, and institutional commitment contributed decisively to the creation of this document.

Summary

Executive Summary

1. Main Objective of the Study and Problem Addressed

The study organizes economic, productive and regulatory information on the medical technology sector in Brazil and in five countries in the Americas (Argentina, Brazil, Canada, Colombia, United States and Mexico [1]). Its primary objective is to map market dynamics, regulatory frameworks, and industry perceptions, in order to identify structural bottlenecks and opportunities that shape innovation, competitiveness, and access to secure devices in the country.

The problem that motivated the work is the growing gap between the rapid expansion of the global market and the institutional capacity of regulatory authorities to keep pace with this evolution. In the Brazilian case, this misalignment is particularly evident in the imbalance between rising demands, increasing technological complexity, and the resources available at ANVISA, which have remained practically unchanged for a decade. This lag generates processes inefficiencies, difficulties in incorporating international best practices, and limitations in the use of modern regulatory convergence instruments.

2. Study Highlights

A. GLOBAL LANDSCAPE AND TECHNOLOGY TRENDS

The global sector reached USD 572.31 billion in 2025, with a projection of USD 886.68 billion by 2032. Growth is driven by demographic aging, the rising prevalence of chronic diseases, the digitalization of healthcare, and the accelerated incorporation of technologies such as artificial intelligence, connected devices, remote monitoring, and robotic surgery. The world's main hubs remain concentrated in the United States, Germany, Switzerland, the Netherlands with China increasingly advancing in production and R&D. These countries lead segments such as *in vitro* diagnostics, implantable devices, minimally invasive therapies and high-precision surgical products. *See Global Market Section.*

B. BRAZILIAN MARKET

Brazil remains the largest market in Latin America, followed by Mexico, Colombia and Argentina. In 2024, it reached around US$ 15.4 billion, growing at a rate of 11.5%, well above the global average. In 2025, apparent consumption stabilized at around US$ 15.5 billion, influenced by the macroeconomic scenario and limitations in the financing of the health system. Imports totaled US$ 6.612 billion between Jan.-Sept. 2025, an increase of 9.3% compared to the same period in 2024. Exports grew 5.7% in the period. The *in vitro* diagnostics segment expanded well above the global average, with an expansion of 28.4%. Despite the stabilization observed in 2025, substantial opportunities remain. Brazil can benefit from the reconfiguration of global supply chains, the growing demand for connected devices, and recent industrial policies focused at the Economic-Industrial Complex of Health. *See Brazilian Market Section.*

C. REGULATION: ADVANCES AND LIMITATIONS

ANVISA maintains strong international alignment, having incorporated 79.3% of IMDRF documents into its regulatory framework. The country remains an active participant in the MDSAP and has expanded the use of *Reliance*. The main challenges include the imbalance between workload and technical staff, the instability of DATAVISA, and the heterogeneity of ANVISA–INMETRO interactions.

1 The order of the country authorities examined are alphabetical as per the original report language of Portuguese.

D. REGULATORY COMPARISON IN THE AMERICAS

There is a significant diversity of regulatory structures, risk classifications, legal deadlines and documentary requirements. Among the countries analyzed, only Brazil, Canada, and the United States publish data on medical device authorization timelines. In all three cases, average approval times for higher-risk devices exceed statutory deadlines. *See International Regulation Section.*

E. PERCEPTIONS OF THE REGULATED SECTOR

The survey conducted by ABIIS indicates that the sector recognizes ANVISA's technical competence, its alignment with international standards and the performance of the SOLICITA system. Dissatisfaction is concentrated on review timelines, instability of DATAVISA, limited opportunities for continuous technical interaction and fragmentation between ANVISA and INMETRO. Perceptions regarding INMETRO's role are heterogeneous, indicating a lack of operational predictability. *See ABIIS Research Section.*

F. STRUCTURAL BOTTLENECKS

The GGTPS workforce has remained practically the same for more than a decade, with 48 employees, well below the minimum estimated requirement of 112 professionals in 2016. This structural lag not only extends average review times but it also undermines regulatory predictability, institutional efficiency and the General Management's capacity to expand its engagement on important issues for the sector. *See ANVISA Section.*

3. Conclusions and proposals

The Brazilian regulatory environment rests on solid foundations, with adherence to international best practices and strong engagement in global convergence forums. However, limitations in personnel, systems, and interagency governance reduce the country's ability to keep pace with innovation and compromise regulatory efficiency. The domestic market shows dynamism above average in segments such as *in vitro* diagnostics, but remains vulnerable to external technological dependence, international trade fluctuations and macroeconomic instabilities. The consolidation of recent industrial policies may increase competitiveness, provided they are accompanied by structural regulatory improvements.

PRIORITY PROPOSALS

1. **Strengthening the workforce**. Increase GGTPS staff to the recommended minimum, with immediate reinforcement in areas subject to higher technical demand, such as materials and implantable devices.
2. **Structured governance ANVISA-INMETRO**. Create a permanent technical committee, through a joint instrument, to harmonize interpretations, review conformity and coordinate regulatory improvement agendas.
3. **Modernization of DATAVISA**. Update the system to optimize the process of regularization of medical devices, improving efficiency and agility.
4. **Recognized technical standards and Declaration of Conformity.** Establish an official list of recognized standards and evaluate the implementation of declarations of conformity, to optimize the regularization of medical devices.
5. **Expansion of Reliance**. Expand the list of Equivalent Foreign Regulatory Authorities (AERs) for Reliance purposes.
6. **Review of INMETRO procedures**. Develop a Standard Operating Procedure with a checklist of good regulatory practices, harmonizing INMETRO's activities with those of regulatory agencies and reduce duplication.

INTRODUCTION

Medical technology plays a central role in the ongoing transformation of contemporary health systems. It encompasses a wide range of products, services and solutions that support activities that range from basic clinical diagnostics to highly complex therapies and precision surgical procedures. This breadth positions the sector simultaneously a driver of scientific innovation, industrial competitiveness and improvement in quality of life.

In recent years, advances in digital technologies, data integration, and the incorporation of artificial intelligence and connected devices have significantly expanded the scope and impact of medical technology on health care. This evolution, however, is accompanied by new regulatory, productive, and institutional challenges, requiring coordinated and evidence-based responses from the public and private sectors. It is in this context that the present study — **"Map of the Medical Technology Sector – Brazil and the Americas"** — was developed, with the purpose of systematizing economic, regulatory and institutional information relevant to understanding the structure, performance and perspectives of this sector in Brazil as well as its regional and international insertion.

The report provides a comprehensive and analytical overview of the medical technology chain, articulating information from official sources, international databases, foreign trade data, and empirical research conducted with the regulated sector. The analysis combines quantitative and qualitative approaches, offering an integrated assessment of the economic and regulatory environment that shapes the performance of the sector in the country.

FORMAT AND METHODOLOGICAL APPROACH

The report adopts a technical-analytical format, combining accessible language and conceptual rigor. Each section is based on a combination of **secondary data collection** and **primary empirical research**, organized within logical framework that starts from the global context to the detailed analysis of the Brazilian scenario and the perceptions of the regulated sector.

The methodology is structured around four main axes:

- 1. Documentary and regulatory survey
- 2. Statistical and economic analysis
- 3. Empirical research with the regulated sector
- 4. Treatment and presentation of results

PURPOSE AND RELEVANCE

The *Medical Technology Sector Map – Brazil and the Americas* was conceived as both a **diagnostic and strategic planning instrument**, intended to support public policy formulation, inform investment priorities and promote regulatory convergence. By consolidating market data, regulatory references and industry insights in a single document, the study offers a comprehensive and up-to-date assessment of the regulatory and competitive environments of medical technology.

The findings confirm that Brazil has **consolidated technical competence**, a regulatory framework aligned with international standards and a growing presence in global convergence forums. However, it also identifies **persistent structural barriers** — human resource limitations, extended review times, duplication of requirements, and deficiencies in institutional communication — that limit the agility and predictability required in a modern regulatory environment.

In the end, the document not only describes the scenario, but proposes pathways for improvement, reinforcing the importance of integrated policies that support innovation, local production and regulatory efficiency. The report provides a clear view of **Brazil's current position, its recent advances, and the opportunities for convergence and development** as the country seeks to consolidate its position as a strategic hub of medical technology in the Americas.

Word from the ABIIS Chair

Bruno Boldrin Bezerra

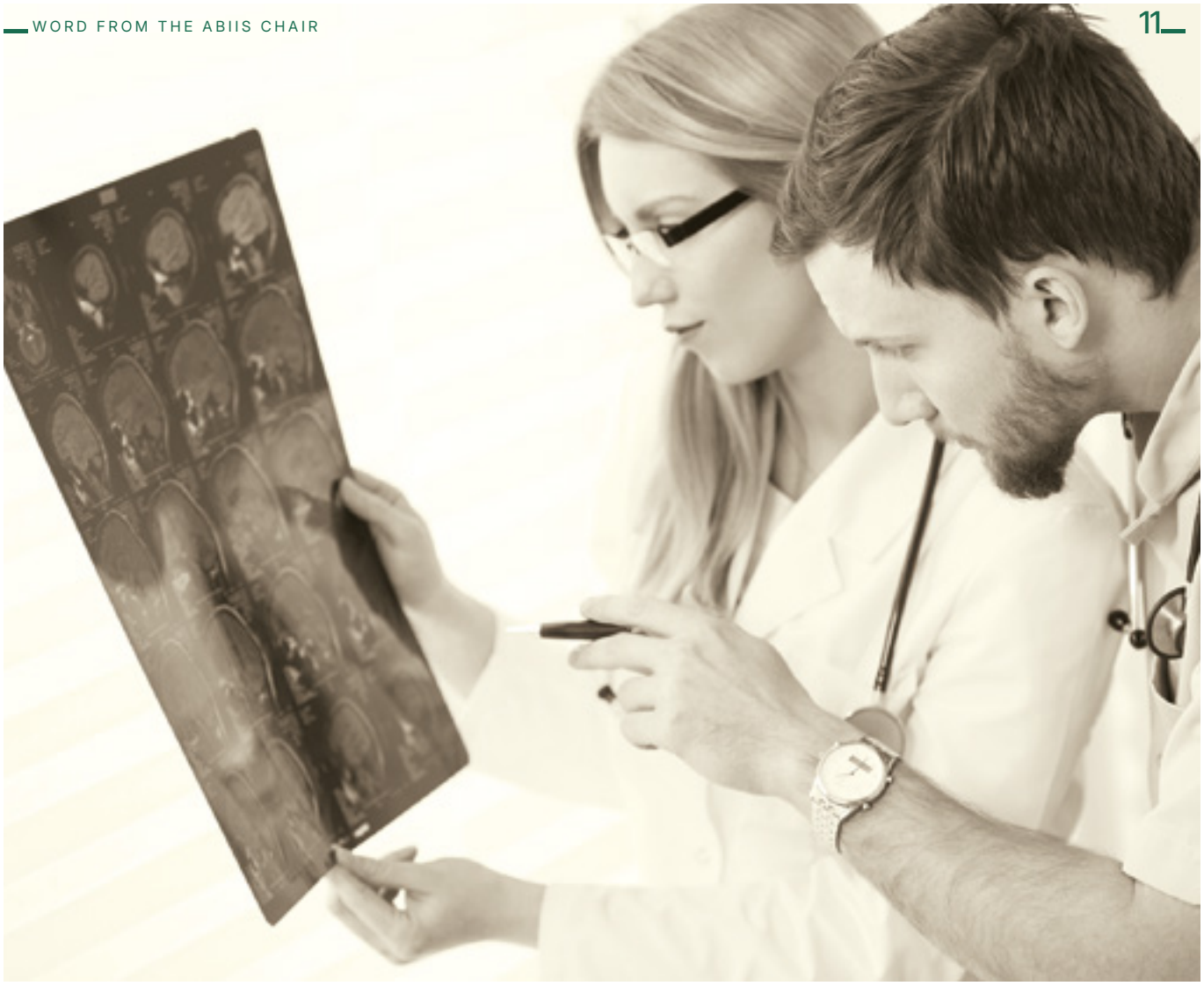
ABIIS was born out of the conviction that a strong healthcare system depends on reliable information, regulatory predictability, and ongoing dialogue between the government, the productive sector, and society. Therefore, we operate guided by six pillars: Smart Regulation; Rational Incorporation of Technologies; Institutional Improvement of Regulators; Improvement of the Business Environment; Ethics and Compliance; and Innovation and New Technologies. For 14 years, our commitment has been to contribute to Brazil having more efficient and sustainable health policies that are aligned with international best practices.

And this mission has materialized in concrete deliveries. With the *Health 4.0* study in 2015, we presented a pioneering diagnosis of the digital transformation in health, highlighting ways to incorporate emerging technologies safely and with a systemic vision. When we celebrated our 10th anniversary in 2021, we presented a Health Agenda 2022/2030 in the publication *Challenges and Proposals for the Medical Device Sector in Brazil*, aligned with the Alliance's pillars and addressed to the candidates for the Presidency of the Republic in 2022. We recommended that the medical device sector should be treated as strategic, both for its economic relevance and its direct impact on the population's quality of life, which has been materializing, in some way, in Brazilian federal government policies. The publication brought structural proposals for innovation, reduction of the Brazil Cost, strengthening the Health Industrial Complex and more efficient tax policies. In addition, we consolidated the *Quarterly Economic Bulletin on Medical Devices - ABIIS*, which has become a reference for qualified information and data on the sector for the press, government, and industry leaders.

Our goal has always been the same: to provide reliable data to guide decision-making. This commitment is even more relevant given the current scenario of the MedTech sector in Brazil. We are experiencing a period of expanding demand, technological acceleration, and tax and regulatory changes. Artificial intelligence, for example, challenges regulators around the world, but offers significant advances in all areas of healthcare. However, in Brazil, this advancement has occurred simultaneously with a structural problem: the continuous loss of professionals at ANVISA without proportional replacement to compensate for the increase in workload. ANVISA, internationally recognized for its technical excellence, faces difficulties in meeting deadlines, even with the adoption of processes and technologies that bring efficiency. This mismatch can affect the population's access to medical technologies, increase uncertainty and regulatory costs for the industry, and hinder the promotion of innovation in healthcare.

In this context, ABIIS is launching the *Medical Technology Sector Map - Brazil and the Americas*, which analyzes the regulatory and economic environment in Brazil and five other countries - Argentina, Canada, Colombia, Mexico and United States – offering a contextualized regional overview, with metrics, deadlines, costs, regulatory efficiency, market data, and international trends.

The Map highlights the growing relevance of the medical technology sector which is responsible for expanding the effectiveness of healthcare systems, driving innovation, and generating positive impacts on productivity and quality of care. It also reveals how Brazilian regulation, although robust, faces bottlenecks: a shortage of civil servants, asymmetries in processes and decisions, challenges in system integration,



and the need to improve cooperation with other regulatory agencies, such as INMETRO and ANATEL for example. At the same time, it points to important advances, such as ANVISA's pioneering spirit and leadership in promoting international convergence and its recognized ability to evaluate complex technologies.

By systematizing this information, the study offers practical evidence to guide the actions of different actors — ANVISA, ministries, Congress, regulatory agencies, policymakers, and companies in the sector. It is a tool to support strategic decisions, identify priorities, and strengthen Brazil's path to global competitiveness.

This project joins other concrete initiatives by ABIIS in the Brazilian regulatory environment. Throughout 2025, we fought for the expansion of ANVISA's staff; we supported the recomposition of the ANVISA collegiate board; the project to reduce analysis queues with the implementation of reliance, and the modernization of internal workflows.

We are making this study available to society with a commitment to continue contributing to stronger, smarter regulation that is aligned with the challenges of the future. We believe that a country that values its regulator, promotes responsible innovation, and adopts evidence-based decisions is better prepared to offer quality healthcare to its population and to position itself competitively on the international stage.


TREND
TABLE
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Word from the ABIIS Executive President

José Márcio Cerqueira Gomes

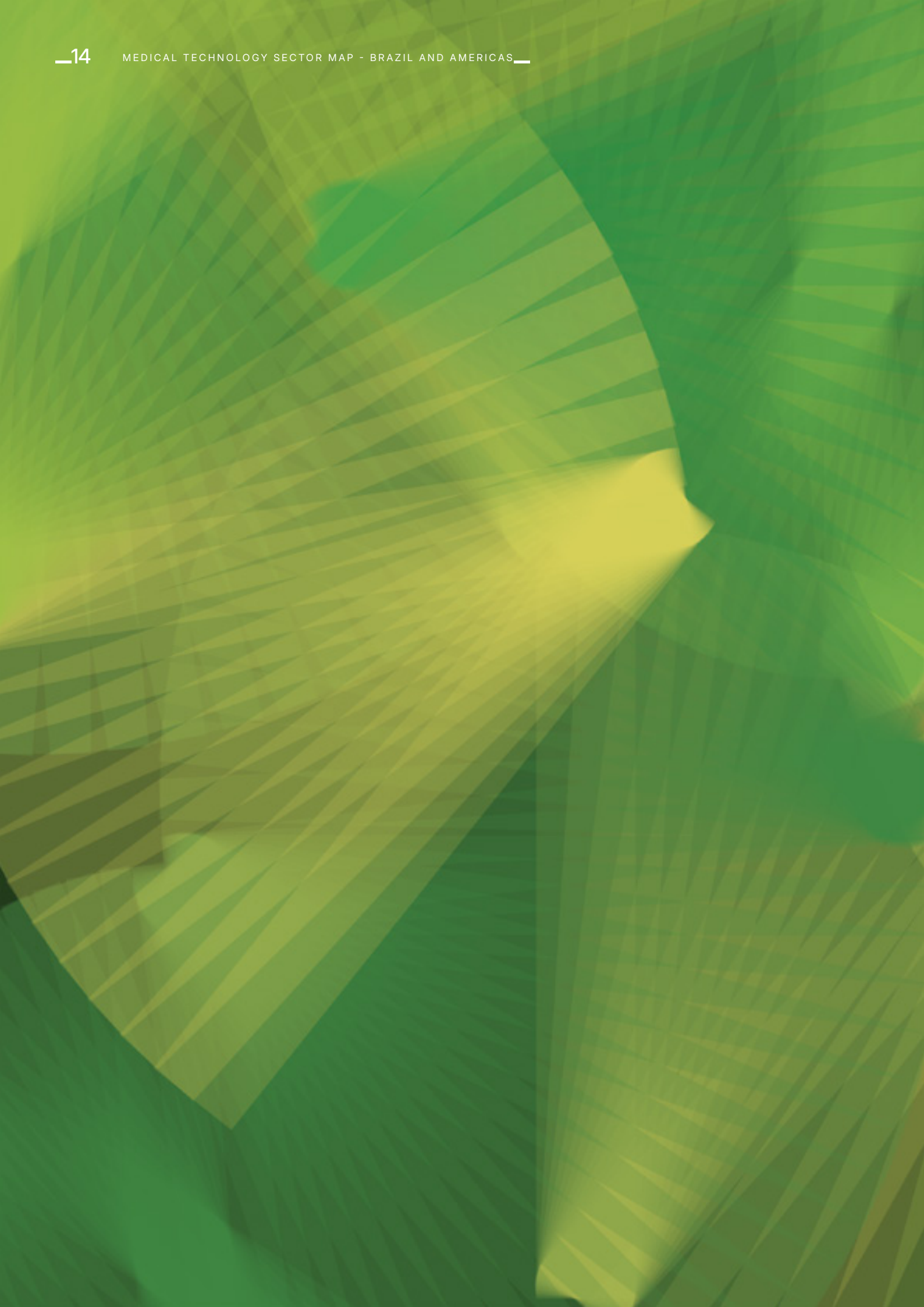
Health regulation is one of the pillars of health security in any country. Brazil has an internationally recognized authority in this field: ANVISA. The *ABIIS Medical Technology Sector Map* demonstrates the Agency's technical soundness, its alignment with global best practices, and its active participation in regulatory convergence forums such as the IMDRF and MDSAP. This is an institutional asset that needs to be preserved and strengthened.

The analysis sought to provide evidence on the impact of the insufficient number of civil servants at ANVISA. This imbalance puts pressure on deadlines, compromises the predictability of processes, and jeopardizes the country's ability to ensure timely access to essential technologies. With the new positions recently opened, this bottleneck should be partially alleviated.

The study also provides regulatory costs in each country and legal deadlines, among other data, offering high-quality knowledge for those seeking to understand the sector more deeply.

Another point addressed is the importance of efficient coordination between ANVISA and INMETRO. Conformity assessment is an integral part of medical device safety, and INMETRO plays a strategic role in ensuring that marketed products meet technical requirements and international standards. Modern regulation requires integration between institutions, and the Map provides objective recommendations in this regard, such as clarity of roles, strengthening technical dialogue, and harmonizing regulatory processes. Structured cooperation between the two agencies reduces asymmetries, improves predictability, and strengthens the competitiveness of Brazilian industry.

Brazil has the potential to further position itself as a regional benchmark in medical technology. To do so, we need a strengthened ANVISA, an INMETRO that is fully integrated into the health ecosystem, and policies that value technical intelligence and institutional cooperation. This study offers evidence, diagnoses, and possible paths forward.



What is Medical Technology

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1. What is Medical Technology

Medical technology encompasses a wide range of medical devices, digital and software platforms, and related services and therapies, used to diagnose, treat, monitor, manage, and alleviate health conditions. It includes products ranging from implantable devices and surgical instruments to digital health platforms and diagnostic reagents, all with the goal of improving patient care.[2]

Medical Device[3] – Any instrument, apparatus, equipment, implant, medical device for *in vitro diagnosis*, software, material or other article intended for use in the area of human health for the purpose of:

- Prevention
- Diagnosis
- Treatment
- Monitoring
- Rehabilitation
- Contraception

ARE CONSIDERED MEDICAL DEVICES

In Vitro Diagnostics

Orthotics, Prostheses and Medical Materials

Medical Equipment

E-Health

Medical devices range from simple, everyday consumer products such as gauze or syringes to more complex products such as orthopedic implants, heart valves, HIV diagnostic kits or MRI equipment and software for medical purposes.

WHERE CAN THEY BE USED?

- Hospitals
- Clinics
- Home-based care
- Hard-to-reach places

WHO CAN USE IT?

- Healthcare professionals
- General public

Estimates from the World Health Organization (WHO) indicate that there are more than 2 million different types of medical devices on the global market, categorized into more than 7,000 generic groups of devices.[4] These products are essential for health care.

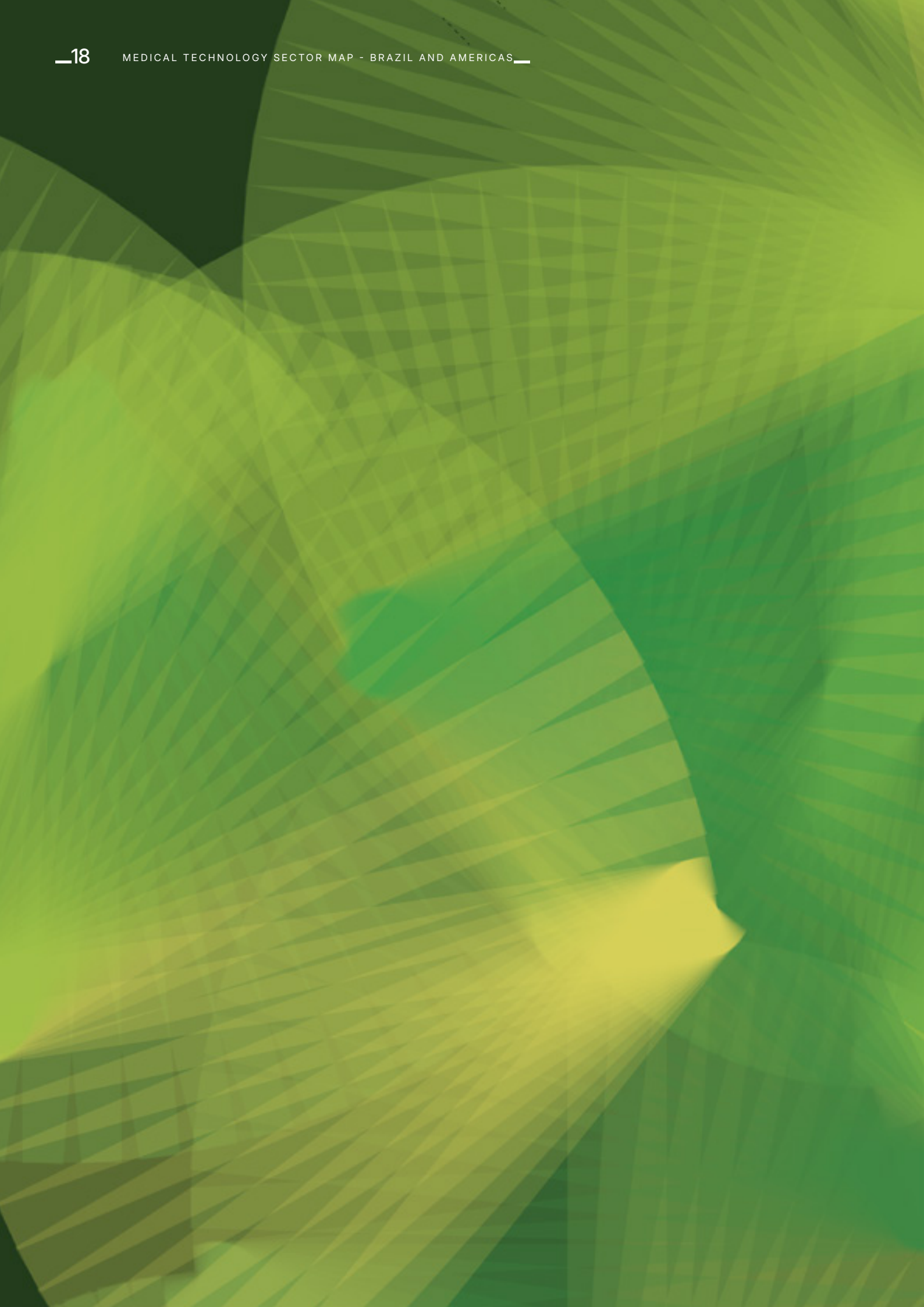
2 What is Medical Tech nology – MedTech Europe
3 The term "Medical Device" is formally defined in Brazil by RDC No. 751/2022.
4 World Health Organization - Medical devices.
5 Global Medical Technology Alliance - Differences between medical devices and drugs.

DIFFERENCES BETWEEN MEDICAL DEVICES AND DRUGS

It is essential to distinguish medical devices from medicines, due to their different characteristics. They are regulated by distinct rules – aspects often unknown to public policymakers, legislators or the general public. The table below compares differences between medical devices and medicines.[5]

	MEDICAL DEVICES	MEDICINES
INDUSTRY	Predominance of small and medium-sized companies.	Predominance of multinationals.
CHARACTERISTICS OF THE TECHNOLOGIES	Usually based on mechanical, electrical and materials engineering with increasing software integration. In *vitro* diagnostic devices have no therapeutic effect.	Based on pharmacology and chemistry; also covering biotechnology, genetic engineering, among others.
INNOVATION	Continuous innovation, driven by scientific and technological advances and the development of new materials. This permanent evolution enables the delivery of greater clinical value to patients, strengthens the competitiveness of the industry and demands an increasingly agile and effective regulatory environment.	A long process, which involves years of research.
LIFE CYCLE	Short (on average 2 years in the market). Most new products bring additional functions and clinical value based on incremental improvements; It usually results in a range of related models for the user to choose from, based on the patient's needs. General absence of patent protection. Dynamic market, with multiple competitors.	Extensive, intensive patent protection.
SHARE	They usually act through physical interaction with the body, or in the case of *in vitro* they do not come into contact with the body.	They usually act systemically throughout the body.

Source: Global Medical Technology Alliance - Differences between medical devices and drugs, altered by the Authors



Industry Overview

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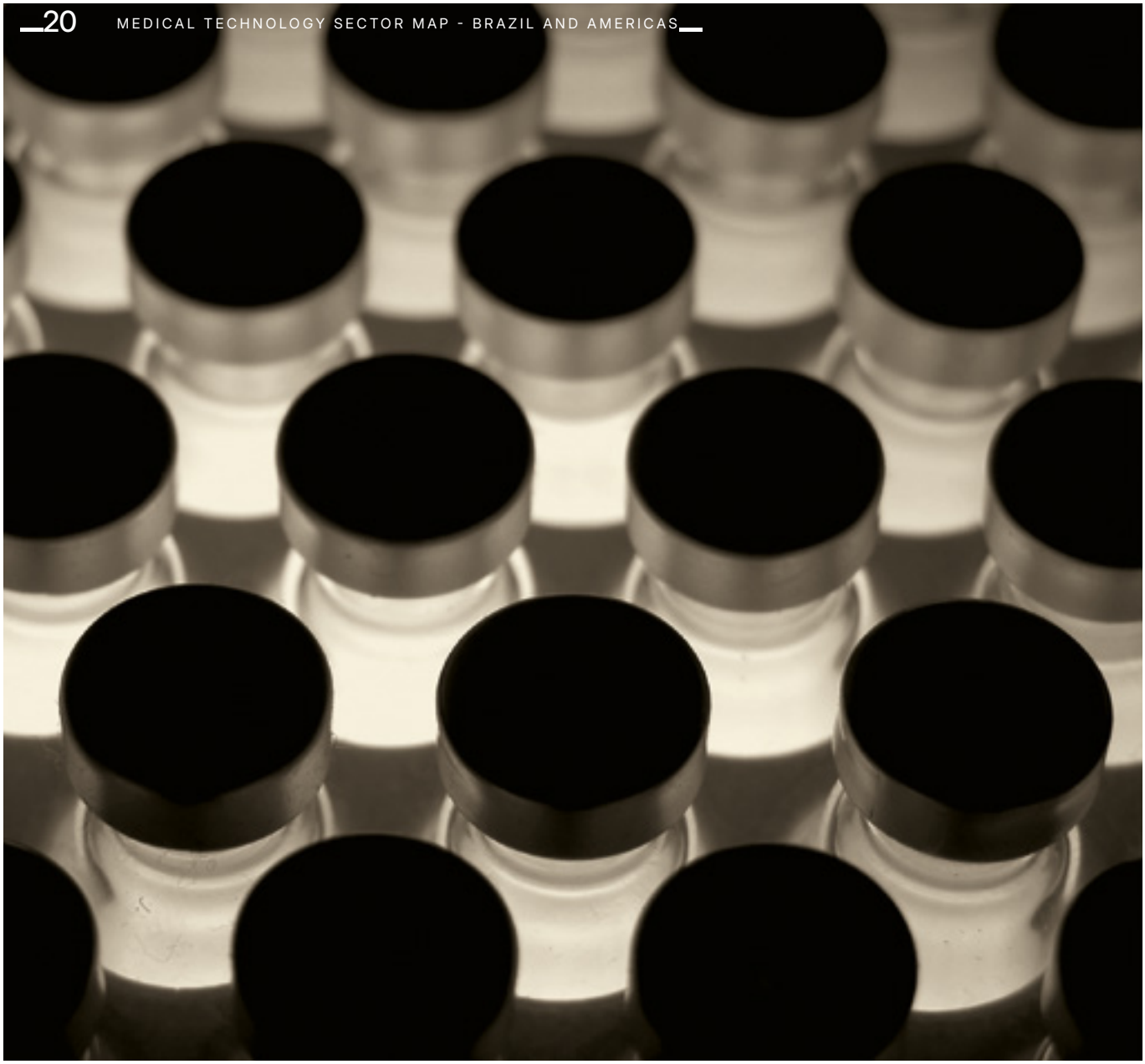
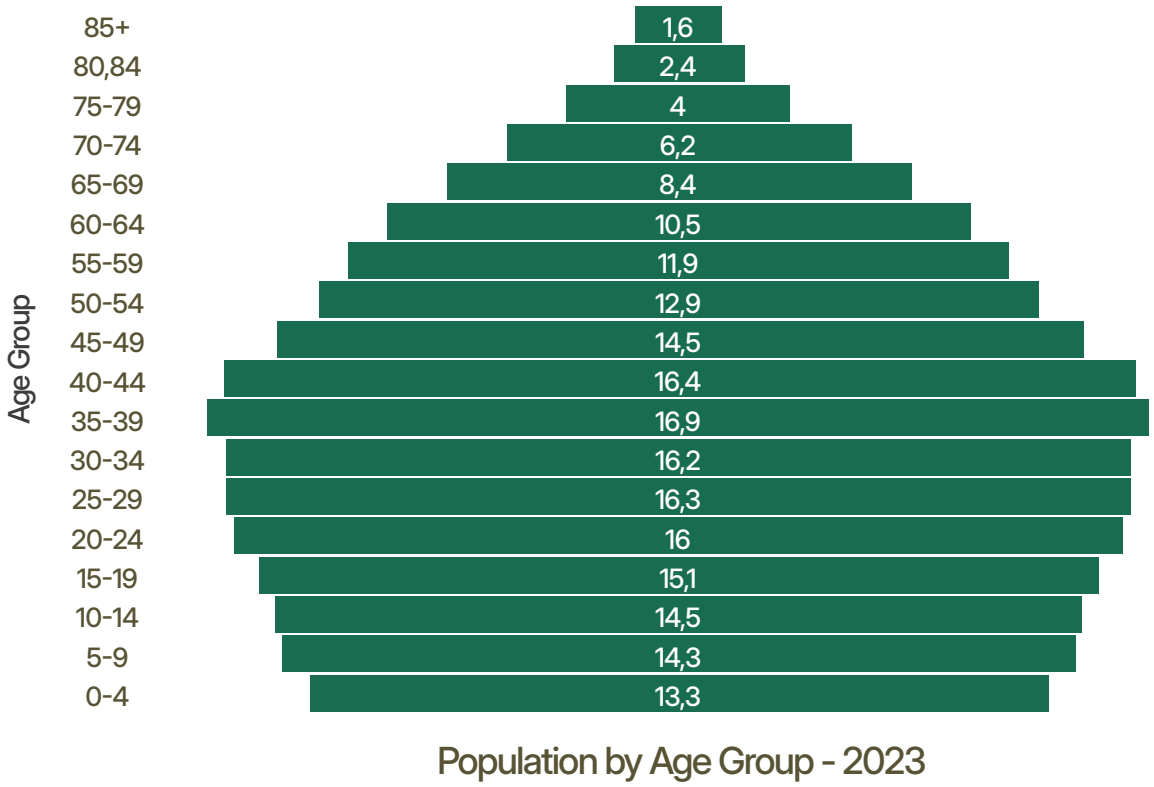


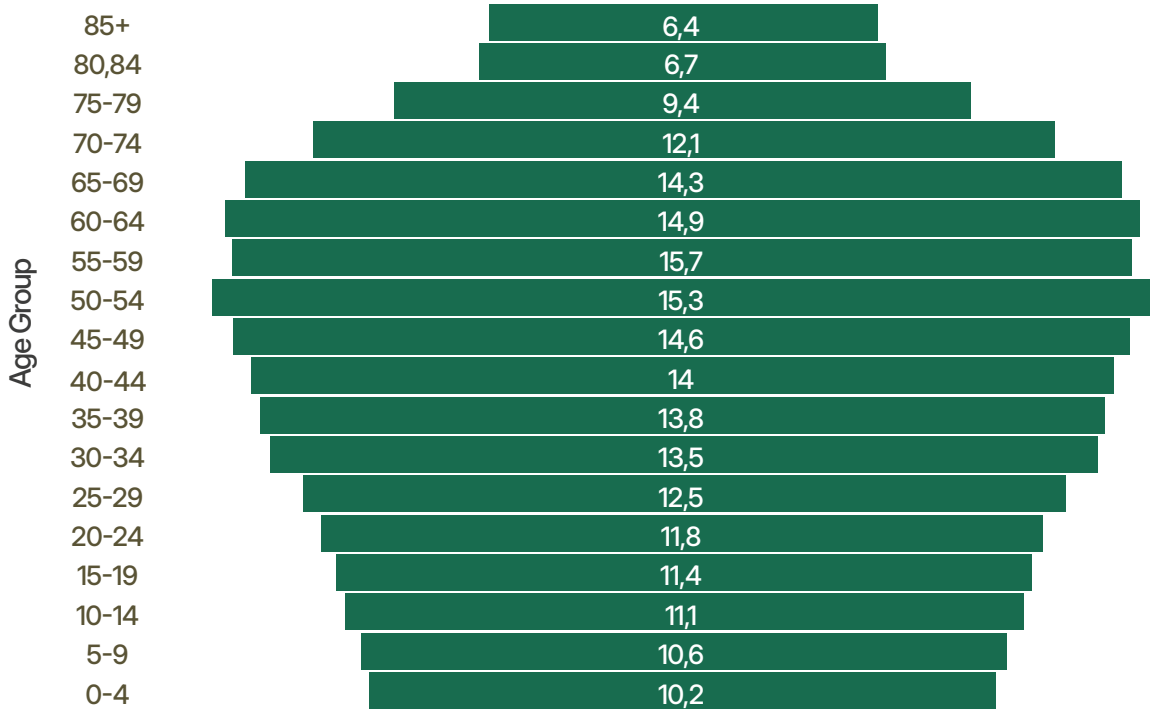
2. Industry Overview

The aging of the population is a global phenomenon. This is documented at the United Nations *World Population Ageing 2019* report on life expectancy. Almost all countries are expected to experience sustained growth in both the size and the share of older people, By 2050, elderly people is projected to exceed 1.5 billion, of whom more than 426 million will exceed 80 years of age.

For Brazil, the WHO projection for the year 2050 compared to 2023 indicates the reconfiguration of the demographic composition, with an increase of 92.7% of the population over 60 years of age.



Population by Age Group - 2023



Projection – Population by Age Group – 2050

Source: WHO - Brazil Health data overview for Federative Republic of Brazil[6]

6 OMS Data – Health data overview for the Federative Republic of Brazil

Associated with this phenomenon, the rising incidence of chronic diseases is increasing pressure on health systems, with a direct impact on the global market for medical devices and on the management of health systems.

Although, on the one hand, this dynamic imposes new challenges, which go beyond the expansion of the medical device sector, requiring its qualification - which involves the incorporation of new technologies - to expand the possibilities of access to health services; on the other hand, the speed of these changes assigns new responsibilities to regulatory authorities and health system managers, who need to review their processes to respond to the transformations that are rapidly arising.

The expansion of the sector is observed by different indicators, including the growth in both global and national market. The table below presents data on the expansion of the sector.

	2024	GROWTH
GLOBAL MARKET	Total 2024 – US$ 542.21 billion	**2025** – US$ 572.31 billion (↑ 5.5%)
		2032 (Projection) – US$ 886.68 billion (↑ 54.93%)
BRAZIL - IMPORTS	Total 2024 – US$ 8.01 billion	Jan. / Sept. 2025 – US$ 6,612 billion (↑ 9.3%)
	Jan./ Sep 2024 - US$ 6,049 billion	
BRAZIL - EXPORTS	Total 2024 – US$ 852 million	Jan. /Sep. 2025 – US$ 650.00 million (↑ 5.7%)
	Jan. /Sep. 2024 – US$ 616 million	

Prepared by the authors[7]

7 Prepared by the authors based on data from Fortune Business Insights (Medical Devices Market Size, Share, Global Growth Report 2032), ABIIS (Economic Bulletin – Edition 48 - 2025), Anvisa (List of Regularized Medical Devices)

TECHNOLOGY TRENDS

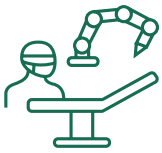
The growth of the global medical device market, driven by the growing demand for healthcare, fosters the development of innovative technological alternatives that enable early diagnosis and treatment of diseases, safer surgeries, the use of telemedicine, and the expansion of people's access to healthcare.

Among the key trends shaping the sector are: [8]

Wearable Devices

Wearable devices enable continuous health monitoring through sensors integrated into clothing, watches, and headphones, among others.

Medical Robots

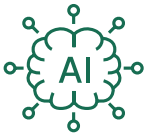


Medical robots are increasingly used for different purposes, such as minimally invasive and high-precision surgeries, rehabilitation or diagnosis.

Immersive Technologies

Immersive technologies such as augmented reality and virtual reality can offer new approaches to treatments and diagnoses.[9]

Artificial Intelligence

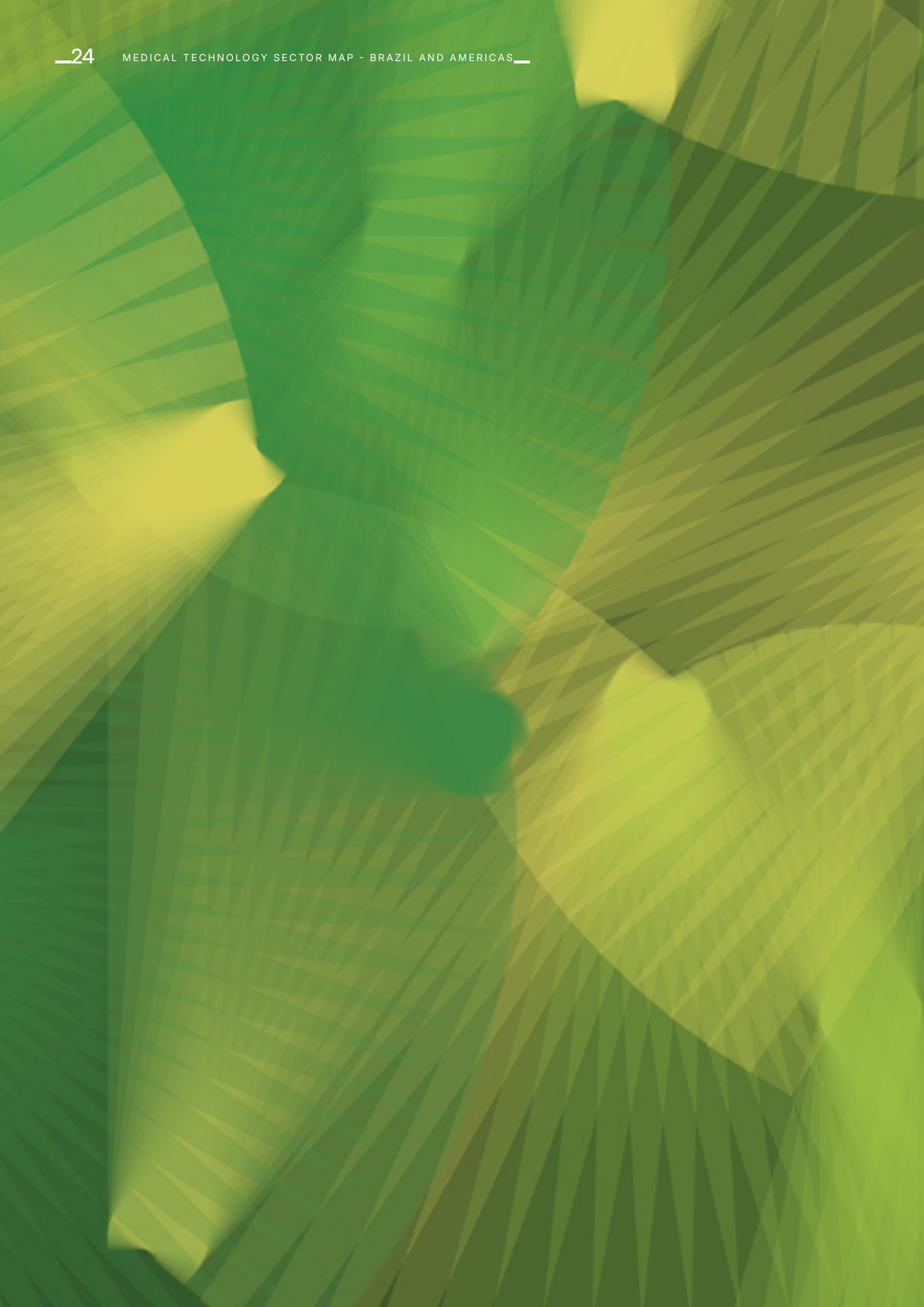


Artificial intelligence (AI) technologies, including machine learning, bring new insights from the analysis of data generated in the healthcare industry.[10]

3D Printing

3D printing t enables tailor-made medical devices compatible with the patient's needs. The technique can be applied to the fabrication of orthopedic and cranial implants, surgical instruments, anatomical 3D molds for surgery planning, among others.

8 StartUs Insigths
9 Food and Drug Administration. 2024 Sep 6 – Augmented Reality and Virtual Reality in Medical Devices
10 IMDRF/AIML WG/N88 FINAL:2025 Good machine learning practice for medical device development: Guiding principles



Industry Data

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3. Industry Data

EXECUTIVE SUMMARY - GLOBAL MEDICAL TECHNOLOGY MARKET

The global medical device market had an estimated value of US$ 572.31 billion in 2025, sustaining an average annual growth rate of 6.5% until 2032. North America maintained its leading position, with a 38.17% share, followed by Europe (27.3%) and Asia-Pacific (23.5%), the latter representing the fastest growing region.

The largest market segments were Therapeutic Devices (25.8%), Implantable Devices (24.3%), In Vitro Diagnostics (15.9%), Monitoring Devices (16.6%) and Surgical Instruments (12%). Market expansion has been driven by rising demand for rapid diagnostics, minimally invasive treatments, and remote monitoring technologies.

Emerging trends are shaping the future of the industry. The use of Artificial Intelligence in medical devices is projected to grow 12% by 2028, followed by wearable devices (11.3%) and robotic surgery (10.5%). These technologies reinforce the personalization of treatments and the efficiency of surgical processes.

Regionally, North America demonstrates leadership across all categories, with strong positions in monitoring and therapeutic devices. Europe has a consolidated position in *in vitro* diagnostics and surgery, while Asia-Pacific grows strongly in implantable devices and monitoring, driven by an aging population and increasing investments in healthcare.

These dynamics position the global medical device market as one of the most innovative and strategic segments of healthcare in the years ahead.

MARKET SIZE IN 2023: **US$ 517.0 BILLION**

MARKET SIZE IN 2024: **US$ 542.21 BILLION**

PROJECTION FOR 2032: **US$ 886.68 BILLION**

REGIONAL LEADERSHIP IN 2024:

NORTH AMERICA, WITH 38.17% MARKET SHARE.

MAIN SEGMENTS:

CARDIOVASCULAR DEVICES, ORTHOPEDIC, DIAGNOSTIC IMAGING, IN VITRO (IVD), MINIMALLY INVASIVE SURGERY, OPHTHALMOLOGY, AND DIABETES CARE.

REGIONAL SHARE:

I) NORTH AMERICA: 38.17% OF THE GLOBAL MARKET.

II) ASIA-PACIFIC: US$ 111.93 BILLION IN 2024, WITH ACCELERATED GROWTH FORECAST..

Overview of the Global Medical Device Market[11]

11 Business Insider, 2025. Available at: https://www.businessinsider.com/tech-powerhouses-betting-on-healthcare-ai-amazon-nvidia-2025-5?utm _ source. Accessed on 06/02/2025; Fortune Business Inside, 12/05/2025. Available at: https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085. Accessed on 06/02/2025; GROMLEY, Brian. Medical-Robotics Startup Mendaera Raises $73 Million for Market Launch. Wall Street Journal. 2024-09-26. Available at: arXiv+16WSJ+16Medi-Tech Insights+16. Accessed on 02/02/2025; Pharmchoices, Global Medical Devices Market Size, Top Ranked Medical Device Companies (2024). Pharmchoices. 2025. Available at https://pharmchoices.com/the-global-medical-device-market-size-2/?utm _ source. Accessed in: 06/02/2025.

3.1 Global Medical Technology Market[12]

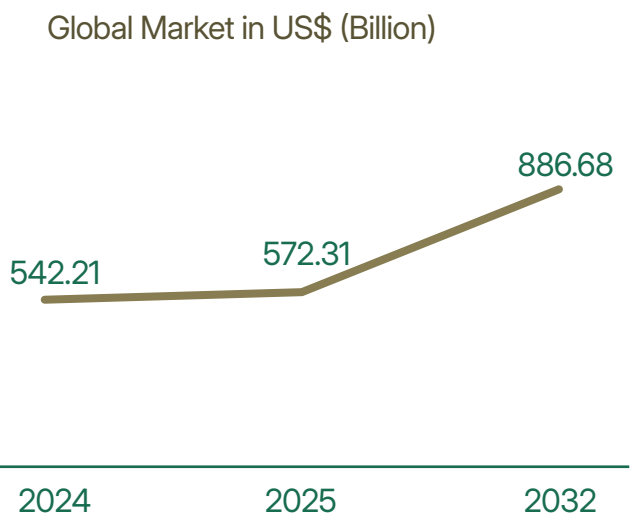
In 2024, the global medical device market consolidated at a level of US$ 542.21 billion, supported by structural drivers such as population aging, the increase in the prevalence of chronic diseases, and the digitalization of health. The industry is expected to maintain a robust expansion trajectory, with a growth rate of 6.5% through 2032, reflecting a growing demand for advanced technological solutions, expand access in emerging markets, and innovations in minimally invasive medical procedures.

In terms of segmentation, therapeutic devices lead with 25.8% share, evidencing the strong demand for technologies that support personalized and less invasive treatments. Implantable devices follow this trend, with 24.3%, driven by advances in orthopedic prostheses, cardiovascular *stents* and neurological implants. The *in vitro* diagnostics (IVD) segment, which accounts for 15.9% of the global market, continues to grow rapidly with the evolution of molecular testing and precision medicine. Remote monitoring devices, supported by the integration of Internet of Things (IoT) and artificial intelligence (AI), reinforce the global movement for real-time and decentralized health management.

Regionally, **North America** remains the largest market with 38.17% of the global market, benefiting from a mature innovation ecosystem, strong industrial base and, by 2024, a relatively stable regulatory environment. **Asia-Pacific** stands out as the fastest-growing market, supported by increased investments in healthcare infrastructure and the growth of the middle classes in China, India, and Southeast Asia. **Europe**, although mature, remains relevant in the segments of diagnostic imaging and robotic surgery. In the **Latin American context, Brazil** consolidates its position as the largest regional market and a *strategic hub* for exports, especially to the United States, which absorbs 22% of Brazilian exports in the sector. The Brazilian production chain has been seeking to increase its competitiveness in higher value-added niches, such as *in vitro* diagnostics, orthopedic implants and connected devices, while adapting to the pressures of a global commercial environment increasingly impacted by new tariff policies and reconfiguration of supply chains.

GLOBAL MEDICAL TECHNOLOGY MARKET GROWTH (2024 - 2032)[13]

The evolution of the global medical device market between 2023 and 2025, illustrated in the figure below, demonstrates steady growth driven by technological advances, increased demand for rapid diagnostics, and an expansion in the elderly population.



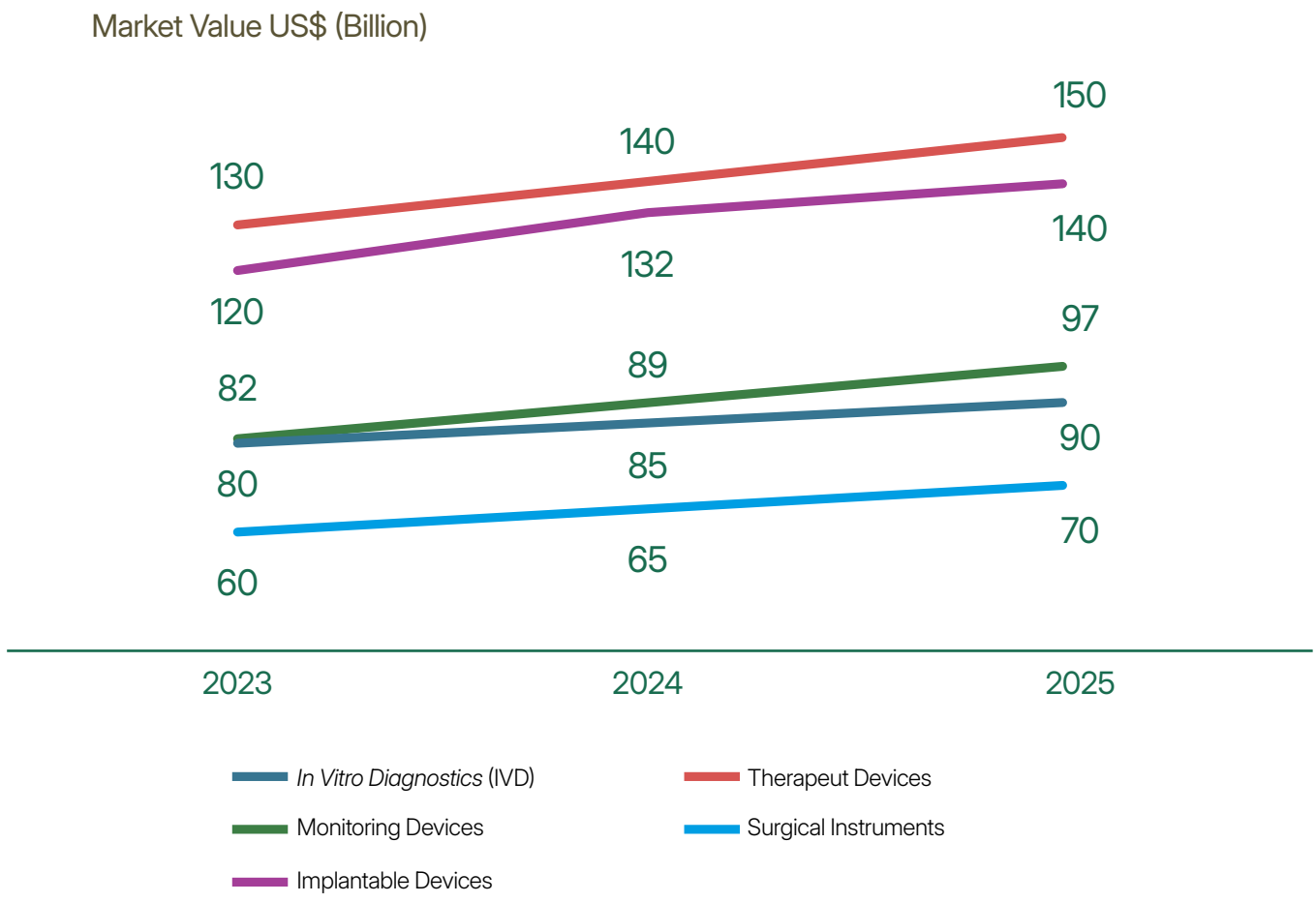
12 Data from Fortune Business Insights: Medical Devices Market Report 2024; Market Data Forecast: Medical Devices Market; GM Insights: Implantable Medical Devices Market; GlobeNewswire: Medical Devices Market Statistics 2024 and Mordor Intelligence: Global Medical Device Technologies Market Industry.

13 Fortune Business Insights/SkyQuest 2024.

GLOBAL MARKET SEGMENTATION (2023-2025)[14]

The trajectory of the different segments between 2023 and 2025, illustrated in the figure below, reveals a trend towards the appreciation of **therapeutic and implantable technologies**, which continue to lead the global market in absolute value.

Therapeutic devices are expected to exceed US$ 150 billion in 2025, closely followed by **implantable devices**. This reflects the consolidation of demand for more complex and personalized interventions, such as smart prostheses, bioactive stents, and neurological implants.



14 Fortune Bsiness Insights / Market Data Forecast / GM Insights (2024).

On the other hand, there is also significant growth in **in vitro monitoring and diagnostic (IVD) devices**—both driven by the digitalization of health, the search for predictive and continuous care models, and the strengthening of patient centered approaches.

Surgical **instruments**, although with lower relative growth, maintain a stable trajectory, reflecting a consolidated base of traditional hospital demand, but with emerging opportunities for disruptions in areas such surgical robotics, 3D visualization and image-guided instrumentation.

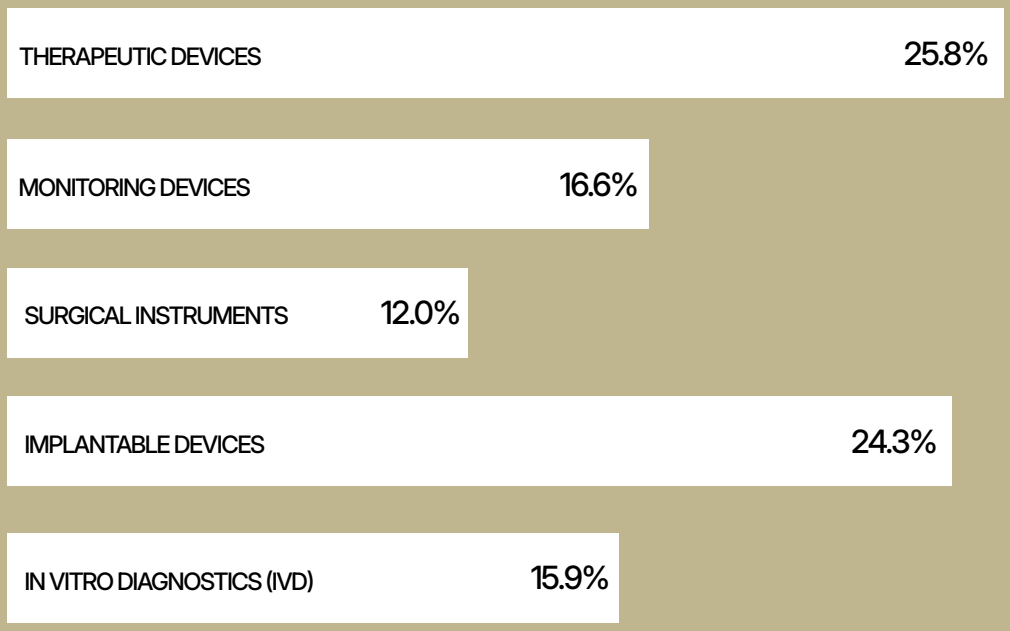
In 2024, the segmentation of the global medical devices market, illustrated in the table below[15], highlights the estimated absolute market value for each segment (in USD billions), the key trends, and highlights of each segment.

SEGMENT	MARKET CAP (US$ BILLION)	HIGHLIGHTS & TRENDS
IN VITRO DIAGNOSTICS (IVD)	86	High demand for fast and accurate testing
THERAPEUTIC DEVICES	140	Advances in minimally invasive treatments
MONITORING DEVICES	90	Growth driven by wearable technologies
SURGICAL INSTRUMENTS	65	Innovations in robotic and laparoscopic surgery
IMPLANTABLE DEVICES	132	Growing Demand for Prosthetics and Stents

15 Prepared by the authors based on data from Fortune Business Insights (Medical Devices Market Report 2024); Market Data Forecast (Medical Devices Market); GM Insights (Implantable Medical Devices Market); GlobeNewswire (Medical Devices Market Statistics 2024) and Mordor Intelligence (Global Medical Device Technologies Market Industry).

As discussed, the global market has two prominent segments, with relatively balanced market shares in 2024, as illustrated in the figure below.

% BY SEGMENT OF GLOBAL MARKET - 2024



- Therapeutic Devices, which represent 25.8% of the market, and
- Implantable Devices, with 24.3%.

These segments are driven by structural factors such as the aging population, the increasing prevalence of chronic diseases, and the growing demand for minimally invasive procedures and advanced implant technologies. In addition, the segment benefits from progress in regenerative medicine and the integration between biomedical engineering and artificial intelligence.

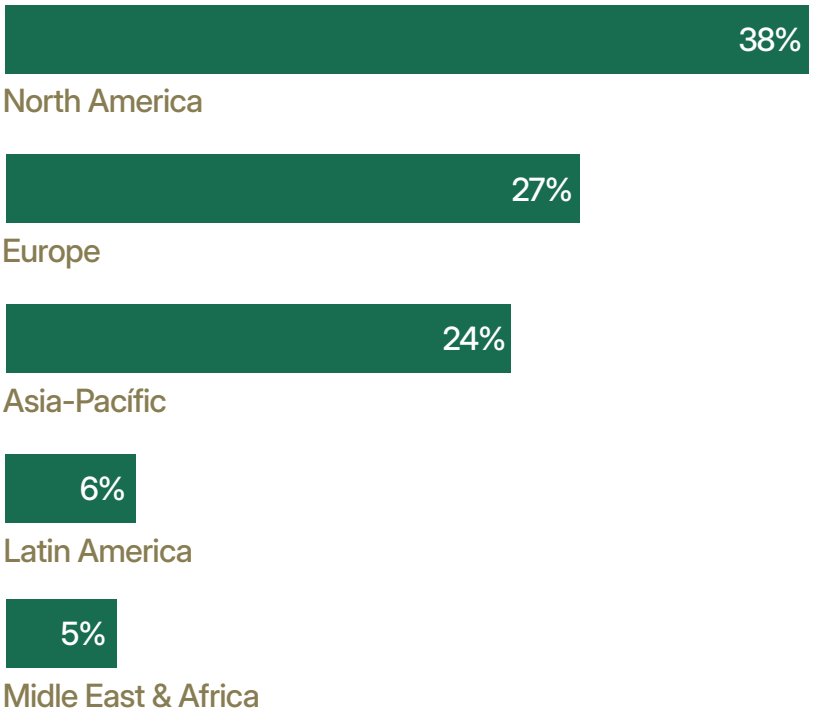
The In Vitro Diagnostics (IVD) **segment**, with 15.9%, also has a strong representativeness, reflecting the growing importance of rapid laboratory tests and personalized medicine. **Monitoring Devices** (16.6%) appear as a fast-growing sector, supported by the expansion of wearable devices and the integration of Internet of Things (IoT) technologies. In particular, growth in this market is being accelerated by the adoption of wearable technologies and smart sensors, with strong interface with *big data*, *analytics*, and clinical data interoperability.

Finally, **Surgical Instruments** accounted for 12% of the market in 2024, supported by advances in robotic surgery and less invasive techniques.

Strategic implications: This segmented evolution indicates that companies and countries seeking greater global relevance will need to align their productive and innovative capacities with areas of high technological intensity and added value. It also reinforces the need to foster public policies that support the digitalization of health and the development of multidisciplinary talent, combining engineering, life sciences, and data science. For Brazil, this segmentation may guide to identify priority areas for national investment, whether via technology parks, tax incentives or international partnerships.

REGIONAL SHARE IN THE GLOBAL MARKET (2024)[16]

As mentioned, North America continues to hold the largest share across the different regions in the global market in 2024, reflecting sustained investments in innovation. On the other hand, Asia-Pacific shows strong growth driven by emerging demand. The figure below illustrates the percentages of each region's global market share.



TOP MANUFACTURING COUNTRIES 2024:[17]

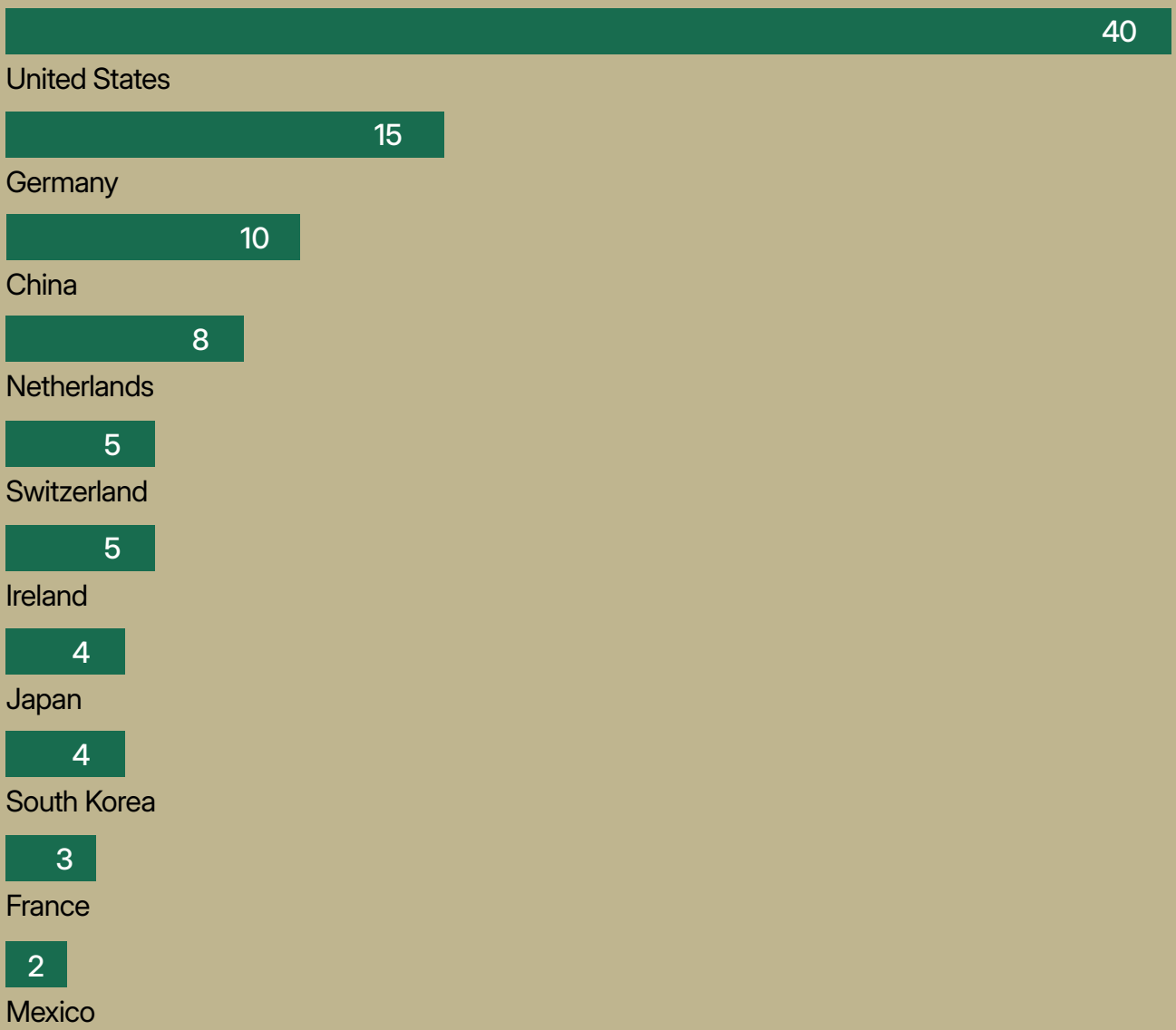
The global concentration of the productive and technological capacity of the medical device sector is still a striking feature of the sector. The **United States** leads global manufacturing, with about 40% of total production, driven by a robust innovation ecosystem, advanced industrial infrastructure and the presence of global leaders such as Medtronic, Johnson & Johnson and Abbott. **Germany**, with 15%, stands out as the most relevant European hub. The country is recognized for its excellence in engineering and diagnostic imaging technologies, represented by players such as Siemens Healthineers and B. Braun.

China occupies the third position, with 10% share, reflecting the fastest rise as a global manufacturer, especially in categories such as basic equipment, monitoring, and low- to medium-value-added devices, with companies such as Mindray gaining an international presence. **The Netherlands** (8%) and **Switzerland** (5%) complete the ranking, both with a strong focus on high-tech segments — Philips, in the Netherlands, is a reference in diagnostic imaging and critical care, while Switzerland is home to leading companies *in vitro* diagnostics, such as Roche.

16 Fortune Business Insights / Mordor Intelligence (2024)
17 Ibid.

The figure below[18] reinforces that, although new regions are emerging, the global leadership of MedTech production still resides strongly in traditional innovation and quality hubs, which combine production scale with investment in research and development.

TOP 10 MANUFACTURING COUNTRIES (%)

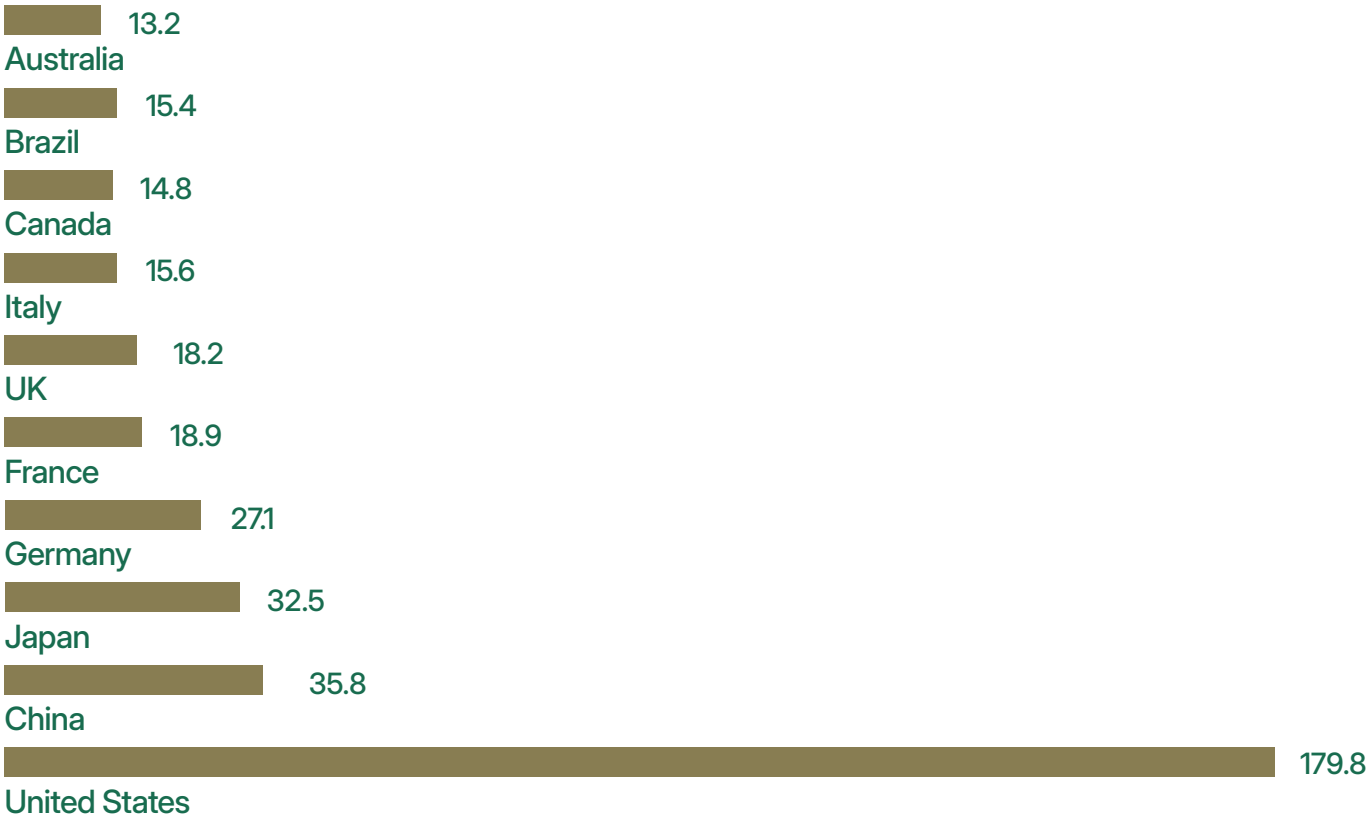


18 Fortune Business Insights / Statista / MedTech Europe (2024)

MAIN CONSUMER COUNTRIES[19]

- **United States:** Largest consumer market, with estimated sales of $179.80 billion in 2024.
- **China:** Third largest global market, accounting for 6.6% of the world market.
- **Japan:** Mature market with high demand for advanced technologies.
- **Germany:** Main market in Europe, with strong demand for high-quality devices.
- **Brazil**: Largest market in Latin America, followed by Mexico, Colombia and Argentina.

TOP 10 CONSUMER COUNTRIES (US$ BILLION)



19 Pharmachoices, Op.Cit. 2024. ElectroIQ. Medical Devices Statistics by Market Share and Revenue. 2024. Available at: https://electroiq.com/stats/medical-devices-statistics/?utm _ source. Accessed on 06/02/2025.

North America, in addition to being the world's largest producer, remains the largest consumer market in almost all segments, leading especially in Monitoring Devices (45%) and In Vitro Diagnostics (IVD) (40%), which reflects the penetration of connected and personalized technologies.

Europe maintains a strong position in Surgical Instruments (26%) and implantable instruments (25%), in line with its track record of excellence in biomedical engineering and robotic surgery. Asia-Pacific appears as the region with the most dynamic growth, with a significant share in Implantable Devices (29%) and Surgical Instruments (28%), driven by the expansion of health coverage and increased investment in hospital infrastructure in countries such as China, Japan and South Korea.

In emerging regions, such as Latin America and the Middle East and Africa, consumption remains more concentrated in basic and essential segments, such as IVD and Therapeutic Devices, but these regions represent a frontier of future growth as their economies and healthcare systems develop. Taken together, the table below compares consumption patterns by region and segment in 2024[20], highlighting not only the current global demand profile, but also regional opportunities for strategic expansion across segments.

SEGMENT	NORTH AMERICA (%)	EUROPE (%)	ASIA PACIFIC (%)	LATIN AMERICA (%)	ORIENTE MÉDIO MIDDLE EAST AND AFRICA (%)
IN VITRO DIAGNOSTICS (IVD)	40	25	23	7	5
THERAPEUTIC DEVICES	42	23	24	6	5
MONITORING DEVICES	45	22	25	5	3
SURGICAL INSTRUMENTS	38	26	28	5	3
IMPLANTABLE DEVICES	39	25	29	4	3

20 Source: Prepared by the author from data from Fortune Business Insights – Medical Devices Market Report 2024; PharmChoices – Global Medical Device Market Size, GlobalData and Mordor Intelligence.

LEADING COUNTRIES IN TECHNOLOGICAL INNOVATION[21]

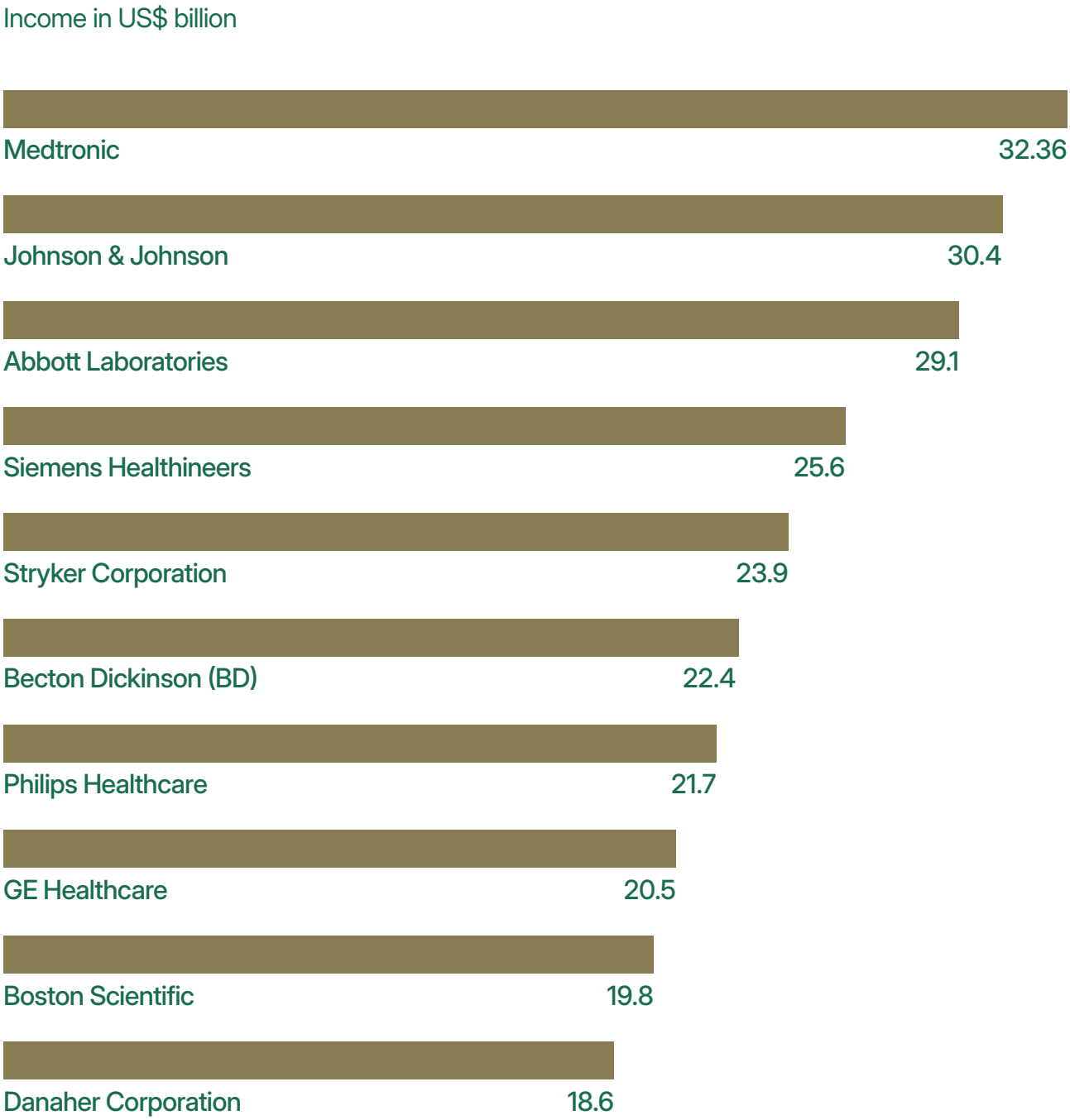
- **United States:** global leader in the sector, with large production centers in California (concentrates many medical technology and research companies, with proximity to universities and health centers), Minnesota (a region called "Medical Alley", historically central in the production of medical devices, especially cardiovascular, orthopedics and implantable technologies), Massachusetts (biotechnology center, with strong ties to research and innovation institutions) and other states with a relevant presence, such as Indiana and Pennsylvania, with a background in manufacturing and engineering.[22]
- **Germany:** A unique aspect of Germany's medical device industry is the presence of family-owned businesses located in rural areas, such as Tuttlingen. This city is often referred to as the "World Center of Medical Technology."
- **China:** It is fast becoming a major player in the medical device industry. Although Chinese companies are not yet among the top 15 global leaders in revenue, the country's rapid growth and substantial investments in the sector underscore its growing relevance.
- **Switzerland:** Maintains a strong position in research and development, especially *in vitro* diagnostics. The country is home to important players in the industry, especially in implants and precision instruments.
- **Netherlands:** The country combines specialized manufacturing, research centers, and a business community well suited to the development of technologies applied to health. Eindhoven serves as the core of this ecosystem, hosting high-tech companies, component suppliers and institutes working on biomedical engineering.

21 SHER, Ajer. Leading Medical Device Companies by Country. Alpha Sophia. 06/20/2024. Available at: https://www.alphasophia.com/blog-post/leading-medical-device-companies-by-country?utm _ source. Accessed in: 06/02/2025.

22 Improve Medical. Available at: https://www.improve-medical.net/resources-13/Top-Medical-Device-Manufacturing-Hubs-in-the-United-States?utm _ source. Accessed on 11/26/2025.

TOP MANUFACTURING COMPANIES (2024)

The figures and table below show the largest medical device companies by revenue in 2024.[23]



23 PROD, Donagh Fitzgerald B. and WILSON, Claire. Top Medical Device Companies in the World ranked by sales revenue for 2024. Get Reskilled. May 2024. Available at: https://www.getreskilled.com/medical-device-companies/?utm _ source=chatgpt.com. Accessed in: 06/02/2025

	ENTERPRISE	COUNTRY OF ORIGIN	MAIN SEGMENTS
1	Medtronic	USA	Cardiovascular, neurosurgery, diabetes
2	Johnson & Johnson	USA	Surgery, Orthopedics, Cardiovascular
3	Abbott Laboratories	USA	Diabetes, cardiovascular, diagnosis
4	Siemens Healthineers	Germany	Diagnostic imaging, oncology
5	Stryker Corporation	USA	Orthopedics, neurosurgery, minimally invasive surgery
6	Becton Dickinson (BD)	USA	Diagnostics, Surgical Devices
7	Philips Healthcare	Netherlands	Diagnostic imaging, intensive care
8	GE Healthcare	USA	Diagnostic imaging, critical care
9	Boston Scientific	USA	Cardiovascular, neurology, urology
10	Danaher Corporation	USA	Diagnostics, Life Sciences

EMERGING TRENDS[24]

- **Artificial Intelligence (AI) Integration:** AI is being incorporated into devices to improve diagnoses and personalize treatments, especially in radiology and remote monitoring.
- **Wearable Devices:** The popularity of devices such as continuous glucose monitors (CGMs) continues to expand, with companies such as *Dexcom* and Abbott leading the market.
- **Robotic Surgery:** As mentioned, companies are advancing robot-assisted surgical systems, offering less invasive procedures and faster recovery.

24 Mordor Intelligence. Medical Devices Market Size & Share Analysis - Growth Trends & Forecasts (2025 - 2030). Mordor Intelligence. 2025. Available at: https://www.mordorintelligence.com/industry-reports/global-medical-device-technologies-market-industry?utm _ source. Accessed in: 06/02/2025; EMR Claight. Medical Devices Market Size Analysis - Market Share, Forecast Trends and Outlook Report 2025-2034. EMR Claight. Available at: https://www.expertmarketresearch.com/reports/medical-devices-market?utm _ source. Accessed in: 06/02/2025, GATLIN, Allison. As Diabetes Battle Heats Up, Spotlight Turns to Dexcom, Abbott. Investors Business Daily. Available at: https://www.investors.com/news/technology/dexcom-stock-abbott-stock-diabetes-devices-continuous-glucose-monitors/?utm _ source. Accessed in: 06/02/2025.

3.2 Brazilian Medical Technology Market

EXECUTIVE SUMMARY - BRAZILIAN MEDICAL TECHNOLOGY MARKET

In 2024, the Brazilian medical device market maintained a solid growth rate, reflected in the 19.4% increase in imports, which totaled US$ 8.012 billion, and the 8.7% increase in exports, reaching US$ 852 million (Source: ABIIS, Economic Bulletin Edition 48). The apparent consumption followed the same expansionary trend, reinforcing Brazil's position as the largest market in Latin America.

Brazilian imports remain concentrated, with the United States (15.3%) and Germany (15.1%) leading as the main suppliers, followed by China, Ireland and Switzerland. These numbers reflect a high Brazilian dependence on advanced technologies produced in traditional hubs, especially in the segments of diagnostic imaging, implantable and surgical support materials.

In terms of exports, the United States also stands out as the main destination (22% of total exports), followed by regional and European partners such as Argentina, the Netherlands, Belgium and Colombia. Brazil's export portfolio is still focused on segments of consolidated competitiveness, such as orthopedic prostheses, dental products and surgical support materials.

The Brazilian sector currently employs 149,955 professionals directly in manufacturing and 301,677 in diagnostic and therapeutic complementation services, consolidating itself as an important generator of qualified jobs.

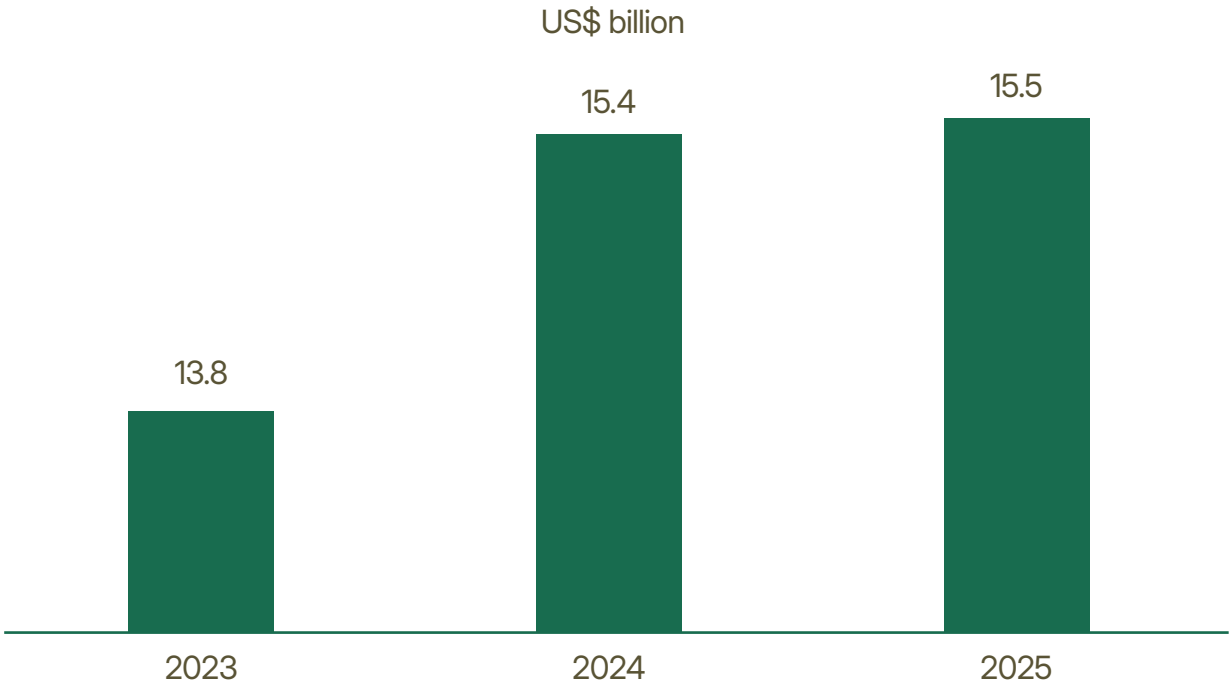
Opportunities for Brazil include the potential to attract new investments in local manufacturing, taking advantage of the reconfiguration of global supply chains and the impact of new U.S. tariff policies, which open space for alternative suppliers. There is also significant growth potential in connected devices, remote monitoring, and *in vitro* diagnostic segments, in line with global healthcare digitalization trends.

Key risks include exposure to redirected trade flows (especially from China and Europe), the need for regulatory modernization and persistent structural challenges related to industrial competitiveness. Overcoming these barriers will be essential for Brazil to move towards a more strategic and integrated position in the global medical device market.

The Brazilian medical device market showed a robust performance in 2024, consolidating its position as the largest in Latin America and recording significant growth compared to 2023.

MARKET SIZE AND GROWTH[25]

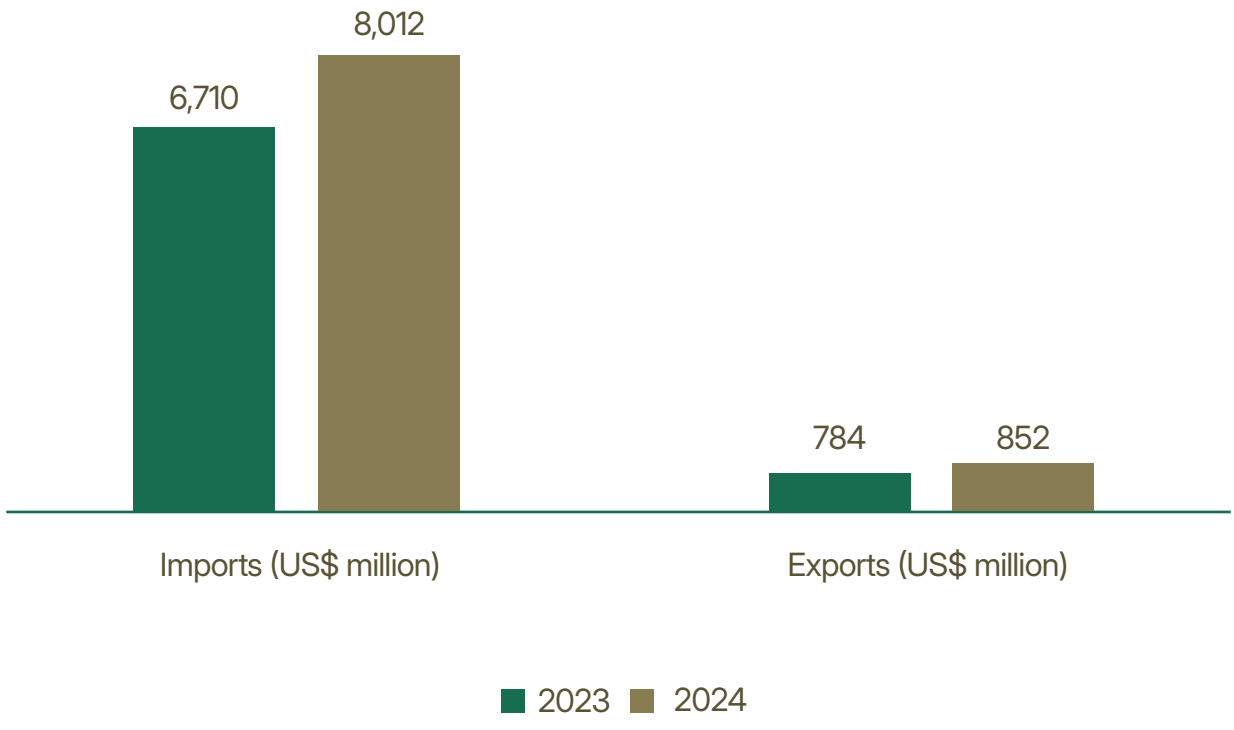
- **Market Value:** In 2024, the Brazilian medical device market was estimated at approximately $15.4 billion, accounting for around 2.5% of the global market.
- **Annual Growth:** Market growth reached 11.5% compared to 2023, mainly driven by the segment of reagents and analyzers for *in vitro* diagnostics, which recorded an increase of 28.4%.
- **Projections for 2025:** Apparent consumption is expected to stabilize in 2025, remaining close to US$ 15.5 billion.



25 MEDICINA S/A. Medical devices and in-vitro diagnostics market grew 57.9%. Medicina S/A. Available at: https://medicinasa.com.br/dispositivos-invitro/?utm _ source. Accessed in: 06/02/2025; SANTOS, Juliana. Healthcare sector creates 5,000 jobs and boosts the medical device market. Business Health. 03/20/2025. Available at: https://www.saudebusiness.com/mercado-da-saude/setor-de-saude-cria-5-mil-empregos-e-impulsiona-mercado-de-dispositivos-medicos/?utm _ source. Accessed in: 06/02/2025. ABIMED. The scenario for medical equipment and devices in 2025 should be one of stability, with complex and interconnected challenges. ABIMED. 01/31/2025. Available at: https://abimed.org.br/noticias/cenario-para-equipamentos-e-dispositivos-medicos-em-2025-deve-ser-de-estabilidade-com-desafios-complexos-e-interligados/?utm _ source. Accessed in: 06/02/2025.

FOREIGN TRADE[26]

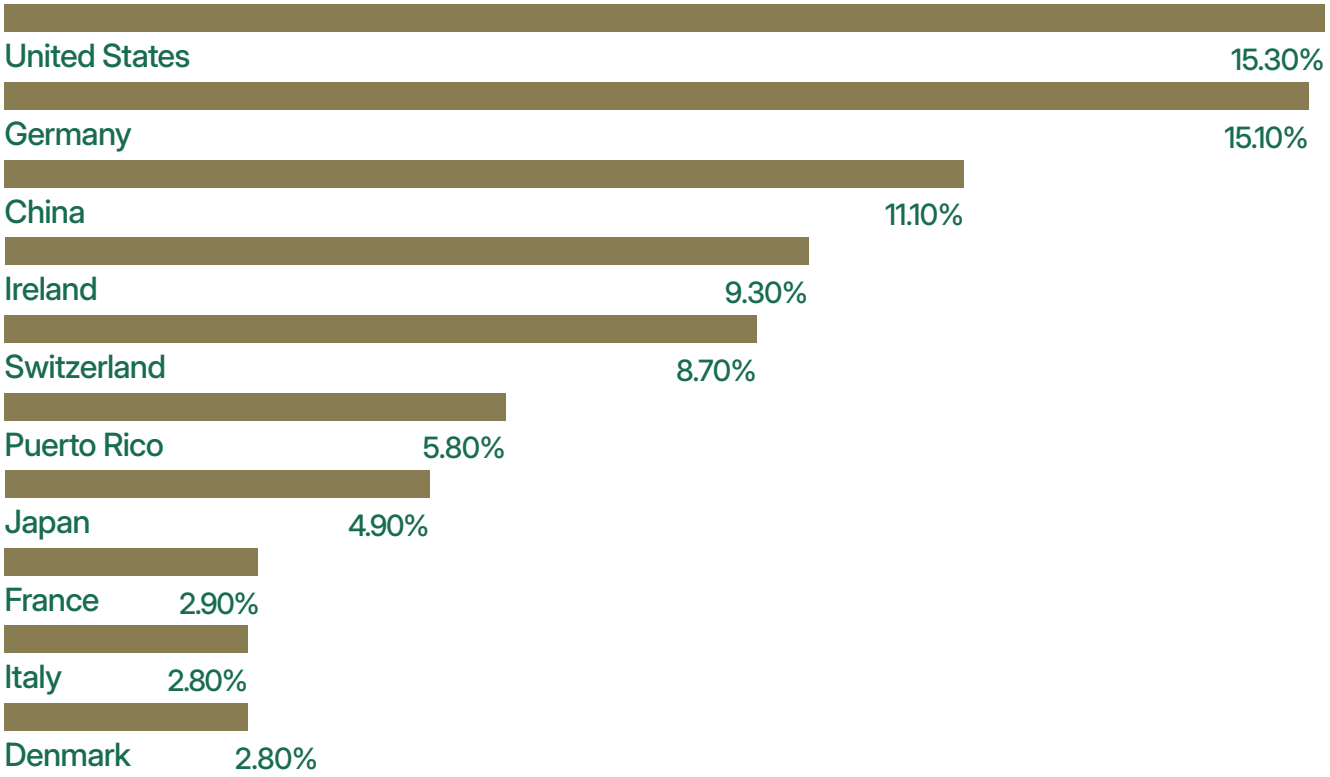
- **Imports:** Brazilian imports of medical devices totaled USD 8.012 billion in 2024, representing an increase of 19.4% compared to 2023 (USD 6.710 billion).
- **Exports:** Brazilian exports of medical devices reached US$ 852 million in 2024, with a growth of 8.7% compared to the previous year (US$ 784 million).



26 Data extracted from the ABIIS Economic Bulletin, Edition 48.

TOP 10 MEDICAL DEVICE EXPORTING COUNTRIES TO BRAZIL (2024)[27]

Brazil's imports continue to be concentrated in a few strategic partners, as illustrated in the figure below.

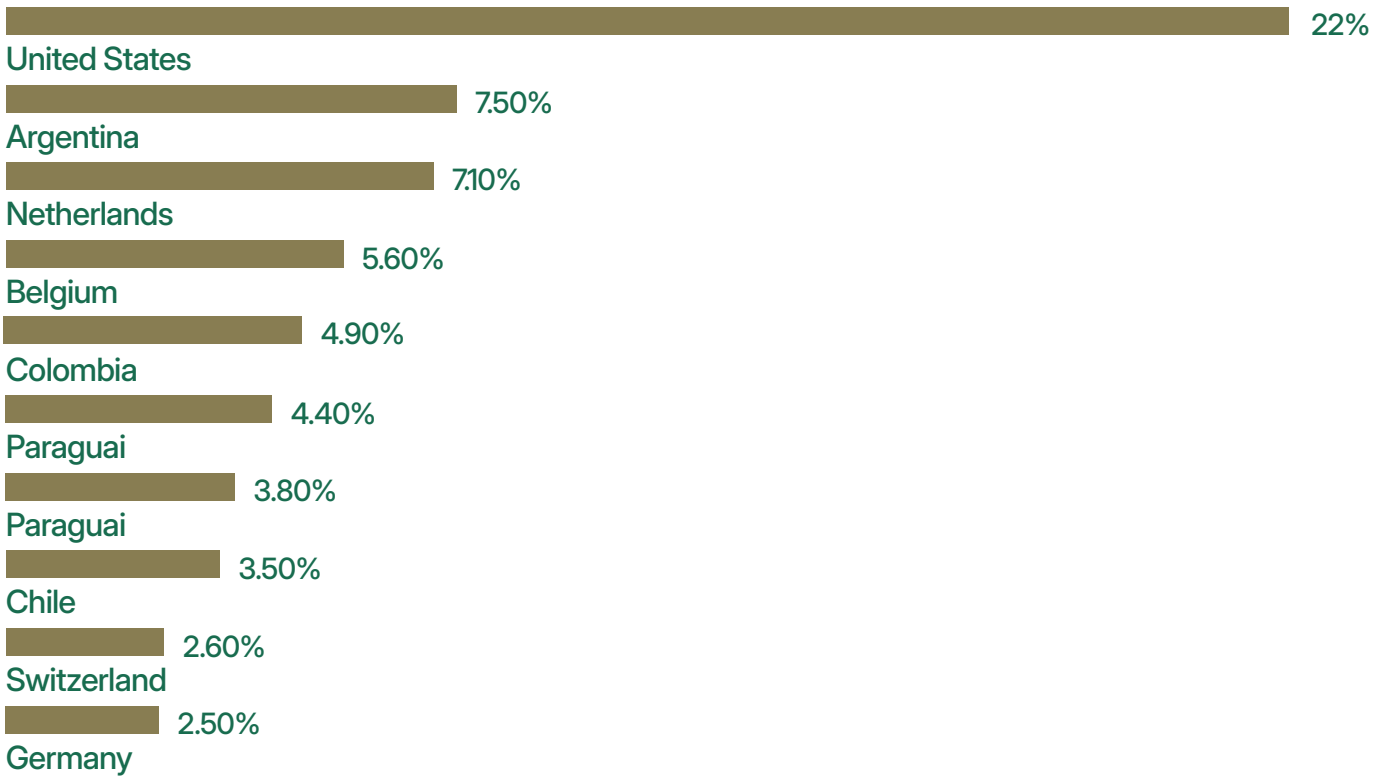


The **United States** (15.3%) and **Germany** (15.1%) share the leading positions, reflecting the Brazilian market's confidence in cutting-edge technologies and internationally recognized quality standards, especially in segments such as diagnostic imaging, prostheses and advanced surgical devices. **China**, with 11.1%, maintains a solid position as a supplier of low- and medium-value-added devices, such as personal protective equipment (PPE), monitoring, and basic devices for hospital use — a role that was expanded during and after the pandemic.

Ireland (9.3%) and **Switzerland** (8.7%) also stand out as key exporters of specific technologies: Ireland, with a strong presence in cardiovascular and therapeutic devices, and Switzerland, with leadership in *in vitro* diagnostics. Markets such as **Puerto Rico**, **Japan**, **France**, **Italy** and **Denmark** complete the ranking, evidencing the diversified yet still highly concentrated nature of Brazil's import agenda. The distribution of suppliers also highlights Brazil's significant dependence on products of extra-regional origin, which raises a strategic alert for the need to strengthen local industry and to diversify international partners, especially in light of potential logistical or trade disruptions.

27 Ibid.

TOP 10 DESTINATIONS FOR BRAZILIAN MEDICAL DEVICE EXPORTS (2024)



The **United States** continues to be the main market and priority destination for the national industry, absorbing 22.0% of Brazilian exports in the sector in 2024 (Figure above).

The presence of the USA as the main market demonstrates the competitive capacity of certain niches of Brazilian production, such as orthopedic devices, surgical support materials and dental products, segments in which Brazil has developed quality and cost differentials. In second place, **Argentina** (7.5%) reflects the natural trade integration of the Southern Cone, followed by the **Netherlands** (7.1%) and **Belgium** (5.6%), which function not only as final markets, but also as *logistical hubs for redistribution to other European markets*.

The presence of **Colombia**, **Mexico**, **Paraguay** and **Chile** reinforces the strategic role of Latin America as a relevant and growing destination for the Brazilian medical device industry. At the same time, the inclusion of Switzerland and Germany among the top 10 destinations points to growing opportunities for penetration in mature markets with high regulatory requirements. Taken together, the export profile depicted in the figure reveals diversified structure, with regional concentration in the Americas and gradual expansion into Europe, while also indicating significant room for expansion in Asian markets and the Middle East, regions that remain relatively underexplored by the national industry.

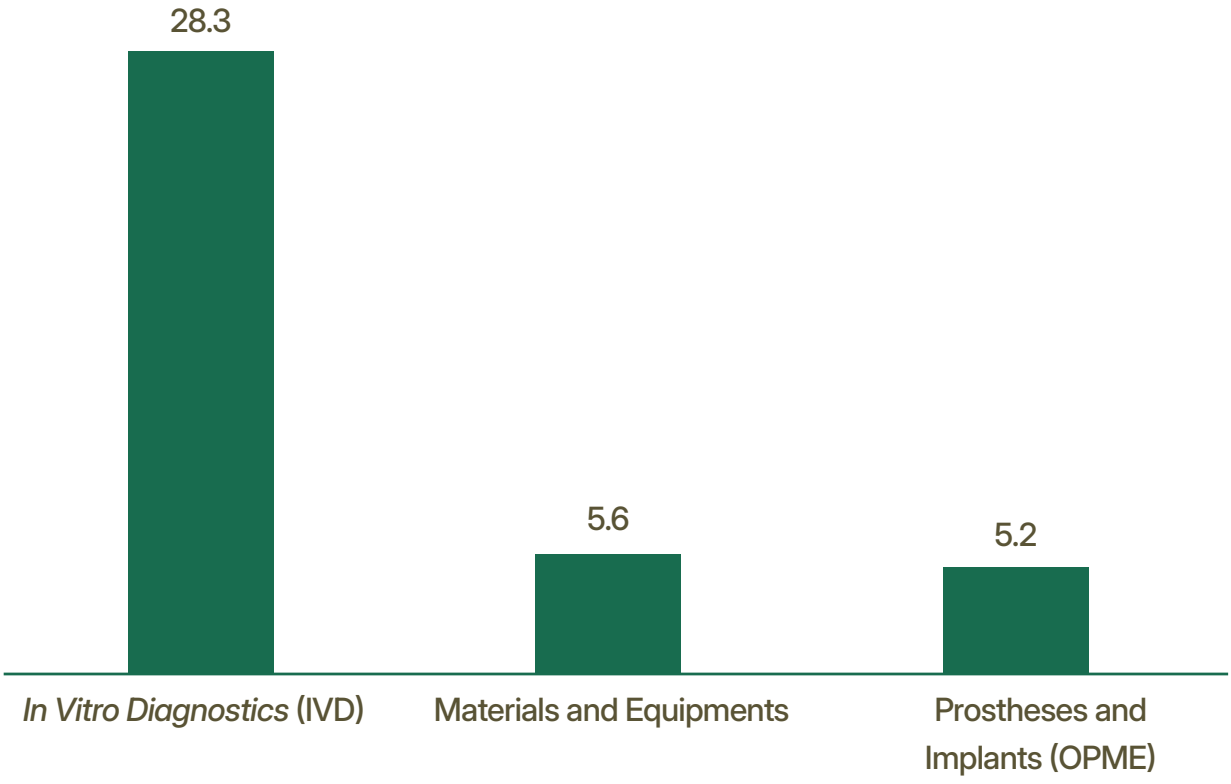
BRAZILIAN MARKET SEGMENTATION[28]

- **In Vitro Diagnostics (IVD):** This segment stood out with a growth of 28.4% in 2024, reflecting the increased demand for rapid and accurate tests.
- **Healthcare Materials and Equipment:** Recorded an increase of 5.6% in 2024, driven by the modernization of hospital infrastructures.
- **Prostheses and Implants (OPME):** This category grew by 5.2% in 2024, in line with the aging of the population and the increase in orthopedic procedures.

GROWTH BY SEGMENT (2024)

When analyzing the growth of medical devices in Brazil by segment, as illustrated in the figure below, the **In Vitro Diagnostics (IVD)** segment stands out, showing a significant expansion of **28%**. This growth reflects the strengthening demand for laboratory tests, rapid diagnostics, and technologies aimed at the prevention and monitoring of chronic and infectious diseases.

In contrast, the **Materials and Equipment and Prosthetics and Implants (OPME)** segments experienced more modest growth, of **5.7%** and **5.2%**, respectively. These figures indicate greater stability and possible saturation or dependence on longer technological renewal cycles. This asymmetry suggests strategic opportunities for investments and innovation, especially in the diagnostic sector, while reinforcing the need for policies to stimulate local production and the adoption of technologies in other segments.



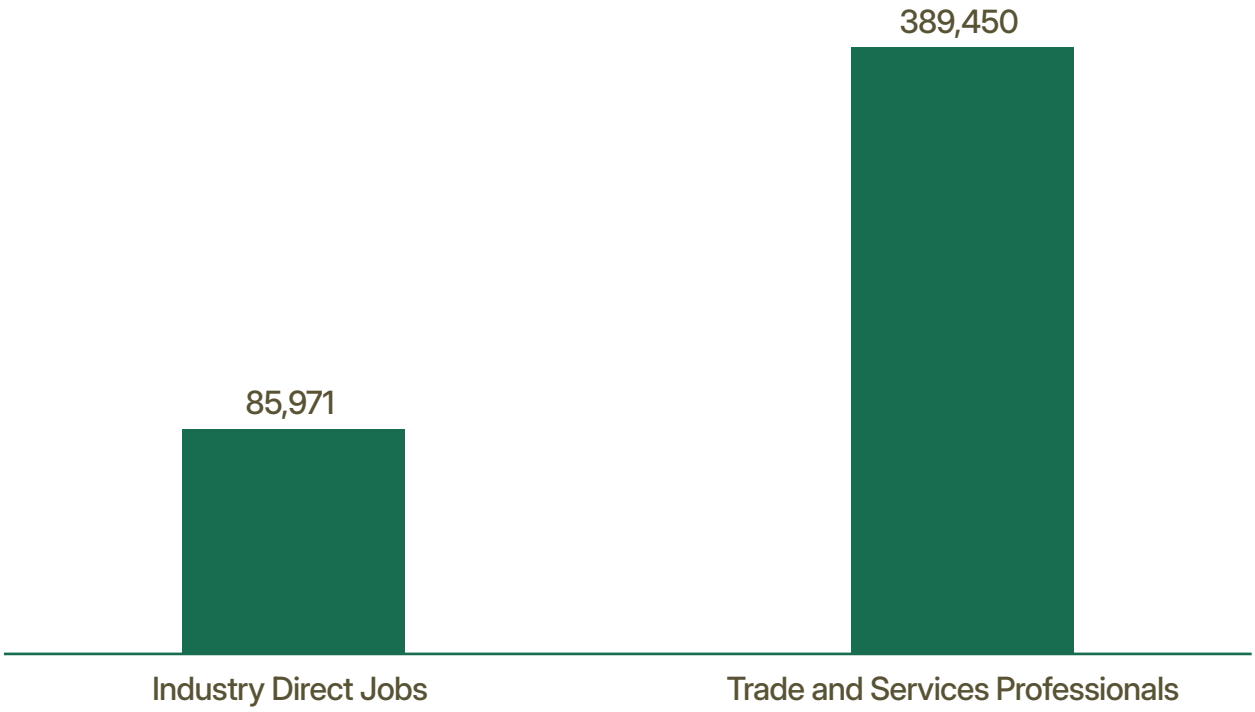
28 Health Business, 2024.

EMPLOYABILITY AND NATIONAL INDUSTRY[29]

In 2024, the Brazilian medical device sector generated:

- 85,971 direct jobs in the medical equipment and devices industry; and
- 389,450 jobs in diagnostic and therapeutic complementation services, including laboratories, clinics and specialized services linked to the sector.

While approximately 85% of the professionals employed in the sector are concentrated in commerce and services activities, only 15% work directly in manufacturing, totaling 85 thousand industrial jobs. This difference shows that, although the production base is relevant, the sector generates more opportunities in activities related to marketing, technical support, logistics, representation and distribution, which serve as the interface between the product and the health system.



This employment profile highlights the potential to expand the industrial base through policies that encourage local manufacturing, which could not only improve the trade balance, but also expand industrial jobs with higher technical qualifications and offering better wage levels. In addition, the high employability in services underscores the importance of the sector as an important vector of professional qualification and economic inclusion, especially in the areas of health, technical sales and specialized service.

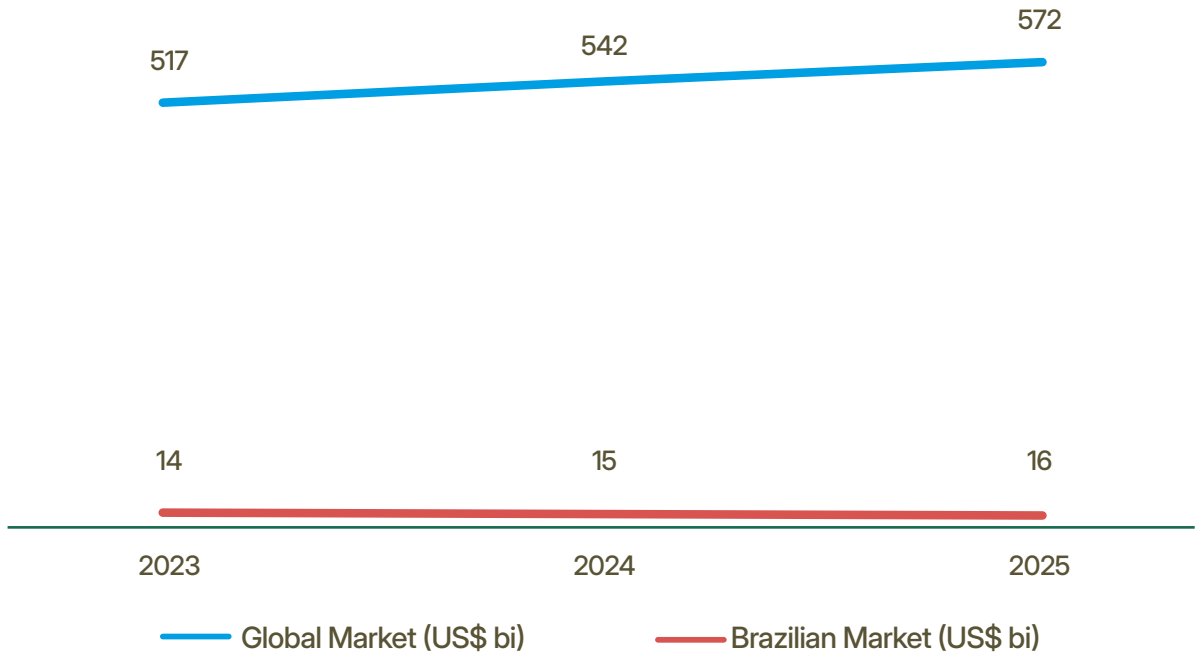
29 ABIIS Economic Bulletin, Issue 48, 2024.

3.3 Prospects for the Future[30]

Despite the growth observed in 2024, 2025 presented a scenario of stability, with the apparent consumption of medical devices remaining close to 2024 levels. Factors such economic challenges and reimbursement policies may influence this outlook in 2026 and international geopolitical difficulties project a next year of resilience. The IMF also revised downward its growth forecast for Brazil in 2026.[31]

COMPARISON OF MARKET EVOLUTION: WORLD X BRAZIL[32]

The figure below shows the growth trajectory of the global medical device market compared to the Brazilian market between 2023 and 2025.



30 ABIMED, *Op. Cit.* .2025.
31 ABIIS (Economic Bulletin – Edition 51 - 2025).
32 Data extracted from Fortune Business Insights, 2024 and ABIIS Economic Bulletin, 48/2024.

While the global market expanded from US$ 517 billion in 2023 to US$ 572.31 billion in 2025 (a consistent growth driven by global trends such as population aging, digital technologies, and innovation in minimally invasive therapies), the Brazilian market followed a more modest but still robust curve. In Brazil, the market grew from US$ 13.8 billion in 2023, to US$ 15.4 billion in 2024 and stabilizing around US$ 15.5 billion in 2025.

Brazil's growth in 2024 (+11.5%) exceeded the global average (~6%), driven by one-off factors such as the high demand for post-pandemic *in vitro* diagnostics and hospital investments. The Brazilian market remained stable in 2025 due to internal economic challenges and limitations in the reimbursement system and public financing, mirroring the global market.

Looking ahead to 2026, there is a challenging international scenario, with tariff increases and the use of economic mechanisms as instruments of political pressure that can hinder the flow of trade in medical devices and, consequently, the Brazilian market. On the other hand, at the domestic level, the use of tax incentives and credit lines, such as those offered by the National Bank for Economic and Social Development (BNDES) and the industrial policy New Industry Brazil (NIB), which foresees investments of R$ 300 billion by 2026, are expected to benefit both the Unified Health System (SUS) and the private sector. The Health Economic-Industrial Complex (CEIS), which seeks to increase the national production of medical devices, represents an opportunity to strengthen the production chain and foster technological innovation.[33] These factors may boost the sector in 2026, but there is no guarantee that these incentives will be sufficient to offset the regulatory and fiscal challenges that Brazil continues to face.

33 ABIMED. Available at: https://abimed.org.br/noticias/cenario-para-equipamentos-e-dispositivos-medicos-em-2025-deve-ser-de-estabilidade-com-desafios-complexos-e-interligados/. Accessed on 11/27/2025.

GROWTH BY SEGMENT (BRAZIL VS. WORLD - %)[34]

The percentage growth of the main medical device segments in Brazil and worldwide in 2024 is illustrated in the table below:

SEGMENT	OVERALL GROWTH (%)	GROWTH BRAZIL (%)
In Vitro Diagnostics (IVD)	8.0%	28.4%
Therapeutic Devices	6.5%	5.6%
Monitoring Devices	7.5%	7.0%
Surgical Instruments	5.0%	5.2%
Implantable Devices	6.8%	6.0%

- The In Vitro Diagnostics (IVD) segment in Brazil expanded well above the global average, reflecting accelerated investments in rapid tests and the restructuring of the country's laboratory infrastructure.
- In Therapeutic Devices and Surgical Instruments, Brazilian growth was similar to the global trend, signaling a maturing market.
- In Monitoring and Implantable Devices, Brazil follows global trends, but with still unexplored potential — especially in remote monitoring and connected devices (IoT).

34 Data from Fortune Business Insights; ABIMED; Saúde Business and GM Insights.

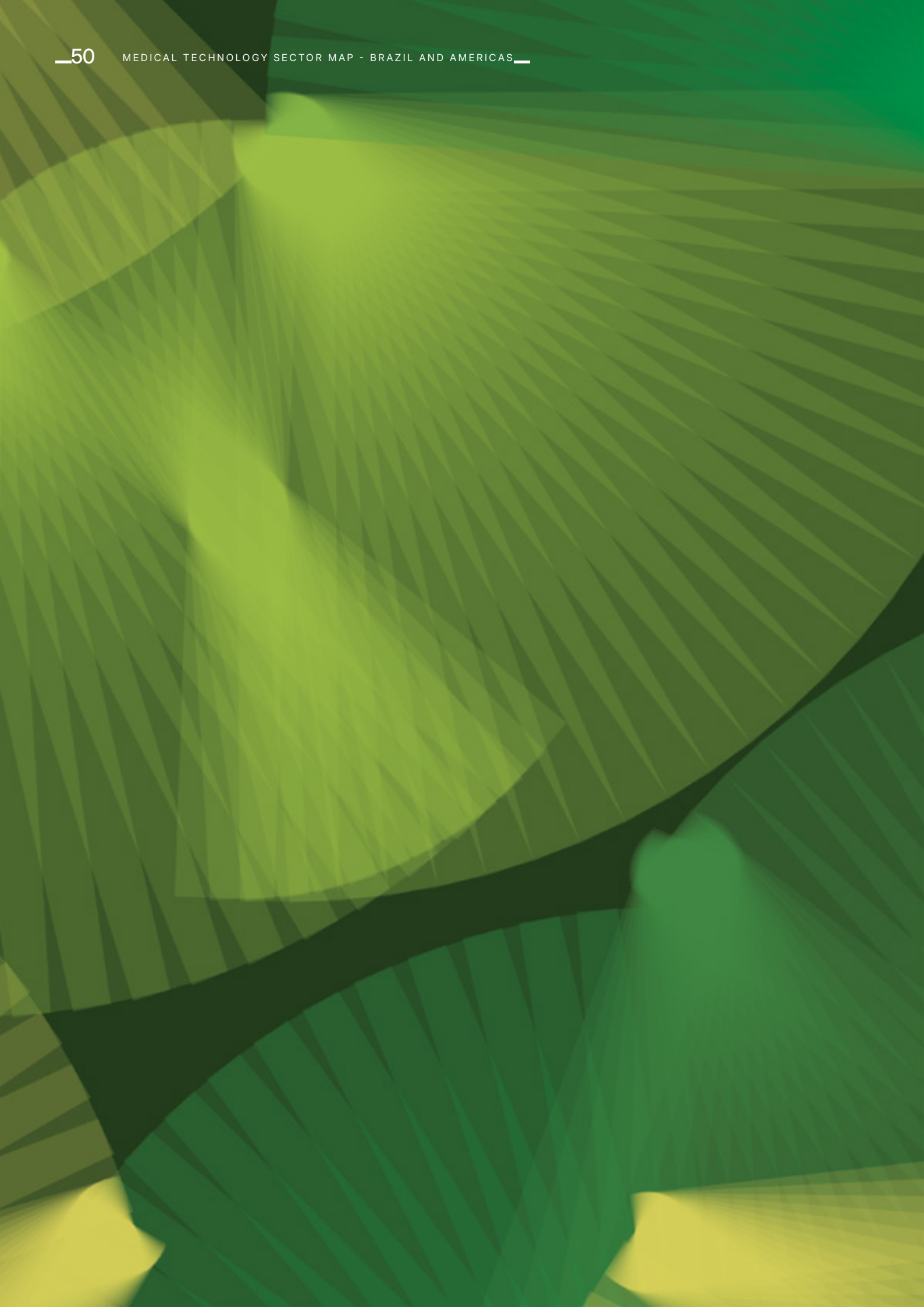
Brazil demonstrates strong performance in niches such as *in vitro* diagnostics, while still seeking alignment with global growth in more advanced technologies (robotics, AI, connected devices). This indicates both investment opportunities and the need for public policies to encourage innovation to bring the country closer to global leaders in medical devices.

RISKS AND OPPORTUNITIES

For Brazil, the opportunities lie in the ability to position itself as an alternative production hub amid the current reconfiguration of global supply chains, especially in the context of new U.S. tariff policies affecting traditional suppliers in China and Europe. There is also space to strengthen exports of segments such as *in vitro* diagnostics, orthopedic prostheses and remote monitoring, niches in which the country already has growing industrial skills. The growing domestic demand for connected devices creates new avenues for market expansion.

On the other hand, risks for the Brazilian sector include the possibility of an increase in domestic competition, due to the redirection of global surpluses, mainly of Chinese and European manufacturers affected by the US trade measures.

In addition, structural challenges persist, such as regulatory bureaucracy, limited production scale in highly complex segments, and the need for investments in innovation and digitalization to compete with global players. To capture emerging opportunities and mitigate these risks, Brazil will need advance articulated industrial policies, stimulate RD&I in the health sector, and build a more agile regulatory environment that converges with international standards.



Medical Device Regulation

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4. Medical Device Regulation

The primary objective of product regulation is the protection of public health. Through it, the population has access to safe medical devices with adequate performance, promoting better public health outcomes[35]. While indispensable, regulation should not inhibit innovation or create unnecessary barriers to trade, investment, or economic efficiency. To this end, it is essential to adopt a globally harmonized approach, capable of eliminating redundant requirements that do not contribute to safety and that reduce the cost of commercializing the product.[36]

Product regulation has become increasingly complex due to the globalization of markets, sophistication of technologies, increased complexity of supply chains, and limitations of financial and human resources by national regulatory authorities (NRAs).[37]

In order to strengthen regulatory systems capable of responding to the above-mentioned challenges, WHO has been working on the development of support tools that assist national regulatory authorities in the development of effective and efficient regulatory frameworks, based on good practices and in the promotion of cooperation, convergence and transparency, through networking, work sharing and regulatory trust (regulatory institute known as *Reliance*, as will be seen below).

The figure below highlights recent WHO publications aimed at reinforcing regulatory frameworks in its member countries.

Regulatory Convergence - Documents published by the WHO

Annex 10 - 2021: Reliance Good Practices in Medical Device Regulation: High-Level Principles and Considerations

Annex 11 - 2021: Good Regulatory Practices in the regulation of medical devices

Annex 3 - 2023 - WHO Global Model Regulatory Framework for medical devices, including *in vitro diagnostic medical devices*

2024 - Global Reference Tools for Assessment of National Regulatory Systems Version 2

35 Global atlas of medical devices. Geneva: World Health Organization; 2017.
36 Harmonized Medical Device Regulation: Need, Challenges, and Risks of not Harmonizing the Regulation in AsiaA Kaushik, KS Saini,1 B Anil, and S Rambabu
37 OMS – Training Materials developed by WHO PPT 2023

Among them, the document "Reliance Good Practices in the Regulation of Medical Devices: High-Level Principles and Considerations" stands out for promoting international cooperation between authorities through *Reliance*. This approach enables more efficient regulation while reducing duplicative efforts.

Reliance is defined as the "act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments, and information of others."[38]

In addition to Brazil, several countries have adhered to the use of *Reliance* as a strategy to address their regulatory challenges.

The countries below consider in their analysis's evaluations carried out by other authorities.

COUNTRIES THAT USE *RELIANCE*

COUNTRY	RNA	RECOGNIZED AUTHORITIES
BRAZIL	ANVISA	TGA – Australia Health Canada – Canada MHLW - Japan US FDA – United States
AUSTRALIA	*Therapeutic Goods Administration* - TGA	Health Canada – Canada European Union MHLW and PMDA - Japan HSA – Singapore OMG
MEXICO	*Comisión Federal para la Protección contra Riesgos Sanitarios* COFEPRIS	Members of the IMDRF Steering Committee, including but not limited to: TGA - Australia ANVISA – Brazil Health Canada: Canada NMPA – China FDA – United States PMDA – Japan HSA – Singapore and Members of the Council of Regulatory Authorities (RAC) for Good Manufacturing Practices (TGA, ANVISA, Health Canada, PMDA and FDA)
SINGAPORE	*Health Science Authority* - HSA	TGA – Australia Health Canada – Canada MHLW - Japan European Union US FDA – United States
THAILAND	*Thailand Food and Drug Administration* THAI FDA	HSA - Singapore

Source: Prepared by the authors[39]

38 TRS 1033 - Annex 10: Good *reliance* practices in the regulation of medical products: high level principles and considerations - Annex 10, WHO Technical Report Series, No.1033, 2021

39 HSA's regulatory journey & Regulatory Reliance Singapore Experience; ANVISA – IN 290/2024; and Using assessments from comparable overseas regulators for medical devices

One of the examples of the application of Reliance is the Single Audit Program in Health Products known as MDSAP (*Medical Device Single Audit Program*). The Program allows a recognized auditing organization to conduct a single audit of the company, covering medical device manufacturing best practices and regulatory requirements applied by five regulatory authorities:[40]

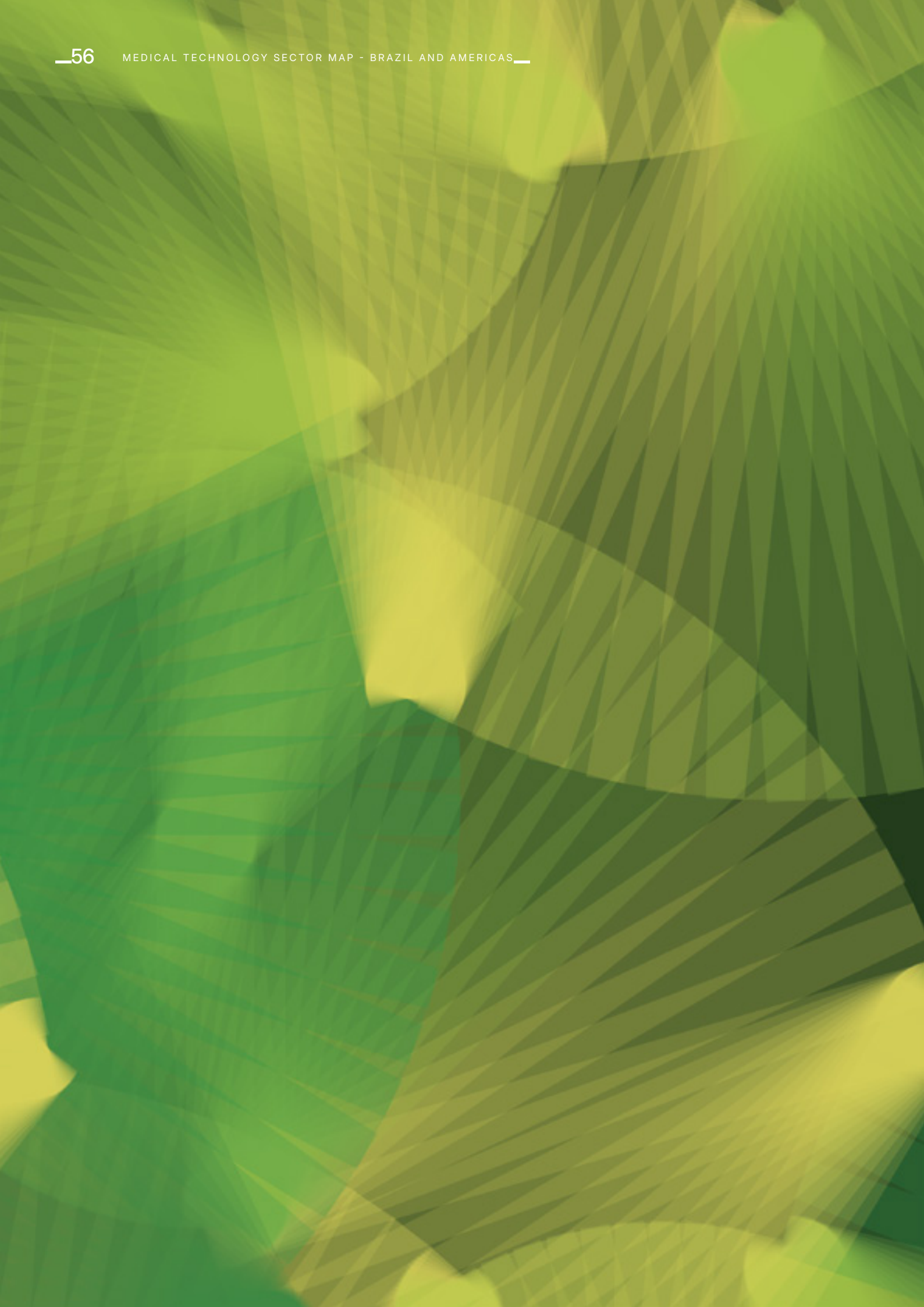
MDSAP AUTHORITIES

AUSTRALIA	Therapeutic Goods Administration
BRAZIL	National Health Surveillance Agency
CANADA	Health Canada
UNITED STATES	Food and Drug Administration
JAPAN	Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PDMA)

Among the benefits identified in the use of the program are (i) the reduction of the regulatory burden for the sector, (ii) the more efficient and flexible use of regulatory resources through work sharing and mutual acceptance among regulators, and (iii) the consistency and standardization of practices, increasing the predictability and transparency of regulatory programs.[41]

Another key initiative to promote regulatory convergence is the International Medical Device Regulators Forum (IMDRF). Established in 2011, the IMDRF is a voluntary group of regulatory authorities from different countries that builds on the work previously developed by the *Global Harmonization Task Force* (GHTF). Its activities include the development of technical consensus documents, addressing topics relevant to the sector and supporting regulatory convergence. The degree of incorporation of these documents into the regulatory frameworks of member countries is one of the indicators monitored by the Forum.

40 MDSAP Medical Device Single Audit Program - About
41 MDSAP Medical Device Single Audit Program – Benefits and Use



Medical Device Regulation in Brazil

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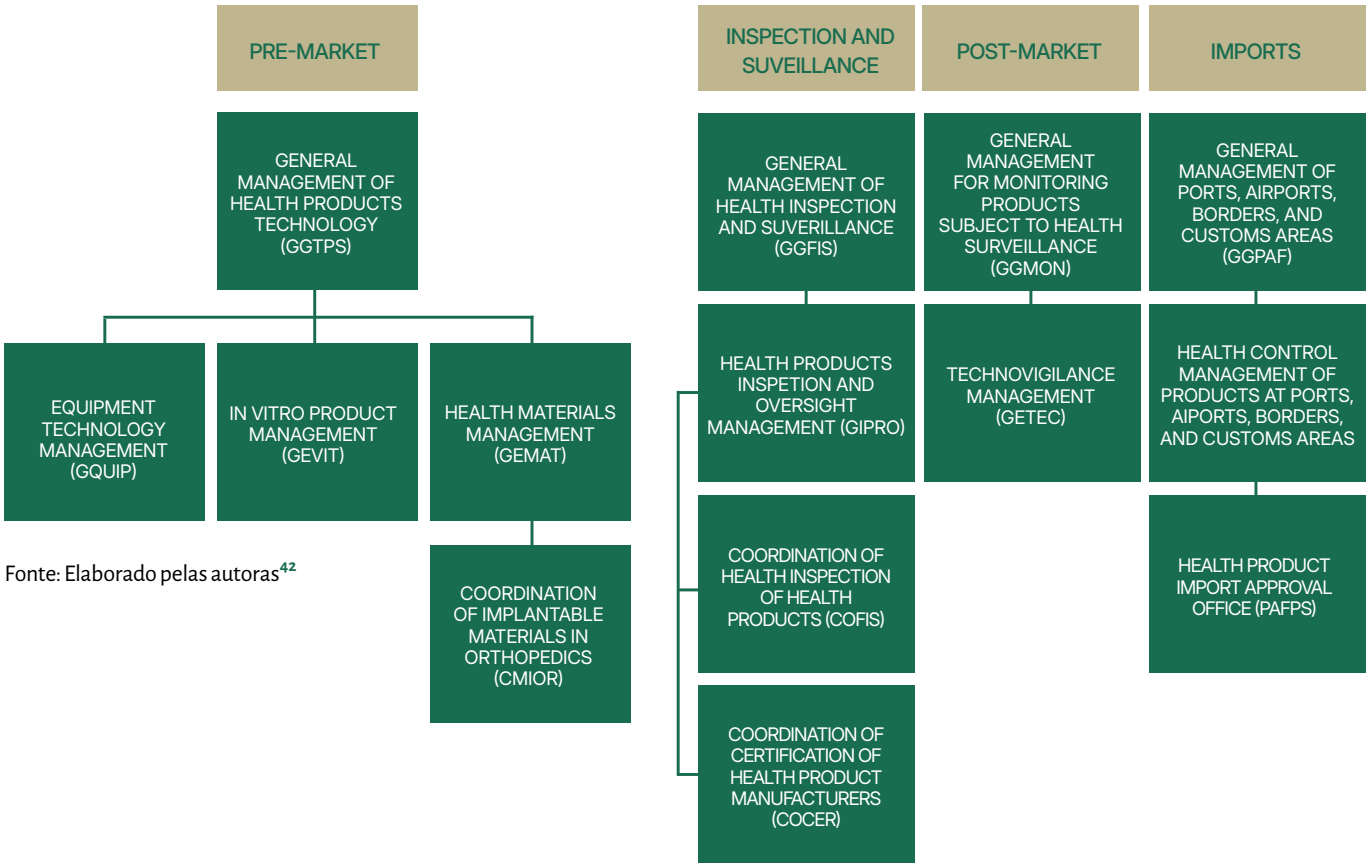
5. Medical Device Regulation in Brazil

ANVISA

The National Health Surveillance Agency - ANVISA, created in 1999 by Law No. 9,782, is the authority responsible for the sanitary control of medical devices, including *in vitro* diagnostic medical devices.

Regulatory activities throughout the life cycle of these products are conducted by four General Managements units. These units are responsible for pre-market evaluation, inspection and inspection of production processes, post-market surveillance and monitoring, in addition to the regulation of import processes, as illustrated by the figure below.



Fonte: Elaborado pelas autoras[42]

Although the sanitary control of medical devices involves different activities, this publication focuses specifically on pre-market control of these products, highlighting key opportunities and challenges.

42 ANVISA – Who's Who

GENERAL MANAGEMENT OF HEALTH PRODUCTS TECHNOLOGY – GGTPS

GGTPS is the area responsible for the pre-market control of medical devices, which includes the registration of higher-risk products and the notification of low and medium-risk products, as well as product changes, revalidations and cancellations.

The evaluation of the product safety and performance is carried out by three Managements units, organized according to the products' characteristics, and the Coordination of Clinical Research in Health Products (CPPRO), is responsible for supporting the three Managements units in topics related to clinical research.

EQUIPMENT TECHNOLOGY MANAGEMENT (GQUIP)	IN VITRO DIAGNOSTIC PRODUCT MANAGEMENT (GEVIT)	HEALTH MATERIALS MANAGEMENT (GEMAT)
Healthcare equipment, medical software, and accessories, such as MRI machines, CT scanners, X-ray machines, multiparameter monitors, pacemakers, oximeters, diagnostic imaging software, and software for physiological, mental, and emotional measurements, among others.	Products used to provide information from samples taken from the human body, such as: HIV self-tests, pregnancy tests, blood typing tests, laboratory equipment such as automated analyzers, among others.	It is the area with the greatest diversity of products, such as gauze, syringes, needles, breast implants, orthopedic implants, heart valves, and surgical sutures, among others.

The preparation of this study is justified by the challenges faced by this area in recent years, especially with regard to the growing demand for product regularization services and the stagnation in the number of GGTPS staff over the past decade. This situation is documented in productivity reports published since 2015.[43] The present analysis addresses factors that directly influence the performance of the area in fulfilling its mission of ensuring the health safety of medical devices, such as regulatory convergence, the use of *Reliance*, human resources and infrastructure constraints, as well as the increase in the volume of submissions.

The study seeks to present data that contributes to the formulation of solutions to a problem that persists over the years.

43 Productivity Reports

REGULATORY CONVERGENCE

ANVISA has been gaining a prominent role in the international medical device scenario, expanding its participation in forums dedicated to regulatory convergence and international cooperation.

As a founding member of the International Medical Device Regulators Forum, ANVISA participates in the organization's Steering Committee, together with authorities from Australia, Canada, China, the European Union, Japan, Russia, Singapore, South Korea, Switzerland, the United Kingdom and the United States. The Joint Committee is responsible for overseeing and all activities of the Forum, including decision-making.

79.3%

Percentage of IMDRF documents fully or partially incorporated into ANVISA's regulations, considering the set of 34 documents listed in the IMDRF Document Implementation Report, updated in September 2025. This indicator highlights the Agency's strong commitment to international regulatory convergence.

Source: IMDRF Implementation Report – September 2025

In addition to IMDRF, ANVISA is also one of the founding authorities of MDSAP and is part of the Regulatory Authority Council (RAC), the program's decision-making body, together with authorities from Australia, Canada, the United States and Japan.

61.2%

It is the percentage of Certificates of Good Manufacturing Practices, issued by ANVISA until the year 2024, based on MDSAP reports.

Source: IMDRF 28th MC Meeting Sapporo- Brazil Update

Another ANVISA initiative related to the use of Reliance concerns the adoption of an optimized procedure for the review and decision-making of applications for registration of medical devices, which takes into account assessments conducted by other regulatory authorities, designated as Equivalent Foreign Regulatory Authority. In 2022, ANVISA published RDC No. 741 establishing the general criteria for the use of *Reliance* across health surveillance processes, favoring the simplification of certain work processes and improving the allocation of available workforce.

In 2024, the GGTPS published Normative Instruction (IN) No. 290 establishing specific requirements for the use of *Reliance* in the review and decision of medical device registration petitions. According to GGTPS, the decision to adopt the use of *Reliance* was driven by: "The volume of petitions in conjunction to the complexity of the documentation (complex and diverse studies) for analysis, as well as the increase in external demands, and the persistent human resources constrains, all of which have been a constant challenge, extending the timelines for completion of the analyses."[44] The IN establishes that the optimized analysis procedure my rely on information from marketing authorizations from Australia (TGA), Canada (Health Canada), the United States (US FDA) and Japan (MHLW).

According to data from ANVISA, between June 2024 and May 2025, only 16.26% of registration applications in Brazil used the *Reliance mechanism*[45]. This proportion is expected to, similar to the increase observed with the adoption of MDSAP since the beginning of the program in 2017.

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44 Webinar Normative Instruction (IN) No. 290, of April 4, 2024 Main questions about the analysis of petitions for regularization of medical devices with the use of analyses by known regulatory authorities.

45 Regulatory Journey – Hospitalar 2025 – Reliance – Adhesion, approvals – rejections

HUMAN RESOURCES

According to data from Brazil's Transparency Portal[46], ANVISA's workforce comprises 1,689 professionals, including permanent staff, personnel seconded from other public agencies and interns. Among these, 113 professionals work directly in activities related to medical devices, distributed across different General Management units responsible for the sanitary control of these products. The GGTPS workforce is composed of 48 staff members, distributed as shown in the table below:

POSITION	GGTPS	CPCPS	GQUIP	GEVIT	GEMAT	CMIOR
VISA Specialist	2	1	8	7	9	6
Technical Administrative	4		1	1	1	1
Technician in Regulation and Sanitary Surveillance	1		1	1	4	

Source: Transparency Portal - accessed on 07/18/2025

From the staff list above, two are on leave, reducing the number of active civil servants to 46. The unit is also supported by 13 interns distributed across GGTPS (6), GEMAT (6) and GQUIP (1).

46 Transparency Portal – accessed on 07/18/2025

Overall staffing levels have remained practically unchanged in relation to that observed in 2015, as shown in the table below.

POSITION	GGTPS	GQUIP	GEVIT	GEMAT
VISA Specialist	3	8	7	15
Administrative Technician	2	1	1	1
Technician in Regulation and Sanitary Surveillance		2	1	6

Source: Productivity Report – 2015 - ANVISA

48

Number of GGTPS servers in 2024, 1 more when compared to the workforce in 2015.

112

Workforce sizing carried out by ANVISA in 2016..

In 2016, ANVISA conducted a workforce assessment study, considering the activities in place at the time. The analysis identified the need to expand staffing by 67 additional servers, resulting in a total requirement of 112 professionals dedicated to activities related to the regularization of products[47].

The shortage of human resources at GGTPS is a structural bottleneck for the institution, compromising the agility and predictability of regulatory processes, which can negatively impact the population's access to innovative technologies and essential medical devices.

THE DEFICIT OF SERVERS AFFECTS THE ENTIRE AGENCY

In 2021, a workforce assessment conducted by the General Management of Personnel Management (GGPES), highlighted the need to recompose ANVISA's staff of civil servants. In 2007, the Agency had a total of 2,360 employees. By 2021, this number had declined to 1,658, representing a reduction of 30% in its workforce.[48]

In 2023, ABIIS and 15 other health associations submitted a manifesto in favor of increasing the number of vacancies to rebuild the Agency's workforce. At that time, a public tender was authorized, but with only 50 vacancies.[49]

In 2025, in a statement published on ANVISA's website to mark its 25th anniversary, the agency drew attention to the staff attrition: "In 2007, the Agency had about 2.7 thousand employees. Today, there are only 1.5 thousand."[50]

Also in 2025, the federal government published Provisional Measure No. 1,301/2025 creating 129 new positions for specialists in health regulation and surveillance, and Ordinance 4,366/2025 created 14 vacancies for technicians, health regulation and surveillance. It is expected that the GGTPS will receive a significant share of new professionals, reducing the workload and pressures resulting from the staff shortages and enabling the institutional strengthening of the Agency.

PRE-MARKET CONTROL

ANVISA's pre-market control is designed to evaluate the safety and performance of medical devices, ensuring that they can be marketed in the country. This evaluation, based on specific standards and procedures, varies according to the level of risk the product represents to the user or to the population.

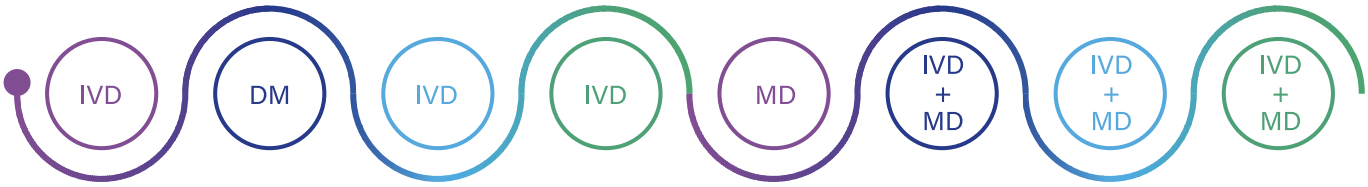
48 Management Report 2021 - ANVISA
49 Abiis - Manifesto calls for an increase in the number of vacancies in public tenders for positions at ANVISA - 2023
50 Learn a little about ANVISA's history, commitments and challenges for the coming years

MEDICAL DEVICE REGULATION

Considering the deficit of staff at GGTPS and the growing demand for product regularization, the regulation of medical devices was subject to several modifications, aimed at simplifying the requirements applicable to the regularization of low- and medium-risk products, allowing the staff to focus on the evaluation of higher-risk products (classes III and IV). Currently, class I and II medical devices are subject to a simplified procedure, known as notification, under which the company informs to ANVISA its intention to market the products, proving its manufacturing and/or import rights. Although the procedure does not involve technical analysis, ANVISA may review the notification at any time if any irregularity is detected.[51] Class III and IV MD are subject to registration.

The figure below illustrates the timeline of the main regulations related to MD regularization.

Timeline - Medical Devices Regulation



Ordinance 8/98

It establishes regulatory requirements applicable indiscriminately to all products, regardless of health risk.

RDC 185/01

Technical requirements for the regulation of health products.

It establishes rules for the classification of products according to health risk.

RDC 206/06

It establishes risk classification for IVD products and a "Cadastro" for class I (low risk) products.

RDC 36/15

It establishes the risk classification of IVD products and the "Cadastro" of class I and II products (low and medium risk.

RDC 40/15

It establishes the "Cadastro" of products risk classes I and II (low and medium risk).

RDC 270/19

It establishes a Notification for class I risk products. The notification exempts technical analysis for product regularization.

RDC 340/20

It establishes procedures for changes to information in the medical device regulatory process.

RDC 423/20

It establishes a Notification for products classes I and II.

51 RDC No. 751 of September 15, 2022 and RDC No. 830 of December 6, 2023

CURRENT REGULATIONS FOR REGULARIZATION OF MEDICAL DEVICES

- RDC No. 751 of 2022 – Establishes harmonized risk classification rules in Mercosur, notification procedures (classes I and II) and registration requirements (classes III and IV), labeling and instructions for use requirements for medical devices.
- RDC No. 830 of 2023 - Establishes harmonized risk classification rules in Mercosur for *in vitro* diagnostic medical devices, including instruments, the notification procedures (classes I and II) and registration requirements (classes III and IV), labeling and instructions for use.

RISK CLASSIFICATION

RDC NO. 751 OF 2022 – MEDICAL DEVICES
PRODUCTS CLASSIFIED ACCORDING TO THE INTRINSIC RISK THEY POSE TO THE HEALTH OF THE USER, PATIENT, OPERATOR OR THIRD PARTIES.

Class I	Low risk
Class II	Medium risk
Class III	High risk
Class IV	Maximum risk

The classification of products into the different classes is based on rules defined by the regulation. RDC No. 751/2022 is the result of the incorporation of MERCOSUR/GMC/RES Resolution No. 25/21 – MERCOSUR Technical Regulation for the Registration of Medical Devices. This regulation is primarily based on the risk classification adopted by Regulation (EU) MDR 2017/745 of the European Union.

RDC NO. 830 OF 2023 – MEDICAL DEVICE FOR IN VITRO DIAGNOSTICS PRODUCTS CLASSIFIED ACCORDING TO THE INTRINSIC RISK THEY POSE TO THE HEALTH OF THE USER, PATIENT OR PUBLIC HEALTH.

Class I	Low risk to the individual and low risk to public health
Class II	Medium risk to the individual and/or low risk to public health
Class III	High risk to the individual and/or medium risk to public health
Class IV	High risk to the individual and high risk to public health

The classification of products into the different classes is based on rules defined by the regulation. RDC No. 751/2022 is the result of the incorporation of Mercosur/GMC/RES Resolution No. 24/21 – Mercosur Technical Regulation for the Registration of Medical Devices for In *Vitro Diagnostics*. This regulation is primarily based on the risk classification adopted by Regulation (EU) MDR 2017/746 of the European Union.

CONFORMITY ASSESSMENT OF MD AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS (EPSP)

According to RDC No. 751/2022, manufacturers and importers must prove the safety and performance of their products through compliance with a specific regulatory requirement established under—RDC 848/2024.

For products classified as risk classes I and II, subject to notification procedure, must keep in their premises a technical dossier including, among other information:

- List of applicable essential safety and performance requirements
- List of technical standards
- Physical and mechanical characterization
- Material characterization
- Biocompatibility assessment, etc.

For products classified as risk classes III and IV, the technical dossier must be submitted to ANVISA together with other documents provided for by the regulation, in order to support Agency's technical evaluation for the granting of registration.

When necessary, ANVISA may request additional information or documents, including the clinical study report specifically designed and conducted for the investigation of the medical device of interest. The structure of the technical dossier is aligned with the IMDRF document IMDRF/RPS WG/N9 (Edition 3) FINAL:2019 - *Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC).*

Certain products, regardless of the risk class, listed by ANVISA in specific regulations, are subject to compulsory third-party certification. In such cases the company must present a Certificate of Conformity issued under the Brazilian Conformity Assessment System (SBAC) by the National Institute of Metrology, Quality and Technology (INMETRO), a topic discussed further below.

- For registration purposes, the compliance of intrauterine devices containing copper, as well as plastic bags intended for the collection, storage and transfer of human blood and its components, must be demonstrated by means of a prior analysis report issued by the National Institute for Quality Control in Health, according to requirements established by specific regulations. For MD IVDs subject to regularization, under RDC No. 830/2023 and according to their risk class, a technical dossier must be submitted to ANVISA containing, among other information, the requirements related to the product safety and performance, such as, list of applicable technical standards; certificate of conformity for instruments subject to compulsory certification under specific regulations; performance studies; stability studies; clinical performance, among others.

  Annex II of the relevant RDC provides a table specifying the documents that must be submitted to ANVISA for product regularization.

  Products intended for dengue diagnosis and tests used for blood screening by blood banks, such as reagents for immunohematology (ABO system, Rh system and irregular antibodies), hepatitis B and C, syphilis, HIV, Chagas disease and HTLV are subject to laboratory analysis, carried out by the National Institute for Quality Control in Health (INCQS). of the Osvaldo Cruz Foundation.

- Medical devices and/or accessories that contain telecommunica-tions modules and whose emissions produce an electromagnetic field, as defined by specifications established by the National Telecommunications Agency (ANATEL), must prove their safety by submitting test reports or an approval certificate issued by the Agency.

ANVISA – INMETRO INTERFACE IN THE CONFORMITY ASSESSMENT OF MEDICAL DEVICES

INMETRO, in partnership with ANVISA, plays a central role in structuring Brazil's medical device conformity assessment system. This collaboration is regulated by the Technical Cooperation Agreement signed through Interministerial Ordinance No. 692/2009, which assigns to ANVISA the responsibility for regulation of medical devices (market authorization, inspection, enforcement and determination of mandatory certification) and to INMETRO the development of conformity assessment schemes.

ANVISA determines which medical devices are subject to compulsory certification, through Resolutions of the Collegiate Board (RDC) or Normative Instructions (IN).

INMETRO is responsible for coordinating conformity assessment activities, developing technical requirements (Conformity Assessment Requirements - RAC), establishing operational guidelines for Product Certification Bodies (OCPs), managing the certification scheme, participating in technical meetings with representatives from ANVISA, the Brazilian Association of Technical Standards (ABNT), testing laboratories, OCPs and industry associations, according to the model established under INMETRO Ordinance No. 321/2010.

In its interaction with OCPs, INMETRO is responsible for publishing clear and up-to-date technical rules, resolving doubts and harmonizing operational understandings in order to mitigate divergent interpretations, train certification bodies and prevent duplication of requirements through the traceability of regulatory requirements.

The Conformity Assessment Programs currently in force are listed in the figure below.

PACIFIERS - INMETRO ORDINANCE No. 301/2021

STERILE AND GINGIVAL HYPODERMIC NEEDLES - INMETRO ORDINANCE No. 84/2021

STERILE HYPODERMIC SYRINGES - INMETRO ORDINANCE No. 458/2021

BABY BOTTLES AND NIPPLES - INMETRO ORDINANCE No. 216/2021

TRANSFUSION AND INFUSION EQUIPMENT - INMETRO ORDINANCE No. 461/2021

ELECTROMEDICAL EQUIPMENT - INMETRO ORDINANCE No. 384/2020

BREAST IMPLANTS - INMETRO ORDINANCE No. 5/2022

MALE CONDOMS - INMETRO ORDINANCE No. 266/2021

INMETRO – APPLICATION OF GOOD REGULATORY PRACTICES

Since the publication of Ordinance No. 30/2022, INMETRO has incorporated guidelines compatible with the current legal system (including Law No. 13,874/2019 and Decrees No. 10,411/2020 and No. 11,092/2022), which require greater transparency, predictability, and technical reasoning in normative acts.

Among the advances already observed are the elaboration of a regulatory agenda, the conduct of public consultations with broad stakeholder engagement, participation in international regulatory harmonization forums and progressive alignment with international standards (e.g. ISO, IEC, etc.) and OECD and WTO guidelines (such as the Agreement on Technical Barriers to Trade – TBT).

Despite these advances, there is room to improve full adherence to instruments such as Regulatory Impact Analysis (RIA), systematic publication of regulatory justifications, and development of Standard Operating Procedure (SOP) for the preparation and review of CAR.

PERSISTENT BOTTLENECKS AND OPPORTUNITIES FOR IMPROVEMENT

Despite the normative advances and the institutional effort for greater transparency and dialogue, critical challenges persist. If addressed in a coordinated manner, these issues could represent a qualitative improvement in the efficiency and legitimacy of the conformity assessment system. Among the main ones:

The systematic application of Good Regulatory Practices (GRP), especially the use of Regulatory Impact Analysis (RIA), as provided for in the current legislation. This instrument can be more consistently applied in the processes of creation and review of CAR for medical devices.

The creation of a Standard Operating Procedure (SOP) aimed at structuring and institutionalizing the regulatory dialogue between INMETRO, ANVISA and the private sector. Such a procedure could overcome the current informality in interactions that allows divergent interpretations of CARs, asymmetric technical decisions between Certification Bodies and the publication of regulations without adequate assessment of technical, economic or operational feasibility.

Currently, the dialogue between regulatory actors (INMETRO and ANVISA) and economic agents occurs in an irregular way and without institutionalization. The absence of structured dialogue mechanisms can undermine the uniformity in the interpretation of the CAR, resulting in asymmetric technical decisions between Certification Bodies, or allows the publication of regulations without a broad assessment of technical, economic or operational feasibility.

There are also concrete opportunities for alignment with international best practices, with special attention to the acceptance of test reports issued by accredited international laboratories, including those operating under schemes such as IECEE – CTF stages 3 and 4, as well as the recognition of MDSAP and ISO13485 as verification instruments compatible with the same objectives of INMETRO's General Product Compliance Regulation.

These practices are not unprecedented and the analysis of international experiences, especially from countries that have already implemented similar measures, can contribute to a review of the practices adopted by Brazil, with a view to increasing the competitiveness of the national industry and facilitating the population's access to safe and innovative technologies.

REGULATORY DEADLINES

Legal deadlines for responding to applications related to the regularization of medical devices are established by RDC No. 743, of 2022.

The table below presents the deadlines applicable to the registration and notification of products.

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PETITION	AREA	TERM
NOTIFICATION – CLASSES I AND II	All	30 days
REGISTRATION – CLASSES III AND IV	Equipment	250 days
	Materials for Use in Health	320 days
	IVD	365 days

Data source: Open Data Portal of the Federal Government - ANVISA[52] - Accessed on 07/19/2025

DEADLINES FOR GRANTING REGISTRATION

Data from class III and IV medical device registrations covering the period from July 2024 to June 2025 were analyzed, disaggregated by *in vitro* diagnostics, medical material, implantable material, and equipment.

- Equipment and materials for medical use: Open Data Portal – Life Cycle of the Analysis of Petitions for Health Products
- In vitro diagnostic device:
  Open Data Portal – Life Cycle of Product Petition Analysis for In Vitro Use

The data below provide information on the number of registrations and the average deadlines practiced for the regularization of medical devices and *in vitro* diagnostic medical devices.

DEADLINES PRACTICED BY ANVISA FOR THE REGISTRATION OF MD AND MD IVDS

The figures below present, on a month-by-month basis for the year 2024, the average time elapsed between the submission of the petition and the publication of the corresponding registration in the areas of *in vitro* diagnostic medical devices, materials, and equipment.

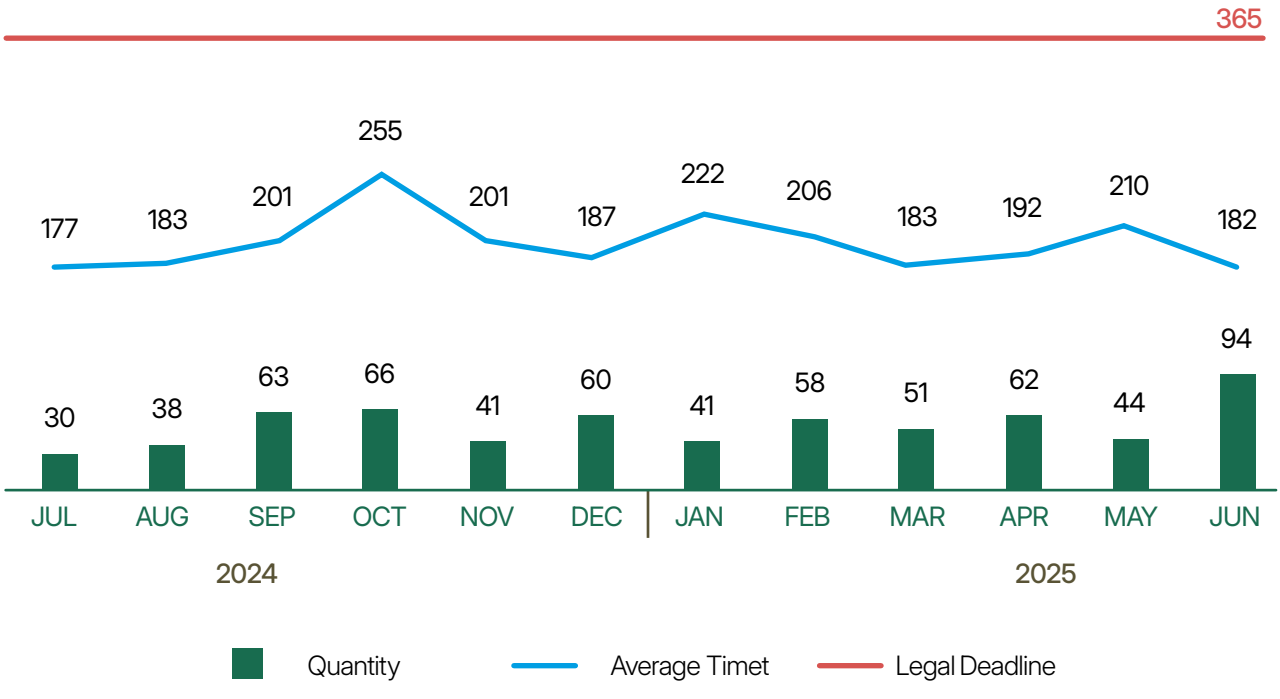
52 Open Data Portal

IN VITRO DIAGNOSTIC MEDICAL DEVICE

1,953 Registration Publications and Notices

TYPE OF PETITION	SITUATION	QUANTITY
NOTIFICATION	GRANTED	1169
	REJECTED	72
REGISTRO	GRANTED	648
	REJECTED	64

No. OF REGISTRATIONS PER MONTH X AVERAGE TIME TO PUBLICATION



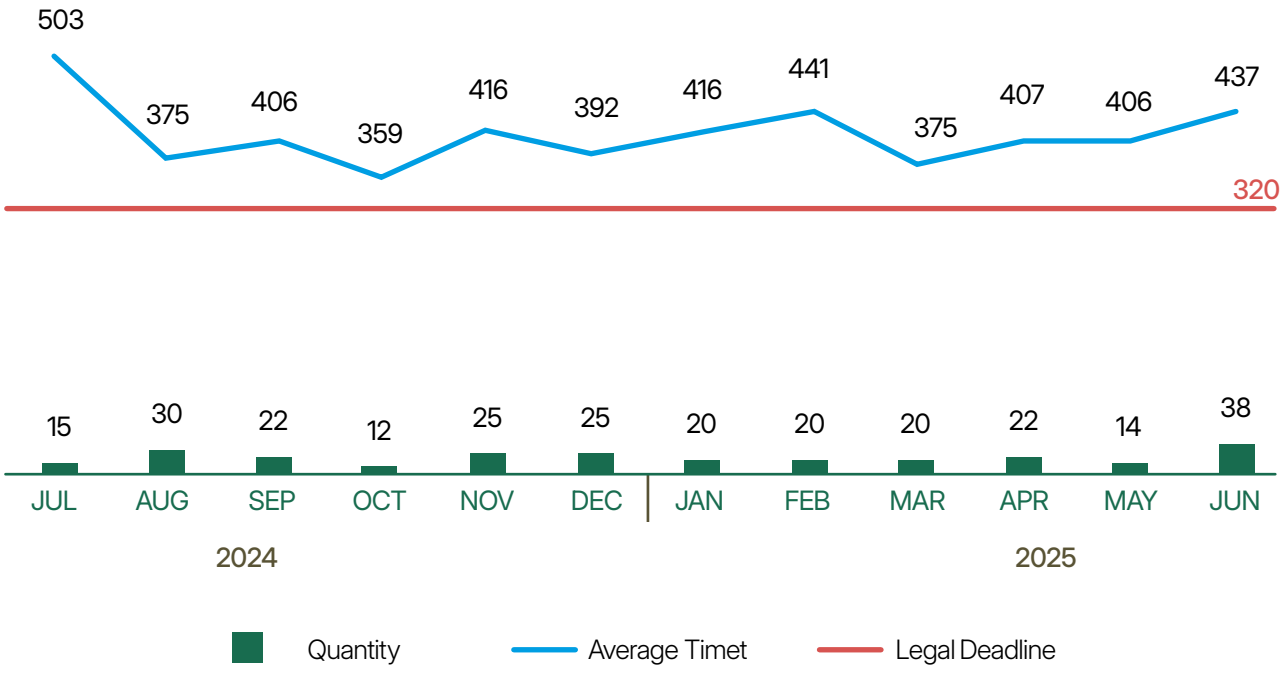
Source: Open Data – ANVISA – Accessed on 11/18/2025

MATERIAL FOR USE IN HEALTH (EXCEPT IMPLANTABLE ORTHOPEDIC)

5,711 Registration Publications and Notices

TYPE OF PETITION	STATUS	QUANTITY
NOTIFICATION	Granted	4,825
	Rejected	514
REGISTER	Granted	263
	Rejected	109

No. OF REGISTRATIONS PER MONTH X AVERAGE TIME TO PUBLICATION



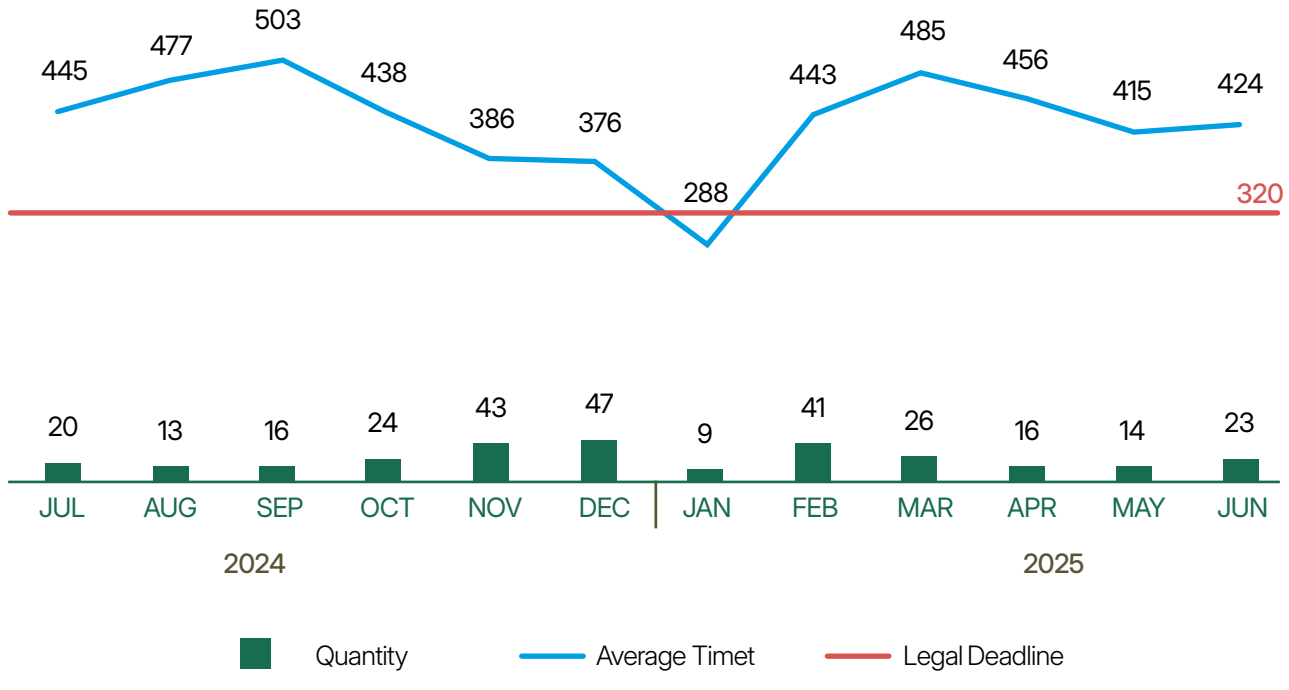
Source: Open Data – ANVISA – Accessed on 11/18/2025

IMPLANTABLE MATERIALS

336 Registry Publications

TYPE OF PETITION	STATUS	QUANTITY
REGISTER	Granted	292
	Rejected	44

No. OF REGISTRATIONS PER MONTH X AVERAGE TIME TO PUBLICATION



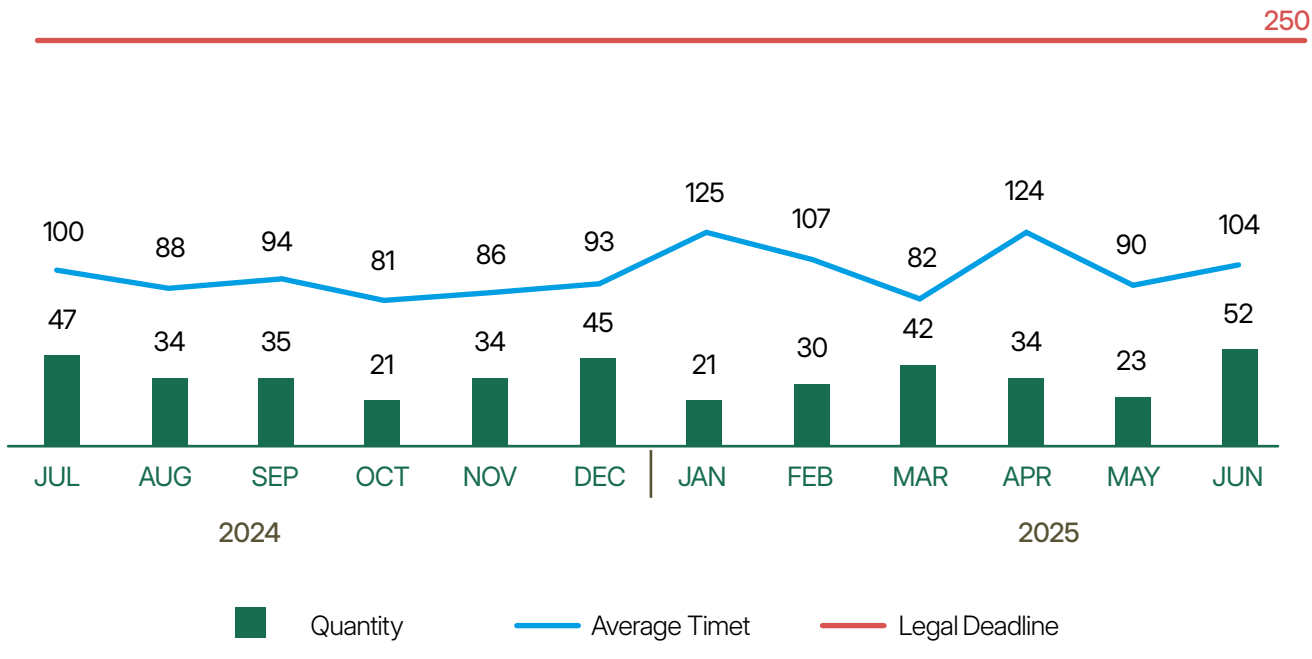
Source: Open Data – ANVISA – Accessed on 11/18/2025

EQUIPMENT

2,166 Publications

TYPE OF PETITION	STATUS	QUANTITY
NOTIFICATION	Granted	1,371
	Rejected	369
REGISTER	Granted	418
	Rejected	8

No. OF REGISTRATIONS PER MONTH X AVERAGE TIME TO PUBLICATION



Source: Open Data – ANVISA – Accessed on 11/18/2025

ELECTRONIC PETITIONING

Applications for the regularization of medical devices are submitted electronically through the "Solicita" system. The implementation of this system contributed to shorter review timelines and has reduced errors arising from manual data transcription during technical analysis.

DATABASE

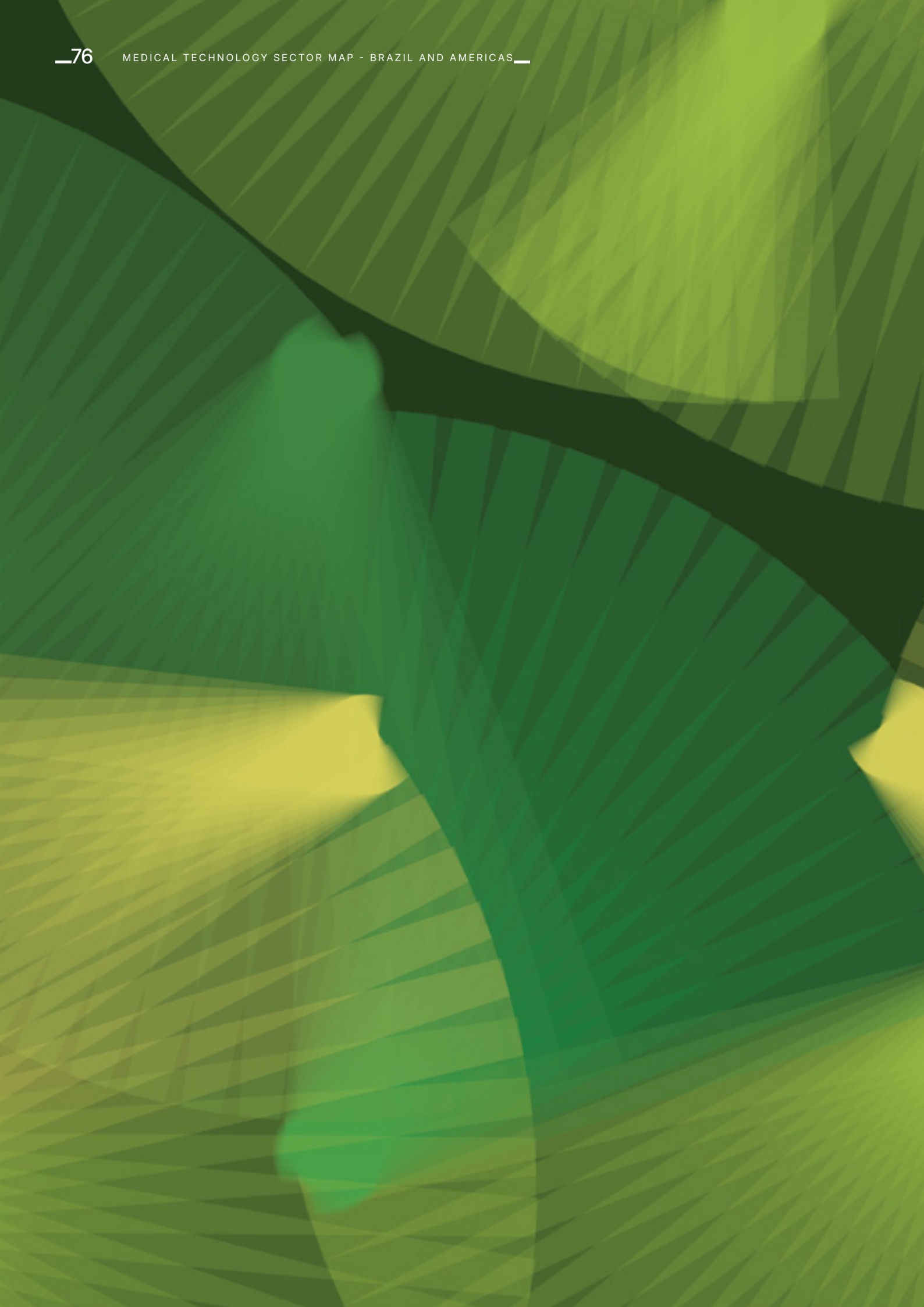
The Agency provides public access to various regulatory information through its Consultation Portal. Available data includes information on medical devices, regularized products, application status, consultation of technical names, etc. The portal can be accessed at: https://consultas.Anvisa.gov.br/#/

FEES

Sanitary inspection fees are regulated by RDC No. 857/2024. This regulation establishes differentiated fee levels according to the company size, and large companies are required to collect the full fee, without the application of discounts.

RISK CLASS	VALUE IN BRL	U.S. DOLLAR VALUE
Class I	R$ 3,514.32	$633.59
Class II	R$ 3,514.32	$633.59
Class III	R$ 49,641.20	$8,949.84
Class IV	R$ 49,641.20	$8,949.84

Source: RDC No. 857/2024 Currency Converter - Central Bank of Brazil -20/10/2025



Medical Technology in the Americas

.06

6. Medical Technology in the Americas

This chapter examines the role of other regulatory authorities that work in the pre-market control of medical devices. Although this is not an exhaustive analysis, it focusses on aspects that have impact on population's access to these products.

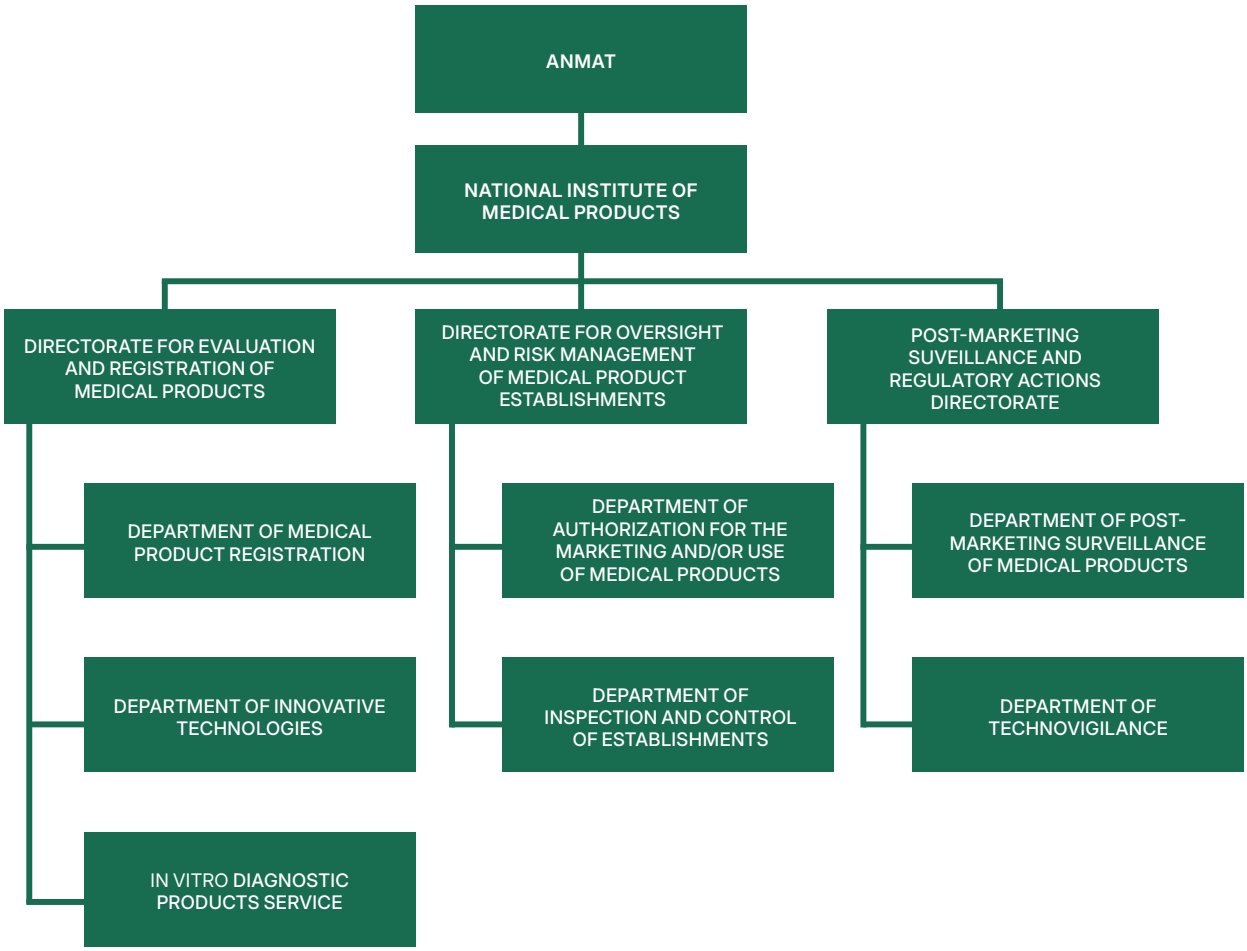
6.1 Argentina

ANMAT

The National Administration of Medicines, Food and Medical Technology – ANMAT, linked to Argentina's Ministry of Health, is the authority responsible for the sanitary control of medical devices, including *in vitro* diagnostic medical devices.

NATIONAL INSTITUTE OF MEDICAL PRODUCTS – INPM

The National Institute of Medical Products is the unit responsible for the control of MD and MD IVDs throughout their life cycle. Its organizational structure is illustrated in the figure below.[53]



53 Structure of the second operational level – Administrative Decision No. 761/2019 – Annex III

REGULATORY CONVERGENCE

In line with international guidelines on regulatory convergence, ANMAT actively participates in regional and international forums. Regionally, ANMAT is present in the Commission on Health Products (COPROSAL), Working Subgroup No. 11 of the Southern Common Market—MERCOSUR, as well as in the Pan American Health Organization (PAHO) Regional Working Group on Medical Devices Regulation.

Internationally, ANMAT is an Official Observer of the Steering Committee of the International Medical Device Forum (IMDRF) and an Affiliate Member of the Medical Device Single Audit Program (MDSAP).

Also noteworthy is the cooperation and convergence agreement signed between ANMAT and ANVISA in November 2021. Under this agreement, both authorities committed to the mutual and automatic recognition of certificates issued for class I and II products, manufactured and marketed between their territories.[54]

41.4%

Percentage of IMDRF documents fully or partially incorporated by ANMAT into its regulations, based on the set of 34 documents listed in the IMDRF Document Implementation Report, updated in September 2025.

Source: IMDRF Implementation Report – September 2025

HUMAN RESOURCES

ANMAT has a staff of 1,217 professionals[55], of whom 100[56] work with medical devices in different units of the National Institute of Medical Products.

PRE-MARKET CONTROL

Manufacturers and importers must demonstrate that their devices comply with safety, performance and quality requirements established by ANMAT as a condition for regularization of products. Key elements of pre-market control established at this stage include company qualifications, good manufacturing practices, and product registration.[57]

54 Agreement on Mutual Recognition, accessed on 10/07/2025
55 Organizational chart, authorities and personnel (data updated on 5/31/2025)
56 INPM verbal information
57 Sobre los procesos de control de Dispositivos Médicos | Argentina.gob.ar

RISK RATING

MEDICAL DEVICES

Provision No. 64/2025[58] establishes the risk-based classification of medical devices into classes I, II, III and IV, with class I representing the lowest risk and IV the highest. The technical requirements applicable to different medical devices are proportionate to their assigned risk class. The rules for classifying products are aligned with Regulation No. 745/2017 of the European Union and harmonized with GMC Resolution No. 25/21 – MERCOSUR Technical Regulation for the Registration of Medical Devices.

In addition to the Provision applicable to risk classification, Provision No. 9,688/2019[59] regulates the product registration regime in the RPPTM (*National Registry of Producers and Products of Medical Technology*), covering devices from classes I to IV, national and imported.

CLASS	CONTROL
Class I – Non-sterile devices, nor with a measuring function or active components listed in Annex II of Provision 64/2025.	**Annex II** - Lists specific Class I products and a list of required documents.
	Proof of Registration in the RPPTM – by means of an affidavit prepared by the manufacturer and endorsed by the INPM.
Other Class I Products or Class II Products	**Annex III** – Lists the required.
	Proof of Enrollment in the documents RPPTM – by means of a Declaration of Conformity prepared by the manufacturer, according to the model issued by the competent authority and endorsed by the INPM.
Class III and IV Products	**Annex IV** - Lists the required documents.

58 Provision No. 64/2025 accessed on 7/10/2025
59 Provision No. 9688/2019

IN VITRO DIAGNOSTIC MEDICAL DEVICES

Provision No. 2,674/1999[60] establishes the technical and documentary requirements applicable to the registration of In Vitro Diagnostic Medical Devices. Provision No. 2,198/2022[61] updates these requirements and the applicable procedures related to the RPPTM of *in vitro* diagnostic medical products, in Groups A, B, C, and D, both domestic and imported.

CLASS	CONTROL
Groups A and B	**Annex II** - Lists the required documents.
	Proof of Enrollment in the RPPTM – by means of a Declaration of Conformity prepared by the manufacturer, according to the model issued by the competent authority and endorsed by the INPM.
Groups C and D	**Annex III** - Lists the required documents.

60 Provision No. 2674/1999
61 Provision No. 2198/2022

CONFORMITY ASSESSMENT OF MD AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS (EPSP)

Proof of compliance with ANMAT's Essential Principles of Safety and Performance requires the submission of information on tests performed, which vary according to the risk class of the product.

Locally manufactured MD must be submitted, among other documents provided for in Provision No. 9688/2019, as follows:

- Class I devices regularized by means of an Affidavit:
  - Declaration of tests demonstrating compliance with essential safety and performance requirements.
- Classes I devices not covered by an Affidavit and class II devices:
  - Declaration of tests demonstrating compliance with essential safety and performance requirements.
  - Tests conducted according to specific Mercosur technical regulations.
- Classes III and IV:
  - Original tests reports demonstrating compliance with essential safety and performance requirements.
  - Tests conducted according to specific Mercosur technical regulations.

Medical devices that have radiocommunication systems for medical use must be approved by National Communications Entity (ENACOM) according to a specific technical standard.[62]

Locally manufactured MD IVD incorporating electrical equipment must present Test Certificates in accordance with IEC 61010-1 standards (Safety requirements of electrical equipment for measurement, control and use in the laboratory. Part 1: General requirements) and IEC 61010-2-101 (Particular requirements for *in vitro* diagnostic medical equipment (IVD).

These certificates must be issued by laboratories accredited by the *Argentine Accreditation Body* (OAA), ensuring compliance with international safety standards.

In addition, products classified under Group D, which represent higher risk, are subject to specific laboratory analysis. This stage is conducted after the approval of the testing protocol by the INPM, reinforcing the level of technical rigor required prior to market authorization.

62 Ente Nacional de Comunicaciones – Synthesized Resolution No. 863/2020

REGULATORY DEADLINES

Legal deadlines for responding to requests for regularization of MD and MD IVD are established under Provision No. 9,688/2019, which defines the maximum response times applicable to the regulatory authority.

RISK CLASS	TIME FRAME (DAYS)
Class I MD listed in Annex II of Provision No. 9688/2019	Immediate
Other class I or class II MDs MD IVD groups A and B	15
Class III and IV MDs MD IVD groups C and D	110

DEADLINES PRACTICED BY ANMAT FOR THE REGULARIZATION OF MD AND MD IVDs

ANMAT uses the HELENA System, an electronic platform used for procedures related to the registration of MD and MD IVD, including the public consultation of regularized products. Although external users can access the tool to view approved registrations, the platform does not allow the monitoring of the average processing time of submissions in relation to the established legal deadlines. Unofficial data[63] indicate that the average analysis time for high-risk products is 143 days and for low-risk products is 49 days.

FEES

Provision No. 4,058/2025 establishes the fees applicable to the registration of products according to the health risk classification.

HEALTH RISK	ARGENTINE PESO	US DOLLAR*
MD - Class I and II	$238,200.00	$ 166.57
MD - Class III and IV	$392,850.00	$ 274.72
MD IVD – Groups A and B	$212,250.00	$148.43
MD IVD – Groups C and D	$268,650.00	$ 187.87

* Currency converter Central Bank of Brazil - 20/10/202[64]

63 Data provided by two companies in the sector.
64 Currency Converter accessed on 9/10/2025

6.2 Canada

HEALTH CANADA

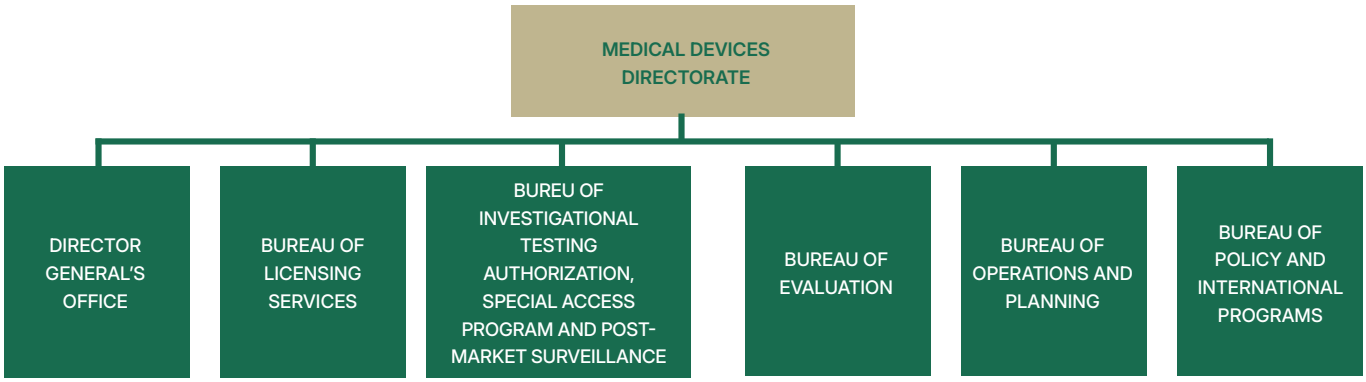
Health Canada is the federal authority responsible for protecting the health and safety of Canadians through the regulation of health-related products and services. The control of MDs throughout their life cycle is exercised by different units organized within four directorates:[65]

- Medical Devices Directorate
- Medical Device and Clinical Compliance Directorate
- Directorate of Commercialized Health Products
- Directorate Shortage of Health Products

MEDICAL DEVICES DIRECTORATE – MDD

Pre-market control of medical devices is exercised by the Directorate of Medical Devices (MDD), the national authority responsible for licensing class II, III and IV devices, conducting reviews of scientific information to assess the product safety and quality, the MDSAP process, assessing post-market safety risks and monitoring post-market incidents.[66]

The Directorate comprises six divisions that cover the following activities, as illustrated below.



65 IMDRF 27th MC Meeting Tokyo - Health Canada Regulatory and Policy Updates
66 IMDRF 27th MC Meeting Tokyo - Health Canada Regulatory and Policy Updates e IMDRF 26th MC Meeting Seattle - Health Canada Regulatory and Policy Updates

REGULATORY CONVERGENCE

Health Canada actively participates in MDSAP, integrating the *Regulatory Authority Council* (RAC), the program's decision-making body. Since 2019, MDSAP has been the sole mechanism accepted for manufacturers of class II, III, and IV products to prove the compliance of their quality management systems, a mandatory requirement for the commercialization of MD and MD IVD in the country.

In addition, Health Canada is a member of the Steering Committee of the International Medical Device Forum (IMDRF).

86.2%

Percentage of the IMDRF documents fully or partially incorporated by Health Canada, among the 34 listed in the IMDRF Document Implementation Report.

Source: IMDRF Implementation Report – September 2025

HUMAN RESOURCES

The *Medical Devices Directorate (MDD)*, created in November 2019, has a workforce of 165 positions.[67]

PRE-MARKET CONTROL

The *Food and Drug Act* (F&DA) and its regulations, especially the Medical Devices Regulations (SOR/98-282), establish the requirements for the control of MDs in the country, including the requirements applicable to their commercialization. The establishment's license is also mandatory for the sale or import of medical devices.

RISK CLASSIFICATION

Products are classified into four classes (I, II, III, and IV), based on the potential risk associated with their use. The classification rules are in line with Directive No. 93/42 of the European Union,[68] in which class I represents the lowest risk and class IV the highest.

Class I (low risk) devices are exempt from a product license for commercialization and are controlled through the establishment's license (*Medical Device Establishment Licensing* (MDEL). For classes II, III and IV, the documentation required to obtain the license varies according to the level of risk, and the Certificate issued by the MDSAP is mandatory for the regularization of these devices.

The Medical Devices Regulations (SOR/98-282) establish the rules for risk classification of MDs. The guidelines *Guidance Document – Guidance on the Risk-based Classification for Non-In Vitro Diagnostic (non-IVDDs)* and *Guidance Document: Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs)* clarify the classification rules respectively for MD and MD IVD.

67 Health Canada Creates New Medical Devices Directorate | RAPS accessed on 7/1/2025
68 Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)

CONFORMITY ASSESSMENT OF MDS AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS (EPSP)

To obtain a medical device license (CDM), manufacturers of class II, III and IV medical devices can demonstrate compliance with safety and efficacy requirements through the use of reference voluntary technical standards, made available by the authority through an official list of Recognized[69] Standards. According to the authority, "The use of Recognized Standards can help ensure that regulations are interpreted consistently. For example, an application for a medical device license or authorization that declares conformity to a recognized standard in the Declaration of Conformity Form often eliminates the need to review test data for those aspects of the device addressed by the standard."[70]

Manufacturers choosing this approach must submit a Declaration of Conformity, available on the Health Canada website.

Where a recognized standard exists, manufacturers may choose to comply with an equivalent or higher standard, or to provide alternative evidence of the safety or effectiveness of the device. In these two cases, the manufacturer must submit detailed information demonstrating the equivalence of the conducted study with the recognized standard or higher, as the case may be.

PREGULATORY DEADLINES

The timelines for medical devices licensing applications vary according to the risk class and are defined in the table below. When the deadlines established for regularization are not met, Health Canada refunds part of the fee to the company, in a cost recovery mechanism.[71]

CLASS	TIME (DAYS)
Class I	Immune
Class II	15
Class III	75
Class IV	90

Source -Safe Medical Devices in Canada - Canada.ca

69 Official List of Recognized Standards
70 Guidance on using standards to support compliance with the Medical Devices Regulations
71 Health Canada Fees Report Fiscal Year 2024-2025

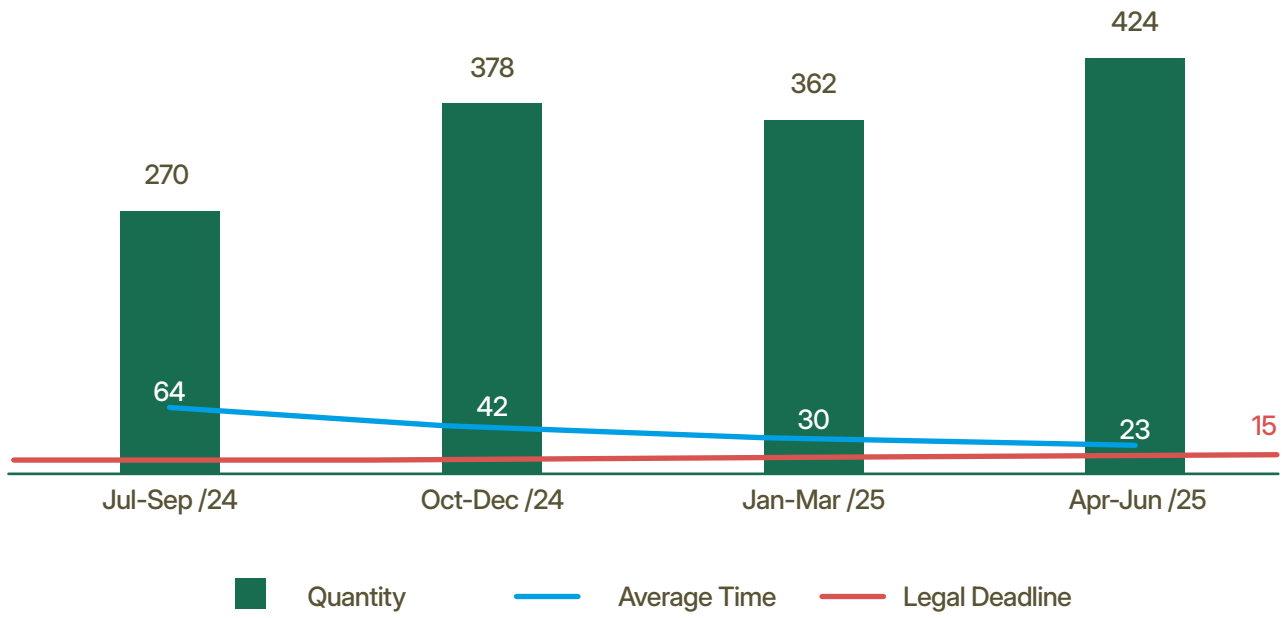
DEADLINES PRACTICED BY HEALTH CANADA FOR THE REGULARIZATION OF MD AND MD IVDs

Medical Device Licenses
Data Source: Quartely Reports - publications@hc-sc.gc.ca

The Medical Devices Directorate publishes the Medical *Devices Directorate Performance Quarterly Report*, which contains detailed metrics on the medical device premarket review process.

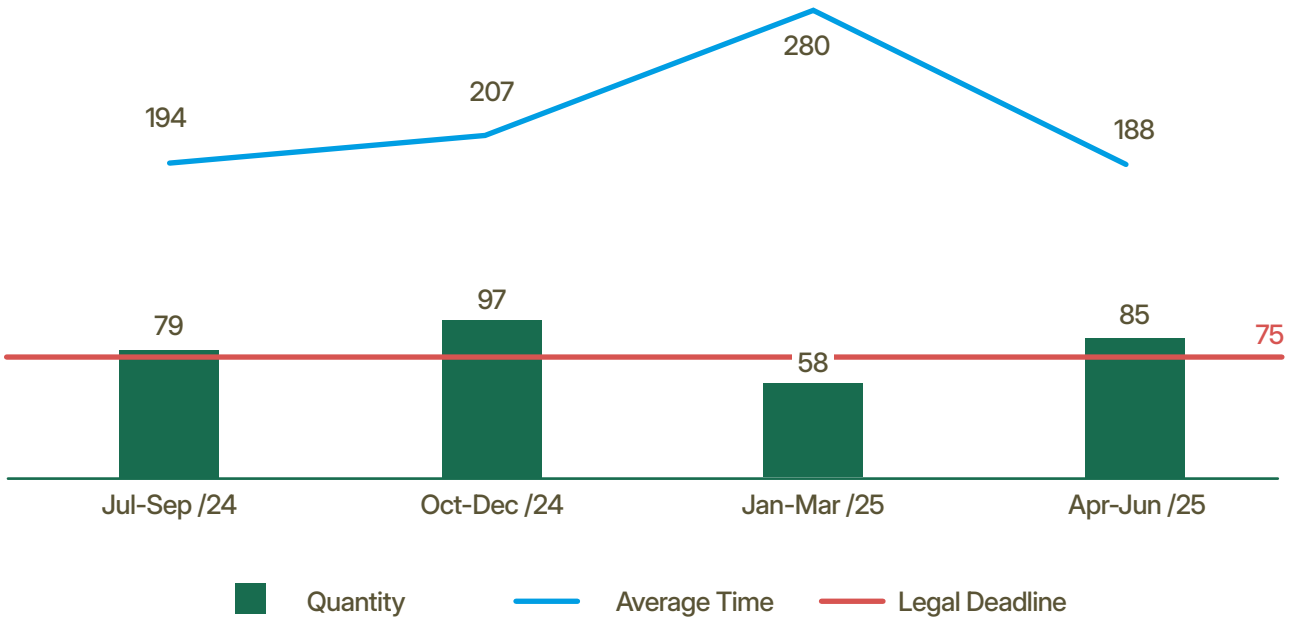
The performance data covering the period from July 2024 to June 2025 presents the volume of medical device licensing applications and the corresponding average decision times, as illustrated in the graphs below for class II, III, and IV products, respectively.

Average time for new class II licensing.[72]

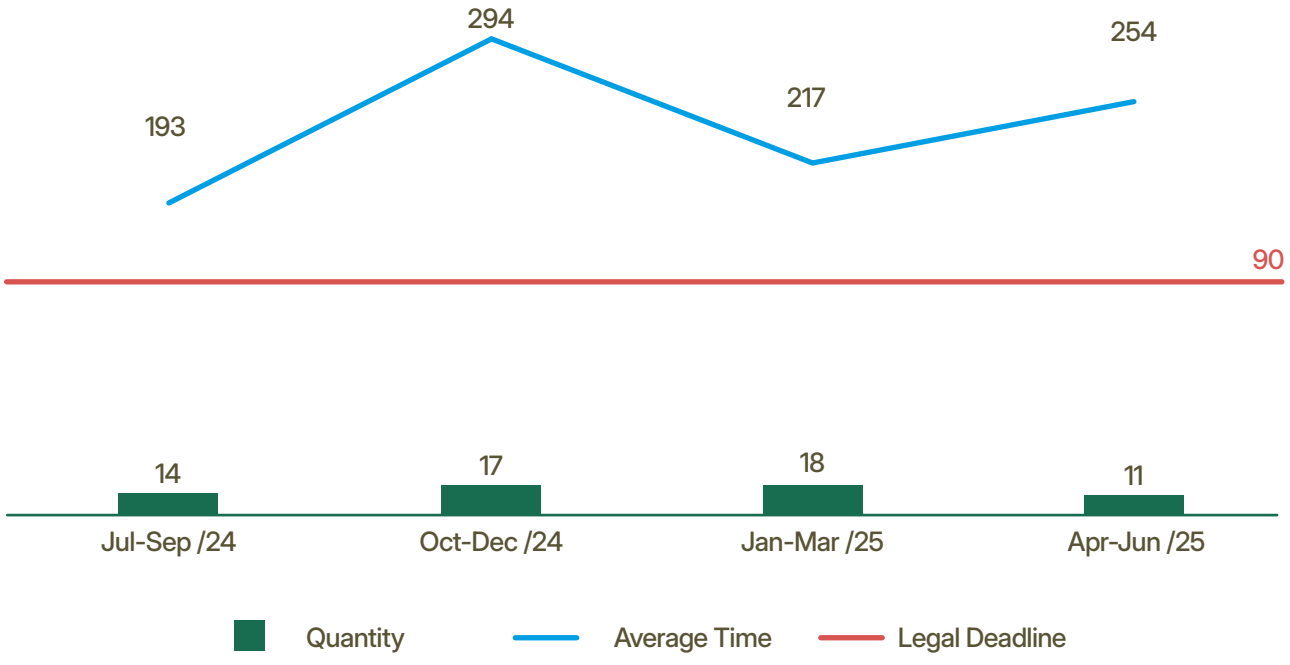


72 MEDICAL DEVICE REPORTS AND PUBLICATIONS - CANADA.CA

Average time for new class III licensing[73].



Average time for class IV licensing.



DATABASE

The **MDALL online query** online database allows users to search for information on active medical device licenses using six parameters: (i) company name, (ii) license name, (iii) device name, (iv) company identification (ID), (v) license number, and (vi) device identifier.

FEES[74]

REQUEST TYPE	CANADIAN DOLLAR	US DOLLAR
Class II License	$ 632.00	$ 450.39
Class III License	$13,926.00	$ 9,924.46
Class III License (MD IVD Near Patient)	$29,664.00	$ 21,140.25
Class IV License	$30,199.00	$ 21,521.52

Currency converter - Central Bank of Brazil - 20/10/2025

74 Fees for examining a licence application, amendment application for licence or amendment to authorization, for medical devices.

6.3 Colombia

INVIMA

The National Institute for Drug and Food Surveillance (INVIMA) is the authority responsible for the implementation of policies formulated by the Ministry of Health and Social Protection. Its mandate covers health surveillance and quality control for various products, including medical devices.[75,76]

DIRECTORATE OF MEDICAL DEVICES AND OTHER TECHNOLOGIES (DDMOT)

The Directorate of Medical Devices and Other Technologies (DDMOT) responsible for the control of medical devices, biomedical equipment, *in vitro diagnostic reagents*, *in vitro reagents* and anatomical components[77]. *In vitro reagents* include general-purpose reagents and anatomical components – a category that includes biological samples, fluids, tissues, organs, among others – which do not fall under the definition of MD IVD established by the Global Harmonization Task Force (GHTF).

REGULATORY CONVERGENCE

INVIMA became an affiliate member of IMDRF in September 2025 and participates in the Regional Working Group on Medical Device Regulation coordinated by the Pan American Health Organization (PAHO), together with countries such as Brazil, Argentina, and Mexico. This group "aims to strengthen the regulatory capacity of MDs through the regional exchange of information."[78] In addition to these initiatives, INVIMA has cooperation agreements and memorandums of understanding with several regulatory authorities across the Americas.

HUMAN RESOURCES

According to the Directory of Public Servants or Contractors, INVIMA has a workforce of 1,620 professionals[79]. Although the Medical Devices Directorate has 65 professionals, not all of them work directly with MD and MD IVD, since the structure of the directorate also includes two other areas: *in vitro* reagents and anatomical components.

PRE-MARKET CONTROL

Requirements for the regularization of products are established under Decree No. 4,725/2005 for MDs, and in Decree No. 3,770/2004 for MD IVDs. The documentation required is proportional to the health risk associated with the use of the device.

75 Invima
76 The Colombian Ministry of Health is technically the medical device regulatory authority in Colombia, being the body that is responsible for initiating, finalizing and maintaining the rulemaking process.
77 Medical Devices | INVIMA
78 Pan American Health Organization
79 Directory of Public Servers accessed on 03/25/2025

RISK RATING

MEDICAL DEVICES

Decree No. 4,725/2005 establishes the criteria for risk classification of MDs based on the potential risks associated with their use and possible failure, considering a combination of factors, such as the duration of contact with the body, the degree of invasiveness, and local effects, compared to systemic effects. The risk classification rules adopted under this the decree are in line with the provisions of Directive 93/42/EEC of the European Union.

The products are classified into four classes, as shown in the table below:

CLASS	CONTROL
Class I **Low Risk***	Subject to automatic registration with general controls not intended to protect or maintain life, or for use of special importance in preventing deterioration of human health, and do not present an unreasonable potential risk of disease or injury.
Class IIa **Moderate Risk***	Subject to automatic registration with special controls at the manufacturing stage to prove their safety and effectiveness.
Class IIb **High risk**	Subject to special controls in design and manufacture to prove their safety and effectiveness.
Class III **Very high risk**	Subject to special controls – intended to protect or maintain life or to play a critical role in prevention or deterioration of human health, or if their use present a potential risk of disease or injury.

Source: Decree No. 4,725/2005

Certain equipment, referred to as Controlled Technology Biomedical Equipment, is subject to special control when they fall under one of the following situations:

- They present high health risk and vulnerabilities associated with the design, manufacture, installation, use or intended purpose.
- They are prototypes intended at technological or scientific advances.
- They are subject to supply control according to a geographic zone within the country, according to a specific law.
- They are used or refurbished.
- They require an investment exceeding 700 statutory minimum wages, according to a specific law.

Such equipment is subject to a "Marketing Permit", a document issued by INVIMA necessary for the manufacture, importation and marketing of these products. The Marketing Permit is linked to other documentary and regulatory obligations established under Decree 4,725/2005.

IN VITRO DIAGNOSTIC REAGENTS

Decree No. 3,770/2004 establishes the risk classification, defining which products are classified in which group of reagents[80] and the corresponding requirements applicable for sanitary regularization purposes.

CLASS	CONTROL
Category I Low risk*	Subject to automatic registration, upon presentation of the product's technical information and the corresponding legal documentation related to both the product and the establishment.[81]
Category II Medium Risk*	
Category III High Risk	Subject to the presentation of the product's technical information and the corresponding legal documentation for both the product and the establishment, with prior approval of the Specialized Chamber of Supplies for Health and Miscellaneous Products of the INVIMA Review Commission.[82]

Source: Decree No. 3,770/2004

*Subsequent control of the automatic sanitary registration – INVIMA may verify at any time the information submitted for automatic registration. When necessary, the authority may request additional data from the registration holder to clarify, supplement or correct information provided in the registration. The deadline for response is 90 business days. Failure to respond within this period, or in case submission is considered unsatisfactory, may result in suspension of registration.[83]

80 Decree 3.770/2004, article 3.
81 Decree 3.770/2004, articles 11 and 12.
82 Decree 3.770/2004, article 8.
83 Cartilla Diligenciamiento Formularios _ compressed.pdf

CONFORMITY ASSESSMENT OF MDS AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS (EPSP)

MEDICAL DEVICES

Decree 4.025/2005 establishes that technical-scientific, sanitary and quality requirements must be observed, including technical studies and analytical evidence. Class IIA, IIB and III devices must present scientific information that proves their safety and a risk analysis consistent with the devices' indications, a list of applicable specific standards, – applied in whole or in part –, and a description of the solutions adopted to meet the essential safety and performance requirements. Class IIb and III devices must present clinical studies to demonstrate safety and efficacy.

For biomedical equipment, compliance with electrical safety must be demonstrated by presenting information on the study conducted and the technical standard used to demonstrate the safety and operation of the device.[84]

Decree No. 3,275/2009[85] establishes that Free Sale Certificates issued by regulatory authorities in the European Union, the United States, Canada, Japan, and Australia are exempt from the obligation to present technical studies, analytical evidence, sterilization methods, and clinical studies for product regularization.

The regulatory framework for medical devices does not explicitly require third-party certification to demonstrate product conformity.

IN VITRO DIAGNOSTIC REAGENTS

In vitro Diagnostic Reagents classified in Category III are required to obtain the "Specialized Technical Concept" issued by the Specialized Chamber for Medical Devices and *in vitro* Diagnostic Reagents, after evaluation of clinical and analytical studies, review of scientific literature and, when necessary, laboratory analysis requested by INVIMA. The Specialized Chamber operates as an advisory body to the Directorate of Medical Devices and Other Technologies.

Products marketed in the United States, the European Union, Canada, Japan and Australia that comply with applicable legal and technical requirements and that are accompanied by a certificate issued by the competent health authority in the country of origin are exempt from this requirement. This certificate must indicate:

- a) the specific name of the *in vitro* diagnostic reagent and, where applicable, its references.
- b) confirmation that the product is freely marketed in that country.
- c) a date of issuance not exceeding one (1) year.[86]

The regulatory framework for *in vitro* diagnostic medical devices does not explicitly require third-party certification to demonstrate conformity.

84 Invima - Circular 5000-0001- 22
85 Decree No. 3725/2009
86 Decree No. 3770/2004 and Decree 4,124/2008.

REGULATORY DEADLINES

Medical Devices[87]	Classes I and IIa	Issued within 2 business days after submission, provided the documentation is complete.
	Classes IIb and III	90 working days after submission.
In vitro diagnostic reagents[88]	Categories I and II	Issued within 2 business days of submission, provided documentation is complete
	Category III	90 working days after submission

87 Medical devices and biomedical equipment | INVIMA
88 In Vitro Diagnostic Reagents and In Vitro Reagents | INVIMA

AVERAGE APPROVAL TIME

The currently available databases do not allow for monitoring of approval timelines for MDs and MD IVDs. Unofficial information indicates the following average review times:[89]

- Medical Device – Classes I and II – average of 45 days
- Medical Device – Classes IIB and III – average of 241 days
- Reactive for *in vitro* diagnostics – Classes I and II – average of 45 days
- Reagent for *in vitro* diagnostics – Class III – Average of 135 days

DDMOT DATABASE

The current records of Medical Devices, Biomedical Equipment and Reagents for *in vitro* Diagnosis may be consulted through downloadable datasets available in Excel format.

FEES[90]

MEDICAL DEVICE			IN VITRO DIAGNOSTIC REAGENTS		
Class	Colombian Peso	US Dollar	Class	Colombian Peso	US Dollar
I	$ 0 (microenterprise) to $ 3,718,704.00	$956.74	I	$ 0 (microenterprise) to $ 2,452,143.00	$630.88
IIa			II		
IIb	$ 0 (microenterprise) to $ 4,209,087.00	$ 1,082.91	III	$ 0 (microenterprise) to $ 3,269,447.00	$841.16
III					

Currency Converter – Central Bank of Brazil – 10/20/2025

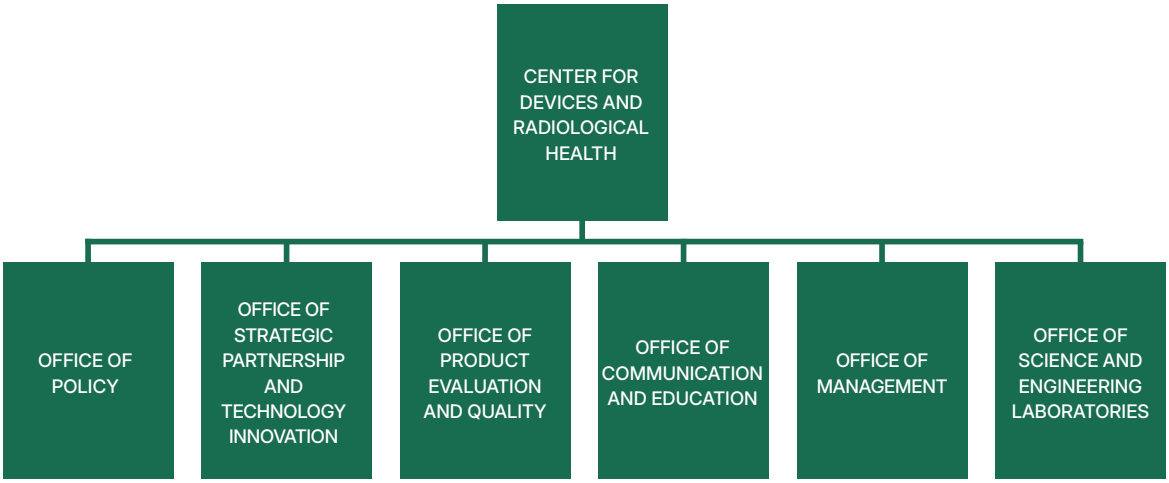
89 Data provided by two companies in the sector.
90 Rates | INVIMA

6.4 United States

The U.S. Food and Drug Administration (FDA) is an agency of the United States Department of Health and Human Services (HHS). It is responsible for overseeing the safety of more than $3.9 trillion worth of medical products (including medical devices), food, and tobacco, consumed in the United States. The devices can be produced in the United States and abroad. It regulates more than 7,000 different categories of medical devices and has more than 25,864 registered establishments, with approximately 62% of the devices used in the country being imported.[91]

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

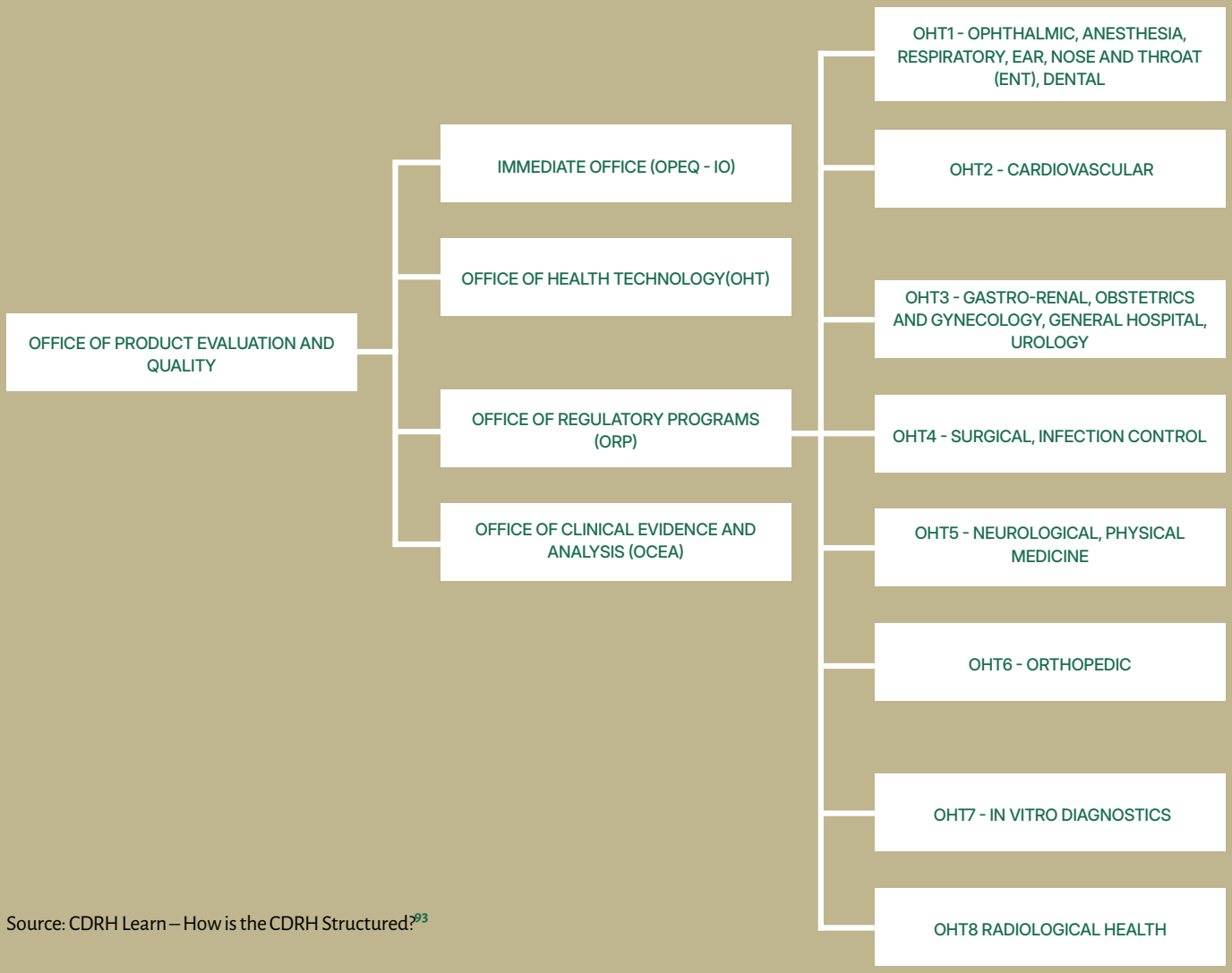
The FDA's Center for Devices and Radiological Health (CDRH) is the area responsible for overseeing medical devices and radiological products. Its structure is composed of eight offices that, together, cover the entire life cycle of these devices — from research and development to evaluation, regulation, communication, compliance and innovation.



91 FDA at a Glance October 2024 – Accessed on 9/29/2025

Among these offices, the Office of Product Evaluation and Quality (OPEQ) stands out, considered a "super office" due to the breadth of its responsibilities. OPEQ is responsible for implementing pre-market review programs, such as 510(k) and *Premarket Approval (PMA)*, in addition to being responsible for the registration of establishments, supporting compliance activities and certain import and export processes, post-market surveillance, among other activities.[92]

The figure below presents the organizational structure of OPEQ.



Source: CDRH Learn – How is the CDRH Structured?[93]

92 CDRD Learn - How Is CDRH Structured?
93 How is CDRH Structured? Accessed on 8/27/2025

REGULATORY CONVERGENCE

The FDA serves as a member of the Steering Committee of the International Medical Device Forum (IMDRF) and is a Regulatory Authorities Council (RAC) member under the Single Audit Program for Medical Devices (MDSAP).

Additionally, through the Office of International Affairs, the FDA maintains channels for the exchange of regulatory information with foreign authorities. This international cooperation is not restricted to public information, but also confidential, made possible through confidentiality agreements signed with authorities from 26 countries – including Argentina, Australia, Brazil, Canada and Chile.

100%

Percentage of documents fully or partially incorporated by the FDA, among the 34 listed in the IMDRF Document Implementation Report.

Source: IMDRF Implementation Report – September 2025

HUMAN RESOURCES

The FDA has a workforce of over 18,000 professionals distributed in all 50 US states and international units.[94] In the CDRH, over 2,000 professionals are allocated[95] working in activities related to the regulation, evaluation and monitoring of medical devices and radiological products.

PRE-MARKET CONTROL

Manufacturers and importers must comply with a set of established pre-market controls before legally marketing a medical device in the U.S. FDA oversight of devices is risk-based, meaning that the level of regulatory controls required to demonstrate reasonable assurance of safety and efficacy is typically commensurate with the level of risk of the device. These controls include, but are not limited to, the registration of establishments, the listing of devices, compliance with FDA Quality System requirements, and, where applicable, the filing of a premarket application, such as 510(k), de novo, or PMA. It should be noted that while certain Class I and II low-risk devices are exempt from 510(k) notification, they remain subject to all applicable premarket controls.

94 About FDA | FDA Accessed 11/1/2025
95 CDRH Annual Report 2024

RISK CLASSIFICATION

The FDA's *Product Classification* database gathers information on approximately 1,700 generic types of medical devices, organized into 16 medical specialties – called panels. This structure allows the classification of the device into one of three classes (Class I, II or III), in addition to providing data on the indication for use, the assigned regulatory class and the applicable requirements for its commercialization.[96] This database is a key tool for manufacturers in determining the proper classification of their medical devices in the United States.

CLASS	CONTROL	TYPE OF SUBMISSION
Class I **Low Risk**	General control – Includes provisions on the registration of establishments, listing of medical devices, quality system and labeling, among others.[97]	Most Class I devices are exempt from 510(k)* pre-market notification.
Class II **Moderate Risk**	General control and, if available, special control, which includes the enactment of performance standards, post-marketing surveillance, patient registries, development and dissemination of guidelines, among other actions necessary to ensure safety and effectiveness[98] – Are applied to well-established MDs.	Most Class II devices require a 510(k) pre-market notification.
Class III **High Risk**	General and Special Control are insufficient to provide reasonable assurance of the safety and effectiveness of the device and require pre-market approval.[99]	Pre-market authorization (PMA) required**.

Fonte: Premarket Notification 510(k)

*For the 510(k), at a minimum, the manufacturer must demonstrate that the proposed device is substantially equivalent to a legally marketed device in the United States (predicate device). In some cases, a 510(k) notification also requires clinical data if the device under review presents significant risks or lacks a suitable predicate. A device may be legally marketed only after receiving a Substantial Equivalency (SE) letter from the FDA confirming that the device is substantially equivalent.[100]

**PMA is the most stringent type of device marketing application required by the FDA, for Class III devices. PMA approval is based on a determination that the application contains sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use(s). High-quality scientific documentation, including robust clinical information and sound scientific analysis are essential for the FDA's evaluation and approval of a PMA application.[101]

96 Device Classification Panels | FDA accessed on 9/24/2025
97 Overall control.
98 Special control.
99 The 510(k) Program, p.2.
100 Premarket Notification 510(k) | FDA accessed 10/1/2025
101 Premarket Approval (PMA) | FDA accessed 10/1/2025

FDA may down classify a device type when new information demonstrates that general controls, or general and special controls, are sufficient to provide reasonable assurance of safety and effectiveness, making a higher classification no longer necessary.

CONFORMITY ASSESSMENT OF MDS AND MD IVDS

Manufacturers must demonstrate substantial equivalence for 510(k) devices and safety and efficacy for PMA devices. This can be proven through the voluntary use of Consensus Standards recognized by the FDA, available in a public database *(Recognized Consensus Standards: Medical Devices)*.[102] The use of these standards contributes to increasing predictability, simplifying pre-market analysis, and providing more transparency to the regulatory process.

The adoption of Consensus Standards by the FDA is a prerequisite for the issuance of the Declaration of Conformity (DoC) issued by the manufacturer, which is a "certification that a device complies with the requirements identified in a standard recognized by the FDA".[103] The purpose of declaring compliance with a consensus standard that FDA has recognized or has decided to recognize is to use such compliance to meet certain premarket requirements and to reduce the amount of data and supporting information that is submitted to FDA. Thus, FDA will be able to determine, in its review, whether the submission meets the applicable premarket requirements. When a DoC is submitted, FDA expects that all required testing by the Consensus Standard have been completed and that compliance with the Consensus Standard has been met prior to submission of the premarket submission.[104]

The FDA also provides for the so-called "General Use" of *Consensus Standards*, applicable when the manufacturer "chooses to demonstrate the conformity of the device with a standard, recognized or not, in whole or in part, but without submitting a DoC". The reasons for the General Use of a consensus standard vary, but may include: (1) the manufacturer has chosen to use a recognized consensus standard without submitting a DOC; (2) the manufacturer has applied a recognized standard with justified deviations; or, (3) the manufacturer has chosen to use a consensus standard that FDA has not recognized.[105] Under General Use, conformance is supported by submitting complete test data and a full test report.[106]

In addition, the manufacturer may participate in the "Conformity Assessment Accreditation Scheme (ASCA Program), a voluntary program in which accredited laboratories perform testing to certain FDA-recognized standards, following an FDA-established framework. The results generated by ASCA-accredited laboratories are accepted by the FDA and can facilitate and streamline FDA's review. Participation in the ASCA program is optional.[107]

102 Recognized Consensus Standards: Medical Devices
103 Standards Overview
104 FDA, p. 5.
105 FDA, p. 9.
106 Standards: Resources and Use in Premarket Submissions
107 Accreditation Scheme for Conformity Assessment (ASCA) | FDA

REGULATORY DEADLINES

The new timelines are established under the *Medical Device User Fee Amendment (MDUFA) Performance Goals and Procedures for Fiscal Years 2023 Through 2027,*[108] as per the table below.

RISK CLASS	AVERAGE – TOTAL DECISION TIME (MDUFA)	DATABASE
Class I and II Notification 510(k)	2024 – 124 days 2025 – 112 days	510 k Database
Class III Pre-Market Approval (PMA)	2024 – 290 days 2025 – 285 days	PMA Database

FDA DEADLINES FOR REGULARIZATION OF MD AND MD IVDs

510 (k) Premarket Notifications

JULY 2024 AND JUNE 2025

TOTAL

3,245 notifications

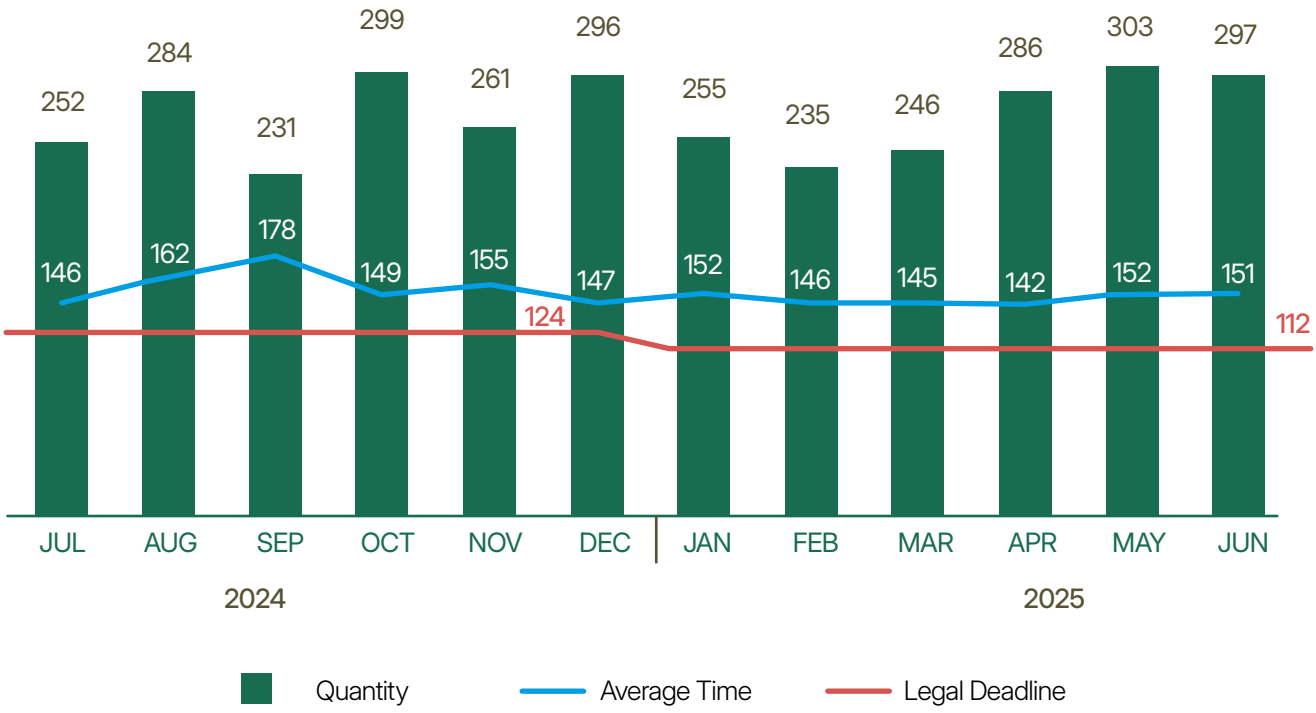
Data Source: FDA Downloadable Base 510(k) Files[109]

The data collected considers the different types of notification:

- Traditional 510(k) – Used for any 510(k) or for changes to legally marketed devices, accounting for 83% of notifications.
- Special 510(k) – Applicable to certain modifications to a manufacturer's own legally marketed devices, provided that the evaluation methods are well established and the results can be analyzed by means of a technical summary or risk analysis, representing 15.6% of the notifications. Other types of less frequent notifications added up to 2.9% of the total.

108 MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 -The total time to decision is comprised of two parts: FDA's review time and Industry's response time.
109 Downloadable 510(k) Files | FDA

The graph below shows the average time for decision on notifications in the period between July 2024 and June 2025.



Premarket Approvals (PMA)

PERIOD: JULY 2024 AND JUNE 2025

TOTAL

38 new approvals

Data source: PMA/PDP Files for Downloading[110]

In addition to pre-market device approvals, the database provides information on different types of PMA supplements. The supplement is a required submission for modifications that impact the safety or effectiveness of the device. These changes must be approved in advance by the FDA before they can be implemented.

110 PMA Approvals | FDA

The following table shows the number of premarket approvals accounted for between July 2024 and June 2025.

	MONTH	QUANTITY
2024	Jul	2
	Aug	5
	Set	1
	Oct	6
	Nov	3
	Dec	3

	MONTH	QUANTITY
2025	Jan	2
	Feb	2
	Apr	3
	May	3
	Jun	3

The following chart shows the average decision time in pre-market approvals (PMA), - same period (July 2024 and June 2025).

Source: PMA DATABASE Accessed on 11/27/2025

The table below shows the volume and average time to decide on changes (supplements) in devices subject to Pre-Market Approval (PMA) for the period of July 2024 and June 2025.

CHANGE TYPE	QUANTITY	AVERAGE TIME (DAYS)
135 Review Track For 30-Day Notice	92	186
30-Day Notice	1469	25
Normal 180 Day Track	211	241
Normal 180 Day Track No User Fee	168	172
Panel Track	17	295
Real-Time Process	270	89
Special (Immediate Track)	73	28
Total	**2300**	**71**

The *30-Day Notice* is used to communicate to the FDA changes in the manufacturing procedure or method that may affect the safety or efficacy of a medical device. If the change qualifies as a 30-day warning, it can be implemented 30 days after the notification is submitted to the FDA. If the agency deems the notice inadequate, it will be converted to a *135 Review Track PMA Supplement.*[111] Normal 180 Day Track *modifications* are for changes that affect the safety and effectiveness of the device and for significant changes to components, materials, design, specifications, software, color additives, or labeling. In general, clinical data provided in support of traditional device approval must still be applicable to support modified device approval. In most cases, only new preclinical tests are needed to prove safety and efficacy.[112]

111 PMA Supplements.
112 PMA Supplements

Changes classified as *Panel Track* refer to significant modifications in the design or performance of the device, or even a new indication for use for the device, which will require the presentation of clinical data to prove its safety and effectiveness.

Real-Time Process *changes*, on the other hand, refer to minor changes to the device, which are reviewed by the applicant in conjunction with the FDA.[113] Special Changes apply for any change that increases device safety or device use safety, as well as certain labeling and manufacturing changes that increase device safety or device use safety.[114]

The U.S. FDA has recently implemented an innovative approach to device modifications, known as Predetermined Change Control Plans (PCCP). A PCCP is a document that outlines what modifications a sponsor will make to a device after approval/clearance, how the modifications will be assessed, and an assessment of their risks. PCCPs can be reviewed in a pre-market submission and, if approved, can be used to implement post-market modifications without resubmission.

DATABASE

Information on 510(k) notifications and PMA premarket authorizations is available from *510(k) Premarket Notification*[115] *and Premarket Approval (PMA) databases.*[116]

FEES - *MEDICAL DEVICE USER FEE AMENDMENTS (MDUFA)* - 2025[117]

APPLICATION TYPE	STANDARD RATE	SMALL BUSINESS
510 (k)	US$ 24,335	US$ 6,084
PMA	US$540,783	US$135,196

113 Medical Device User Fee Amendments FY 2024 - Performance Report to Congress accessed on 10/8/2025
114 PMA Supplments.
115 510(k) Premarket Notification
116 Premarket Approval (PMA)
117 Medical Device User Fee Amendments (MDUFA): Fees | FDA accessed on 7/6/2025

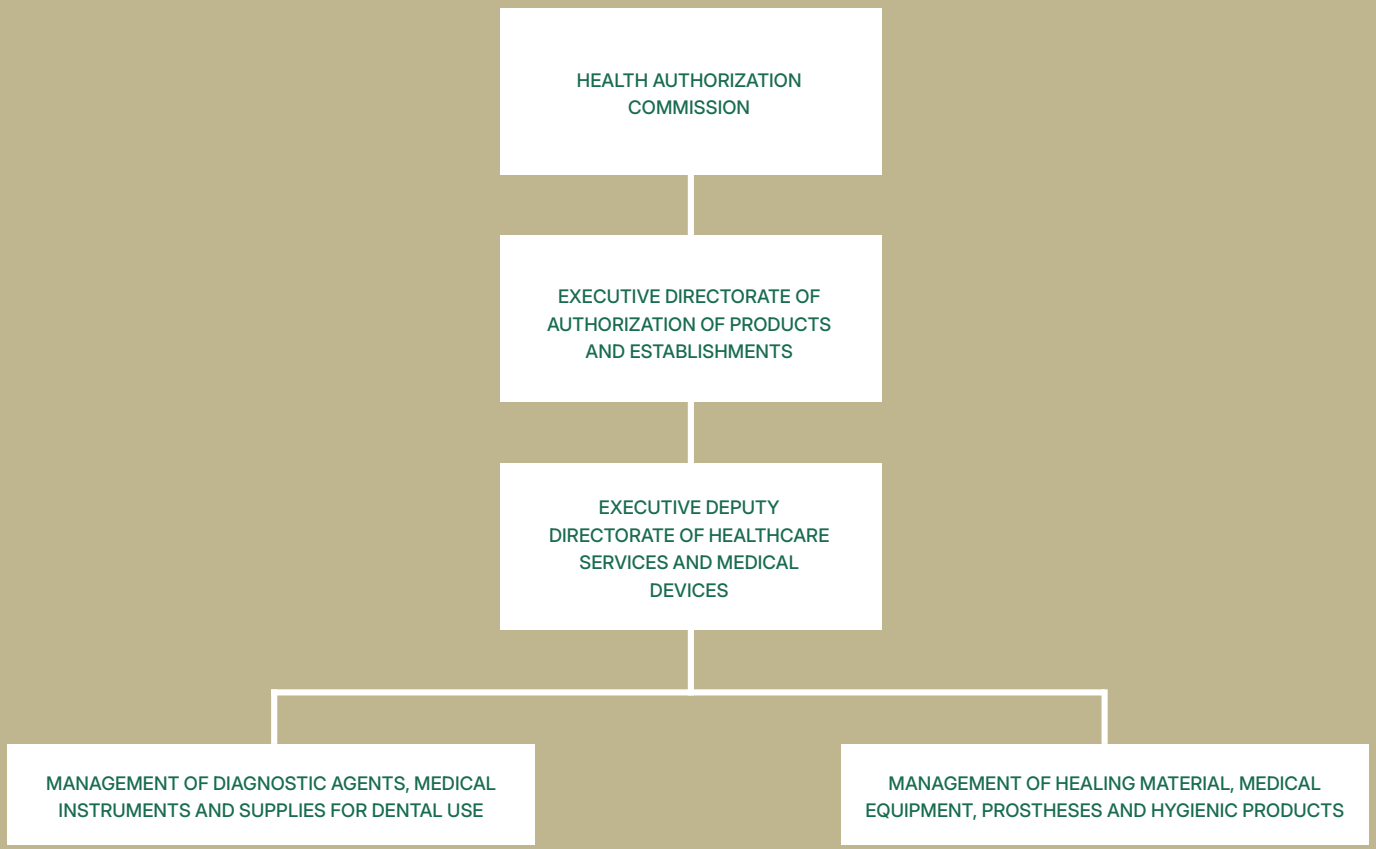
6.5 Mexico

COFEPRIS

The Federal Commission for the Protection against Health Risks (COFEPRIS) is the regulatory body responsible for the sanitary control of medical devices in Mexico[118]. In addition to the General Health Law and the Federal Law of Administrative Procedures, the legal framework governing medical devices is composed of the Regulation of the General Health Law on health research, the Regulation of Inputs for Health, the Mexican Official Standards and the Pharmacopoeia of the United Mexican States – Supplement for Medical Devices 5.0.

HEALTH AUTHORIZATION COMMISSION

The sanitary control of these devices is under the responsibility of the Sanitary Authorization Commission (CAS) together with the Sanitary Operation Commission (COS). Pre-market control is in charge of CAS and its subordinate units. The figure below shows the areas involved in the premarket control of MDs.[119]



118 The Pharmacopeia of United Mexican States (Farmacopea de los Estados Unidos Mexicanos A.C. – FEUM) is a Mexican governmental body, separately established and administratively independent from COFEPRIS that also has a role with medical device regulatory processes. In particular, FEUM often drafts new medical device technical regulations.

119 Manual de Organización Específico de la Comisíons Federal para la protección contra Riesgos Sanitarios65

REGULATORY CONVERGENCE

COFEPRIS participates in both IMDRF[120] and MDSAP as an Affiliate Member. It also participates in the Regional Working Group on Medical Device Regulation coordinated by PAHO, together with countries such as Brazil, Argentina, and Colombia. In August 2025, members of the IMDRF Steering Committee and the MDSAP Council of Regulatory Authorities, including ANVISA, were recognized by COFEPRIS as reference regulatory authorities for purposes of medical device registration and certification of good manufacturing practices under trusted regulatory practices - *Reliance*.

HUMAN RESOURCES

No official data were available regarding COFEPRIS's total workforce or the number of professionals dedicated specifically to medical devices. Unofficial information suggests that about 1,500 professionals work at COFEPRIS, of whom 42 are directly involved with medical device-related activities.

PRE-MARKET CONTROL

Medical devices fall within the definition of Health Supplies,[121] as established by the General Health Law and are subject to pre-market control by the Health Authorization Commission. According to article 262 of the General Law, these devices fall into seven distinct categories: Medical Equipment, Prostheses, Orthoses and Functional Aids, Diagnostic Agents, Dental Inputs, Surgical and Healing Materials, Hygienic Products and Software as a Medical Device. The registration of these products falls under the responsibility of the Management of Diagnostic Agents, Medical Instruments and Supplies for Dental Use as well as the Management of Healing Material, Medical Equipment, Prostheses and Hygienic Products.

120 Note: The IMDRF Document Implementation Report "IMDRF/MC/N84 FINAL:2025 (Edition 2) IMDRF Document Implementation Report", published in September 2025, does not present information on the incorporation of IMDRF documents into the COFEPRIS regulatory framework.

121 General Health Law – Art. 194 Bisis

CLASSIFICATION OF MEDICAL DEVICES

The Health Inputs Regulation defines the classification of products according to the level of risk associated with their use,[122] distributing them into three classes according to the Table below. Criteria for the appropriate classification of medical devices based on their health risk are set out in Appendix II – of the Medical Device Supplement 5.0 Volume II of the Pharmacopoeia of the United Mexican States.[123]

CLASS	CONTROL	TYPE OF SUBMISSION
Class I – Low risk – Established by the Regulatory Agreement of July 7, 2025	Annex I – Lists products requiring registration	Register
	Annex II – Lists products exempt from registration	Exempt from registration
	Annex III – Lists products that are not considered health inputs and are exempt from sanitary registration.	Exempt from registration
Class I - inputs known in medical practice, whose safety and efficacy are proven and, generally, are not introduced into the body.		Medical Device Sanitary Registry
Class II - inputs known in medical practice that may present variations in their material composition or in their concentration and, generally, are introduced into the human body for periods of less than thirty days.		
Class III - new inputs or those recently incorporated into medical practice, or products that are introduced into the human body and remain in place for more than thirty days.		

The Guide for Obtaining the Sanitary Registration of Class I, II and III Medical Devices and the Agreements for the Simplification of Procedures dated July 11 and August 22, 2025 and for the application of the Abbreviated Copy dated August 18, 2025[124], establish the requirements to which medical devices will be subject for the purposes of sanitary regularization, according to class I, II or III. As a general rule, the three classes require sanitary registration. The Regulatory Agreement of July 7, 2025[125] defines lists of products considered Low Risk (Class I) and identifies the type of control applicable.

122 Regulation of Inputs for Health, art. 83.

123 Pharmacopoeia of the United Mexican States. Authors' note - It was not possible to access the Mexican Pharmacopoeia, since the document is available exclusively in printed format and upon purchase

124 Acuerdo -Lineamentos generales para la aplicación de la via regulatoriaa abreviada

125 COFEPRIS – Agreements and Dispositions

CONFORMITY ASSESSMENT OF MD AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS (EPSP)

The Health Supplies Regulation, the Mexican Official Standards and the Pharmacopoeia of the United Mexican States – Supplement for Medical Devices 5.0 define requirements to be observed by establishments for the commercialization of products.

The Guide for Obtaining the Sanitary Registration of Class I, II and III Medical Devices[126] and *the AGREEMENT establishing simplification measures for procedures carried out by the Federal Commission for Protection against Sanitary Risk* of 11/7/2025, establish the administrative, legal, technical and scientific safety and efficacy information that must be submitted for product regularization.

Class I products must present microbiological, functionality and performance tests, to verify compliance with the specifications of the input according to the Mexican Pharmacopoeia or in applicable international standard. If the methodology used is not provided in the aforementioned documents, the manufacturer must provide a description of the analysis method used and a summary of its validation. Electrical test reports must also be submitted when applicable.

For class II and III products, depending on the characteristics, nature and intended use of the device, manufacturers must submit complete test reports to validate the design, functionality and performance of the device, according to specifications of the Mexican Pharmacopoeia; or other recognized ones; or the Mexican Official Standards; or international standards. Electrical test reports must also be submitted where applicable. Electromedical equipment must include specific tests according to the IEC 60601 standard, regarding electrical safety. When no applicable standards exist in the Mexican Pharmacopoeia or international standards, test reports developed by the manufacturer may be submitted.

Class III diagnostic agents for hepatitis B and C, HIV and products intended for blood typing must present evaluation results issued by a laboratory authorized by the Health Department. Evaluations carried out in other countries may be considered when no local laboratories are able to domestically perform the required tests.

The regulatory framework does not explicitly require third-party certification as a condition for demonstrating product conformity.

126 GUIA _ PARA _ LA _ OBTENCION _ DEL _ REGISTRO _ SANITARIO _ DE _ DISPOSITIVOS _ MEDICOS _ CLASE _ I-II-III _ Y _ SOFTWARE _ COMO _ DISPOSITIVO _ MEDICO.PDF

REGULATORY DEADLINES

Mexico (COFEPRIS) Times for Approval of Registrations			
Process	APPROVAL TIMES (BUSINESS DAYS)		
	Regular submissions (before August 2025)	Agreements for Simplification of Processes Regular Submission 07/11 and 08/22, 2025	Agreement for Abbreviated Copy 07/18/2025
Class I Registration Low Risk	30	15	30
Class I Registration	30	20	30
Class II Registration	35	25	30
Class III Registration	60	35	30

Source: *Acuerdos y Disposiciones Cofepris*

DEADLINES PRACTICED BY COFEPRIS FOR THE REGULARIZATION OF MD AND MD IVDs

There is no official public information available that allows calculating the average approval time for product registration. The data below was kindly provided by *the Mexican Association of Innovative Industries of Medical Devices – AMID*. The Table below presents the average time for registration of medical devices in the period from January to September 2025, based on information voluntarily provided by AMID member companies participating in the initiative for data collection. These figures do not reflect the official average times practiced by COFEPRIS for the regularization of products.

RISK CLASS	AVERAGE TIME (DAYS)
Class I	65
Class III	121

Source: AMID

In 2025, COFEPRIS published five agreements[127] with the purpose of simplifying procedures and reducing deadlines for the regularization of products in the country. They are:

- June 11, 2025 – Agreement recognizing as equivalent the evaluation procedures carried out by reference regulatory authorities and defining an abbreviated path for the regularization of products in the country. As reference authorities, countries that are part of the IMDRF Joint Committee and MDSAP authorities will be considered.
- July 18, 2025 – Agreement establishing the guidelines for the application of the abbreviated regulatory pathway of June 11, 2025, including applicable deadlines. superseding those issued in June.
- July 07, 2025 – Agreement defining lists of low-risk products that require registration as well as products that are not considered medical devicess.
- July 11, 2025 – Agreement simplifying procedures, including changes in product registrations subject to immediate implementation.
- August 22, 2025 – Agreement simplifying procedures, reducing administrative documents to be submitted for product registration.

DATABASE

There is no electronic database available. COFEPRIS provides lists[128] in PDF format with information on the registrations of medical devices regularized as of 2017.

FEES[129,130]

CLASS	MEXICAN PESOS	US Dollar
Class I	$15,896.23	$ 846.36
Class II	$23,314.46	$1,246.64
Class III	$29,672.96	$ 1,612.22

Source: Currency Converter Fees – Central Bank of Brazil 10/20/2025

127 Acuerdos y Disposiciones Cofepris | Comisión Federal para la Protección contra Riesgos Sanitarios | Gobierno | gob.mx
128 Medical Device Registry Listings - COFEPRIS
129 COFEPRIS - Tarifa aplicable from 01 de enero al 31 de December de 2025
130 Currency Converter – Central Bank of Brazil (10/20/2025)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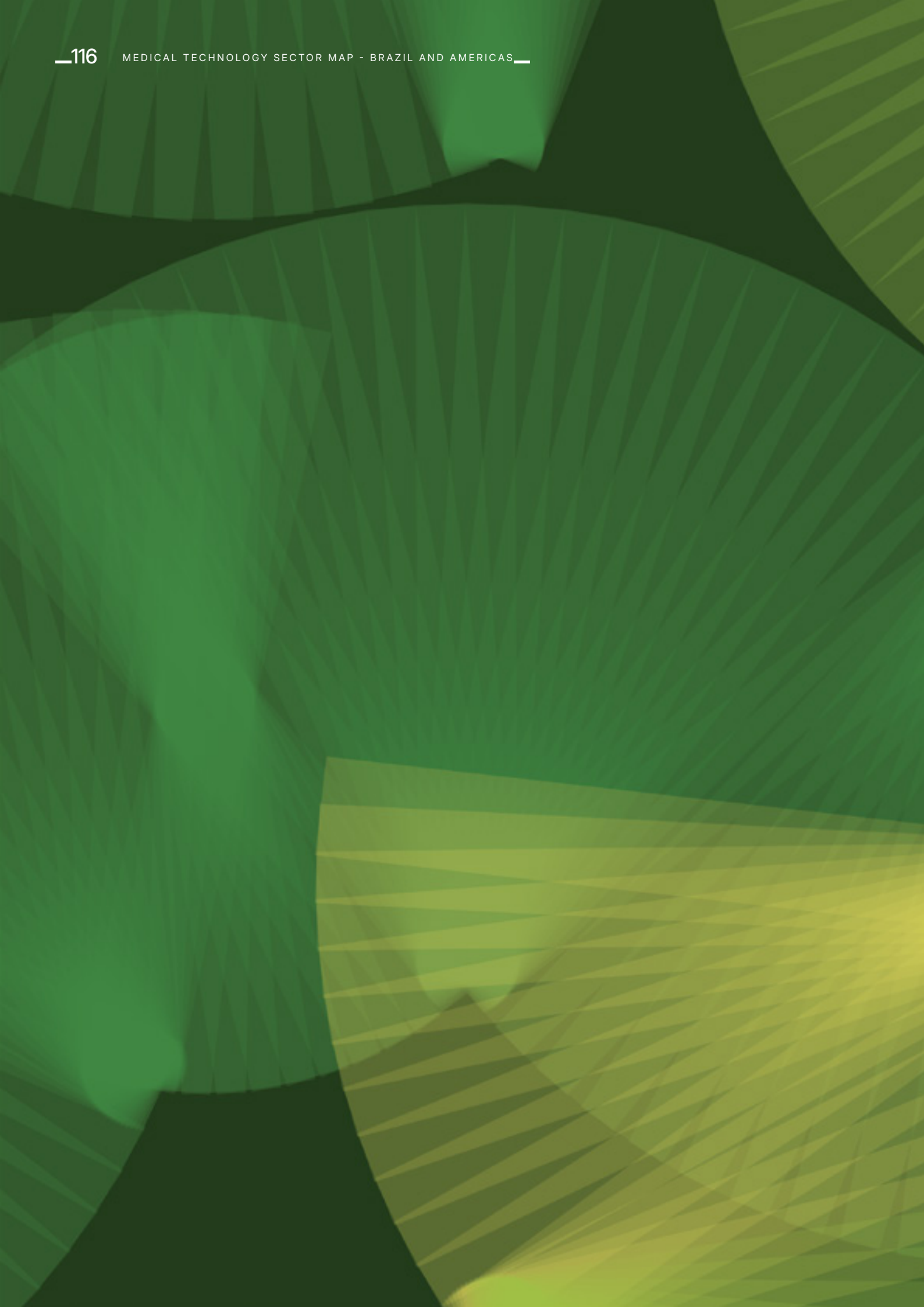


Mapping the Health Sector in Brazil

.07

7. Mapping the Health Sector in Brazil

7.1 Context and Purpose of Research and Applicable Methodology

ABIIS conducted a survey to assess perceptions within the regulated sector about the performance of ANVISA and INMETRO in processes related to the regularization of medical devices. The objective of the research was to identify strengths and weaknesses, to subsidize the proposals for improvement to be discussed with regulatory bodies and public policy makers.

By adopting an empirical approach based on a structured questionnaire, ABIIS sought to expand the representativeness of perspectives in the regulated sector, transforming individual perceptions into systematized evidence. The study is part of a broader effort to strengthen regulatory governance in the health sector, with the goal of fostering more agile, transparent and predictable environment, while fulling preserving the safety and efficacy of medical products placed on the Brazilian market.

To capture stakeholders' perceptions of the bottlenecks and potentialities within Brazil's medical device regulatory system, the survey employed a Likert scale methodolog .[131] This approach presents respondents with a series of statements to which they indicate their level of agreement or disagreement on an ordered scale, typically ranging from one to five. This methodology ensures allows qualitative perceptions to be converted into quantitative data suitable for statistical treatment. This scale generates responses treated as intervals, which allows the calculation of means, medians, standard deviations, and statistical tests.

131 Instrument, developed by Rensis Likert in 1932. It is widely used in social and organizational research to measure attitudes, perceptions, and opinions in a structured way.

SYNTHESIS OF THE RESEARCH METHODOLOGY

ELEMENT	DESCRIPTION
Objective of the research	Identify bottlenecks and strengths in the medical device regulatory process conducted by ANVISA and INMETRO, as well as point out institutional improvement measures.
Institutional context	Research conducted within the scope of ABIIS's activities, focusing on strengthening regulatory governance and promoting speed, safety and effectiveness in regulatory processes.
Collection instrument	Structured questionnaire, with items assessed using a Likert scale from 1 to 5 (ranging from "strongly disagree" to "strongly agree"), applied through a Google Forms form.
Application Period	March 10, 2025 to September 24, 2025
Target population	Companies, associations and stakeholders in the medical device sector that interact with the regulatory processes conducted by ANVISA and INMETRO.
Thematic Blocks Variables analyzed	(i) Workforce in the technical areas; (ii) Clarity and regulatory alignment; (iii) Registration process; (iv) Institutional interaction and communication; (v) Efficiency and continuous improvement; (vi) ANVISA-INMETRO collaboration.
Data processing	Calculation of means, medians and standard deviations for each item; grouping into thematic sections; interpretation of means scores (≤2.5 = bottleneck; 2.6–3.4 = point of attention; ≥3.5 = strength).
Complementary analysis	Identification of highly controversial topics (based on high standard deviation); comparison between ANVISA and INMETRO; assessment of perception dispersion by thematic section.
Purpose	Transformar percepções qualitativas em evidências quantitativas, de modo a orientar Convert qualitative perceptions into quantitative evidence, to guide recommendations for the improvement of the Brazilian regulatory system.

7.2 Data processing

A total of 66 responses were obtained to the questionnaire, structured into 6 thematic sections and composed of 28 questions. These responses were statistically treated to obtain means, medians and standard deviation. The criteria adopted for the classification of the results are presented in the table below.

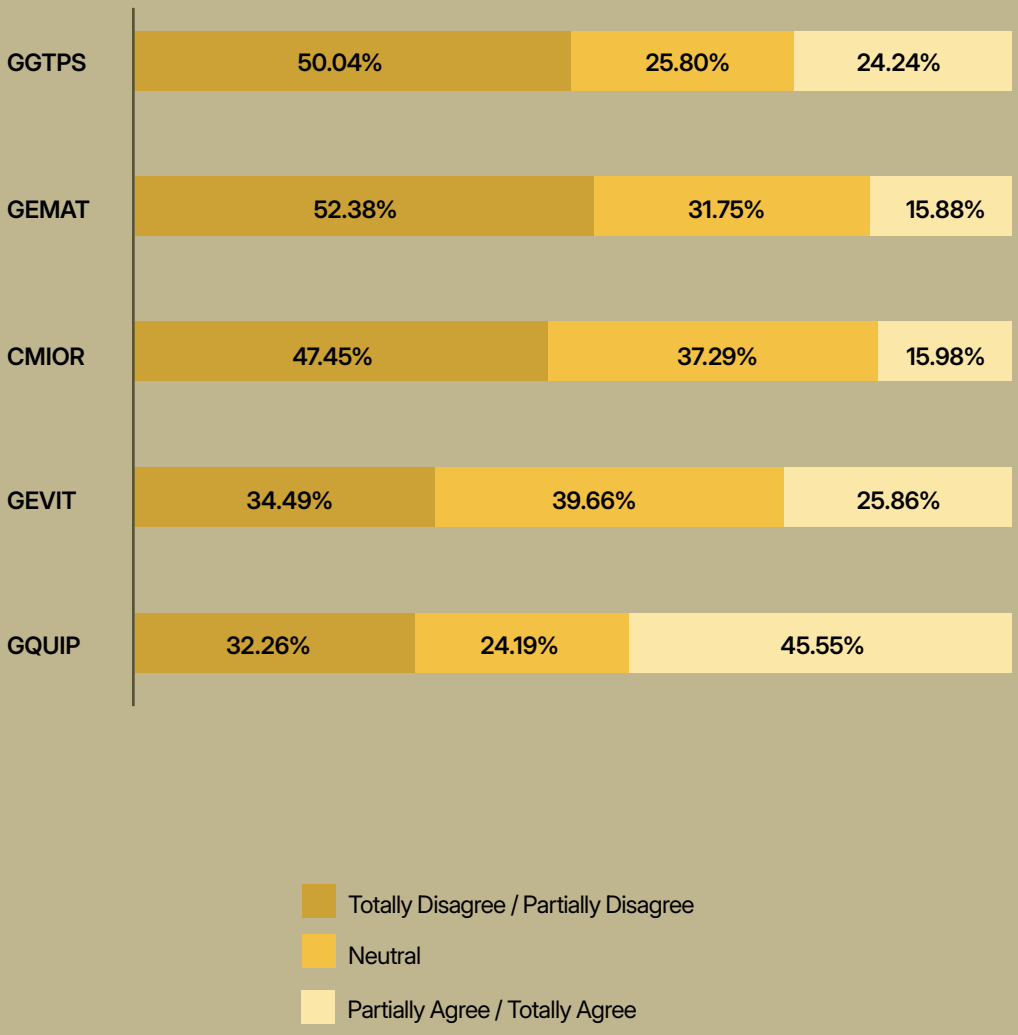
Each response was analyzed according to the mean, median, and standard deviation and classified according to the mean and standard deviation. The median was compared with the mean in cases where the standard deviation was high.

Responses were also assessed qualitatively, to identify the distribution of respondents perceptions for each of the categories.

MEASURE	VALUE	INTERPRETATION
Mean – Sum of all values divided by the number of observations	Averages ≤2.50	Negative evaluation
	Average ≥2.51 and ≤3.40	Alert
	Average ≥3.41	Positive evaluation
Median	Measure of central tendency - represents the central value of an ordered dataset (from lowest to highest), i.e., half of the responses are below the median and half are above.	
Standard deviation	Indicates the degree of consensus among the respondents.	
	Low values ≤ 1.17	Consensus
	High values ≥ 1.18	Controversy
Interpretation	Averages ≤2.50 Standard deviation ≤ 1.17	Bottlenecks
	Average ≥2.51 and ≤3.40 Standard deviation ≤ 1.17	Point of Attention
	Average ≥3.41 Standard deviation ≤ 1.17	Strength

7.3 Research Findings

A. THEMATIC SECTION – WORKFORCE



WORKFORCE	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. The GGTPS workforce is adequate for the execution of its statutory responsibilities.	2.51	2.5	1.17	66
2. GEMAT's workforce is adequate for the execution of its statutory responsibilities.	2.38	2.0	1.08	63
3. The CMIOR workforce is adequate for the execution of its statutory responsibilities.	2.37	3.0	1.12	59
4. GEVIT's workforce is adequate for the execution of its statutory responsibilities.	2.77	3.0	1.14	58
5. GQUIP's workforce is adequate for the execution of its statutory responsibilities.	3.09	3.0	1.18	62
Thematic Section	2.62	2.7	1.18	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

An analysis of responses grouped into "Agree," "Neutral," and "Disagree" indicates that more than 47 percent of respondents expressed strong disagreement with the statement that the workforce is adequate to perform its duties. By contrast, the share of respondents expressing agreement with this statement was below 24.24 percent.

Among the units assessed, GQUIP and GEVIT recorded the highest levels of agreement. GQUIP and GEVIT presented the highest percentages, above 43% for GQUIP and 25% for GEVIT, indicating comparatively more favorable perceptions relative to the other units.

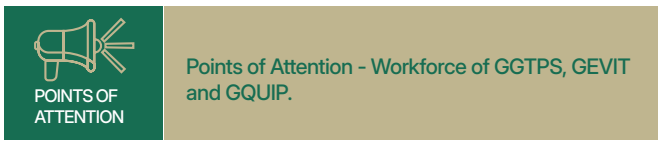
EVALUATION OF STATISTICAL RESULTS

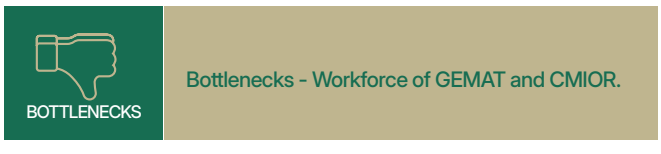
The results indicate a predominantly negative assessment of the workforce adequacy in the different GGTPS management units. The section mean score of 2.62 suggests a perceived shortage of personnel to perform statutory attributions. This result reinforces the perception that human resources constrain is one of the critical factors affecting performance across the multiple areas evaluated. The observed standard deviation indicates variability in perceptions among respondents.

At the individual unit level, the GEMAT and CMIOR presented low averages, being classified as bottlenecks in relation to performance of their duties.

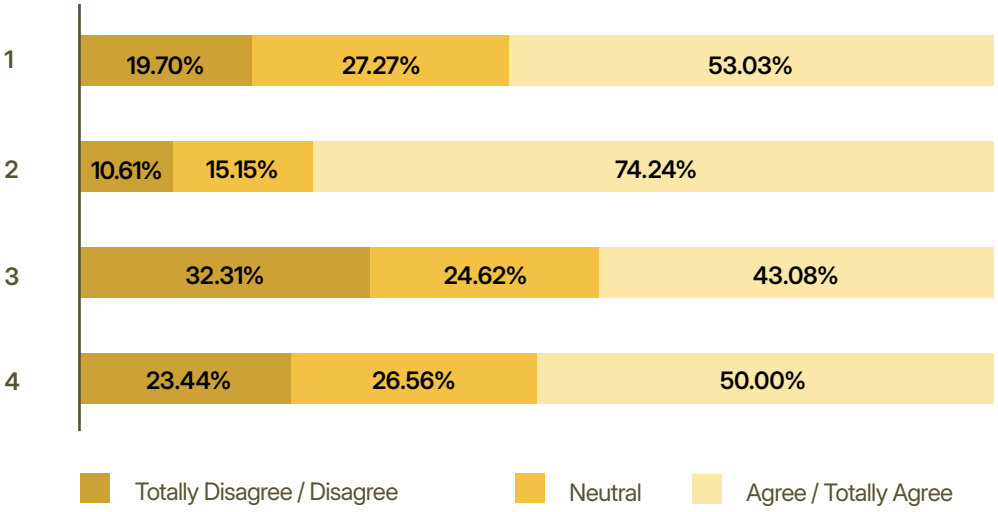
- GQUIP and GEVIT had higher averages (although they are still classified as points of attention). The medians indicate that 31 respondents rated GQUIP as neutral or positive (agree/strongly agree), while this number was 29 for GEVIT.
- The GGTPS, with a mean of 2.51, falls at the threshold between a bottleneck and a point of attention. The low standard deviation indicates consistency in participants' responses.

Taken together, these results reinforce the conclusion that the limitation in human resources is one of the critical factors that impact regulatory speed and efficiency.





B. B. THEMATIC SECTION – REGULATION



REGULATION	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. For the regularization of medical devices, ANVISA provides clear and objective regulations.	3.42	4.0	1.00	66
2. ANVISA's regulations are compatible with the best international practices.	3.83	4.0	0.92	66
3. ANVISA's regulatory process allows for predictability and security for companies seeking to register new medical devices.	3.04	3.0	1.15	65
4. ANVISA is prepared to update its regulations in order to accommodate innovations in the medical device sector.	3.29	3.5	1.15	64
Thematic Section	3.40	3.65	1.1	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

More than half (53.03%) of the participants agree that the regulations are clear and objective, while 19.70% expressed disagreement. The statement assessing the alignment of Brazilian regulations with international best practices received the highest level of agreement, at 74.24%, and the lowest level of disagreement, at 10.61%, making it the most positively perceived item among the respondents.

On the other hand, 43.08% of respondents agreed that ANVISA's process guarantees stability and security to companies, while 32.31% disagreed with this statement.

Regarding ANVISA's ability to update its regulations and incorporate innovations, half of the respondents (50%) agreed, while 23.44% disagreed and 26.56% remained neutral.

EVALUATION OF STATISTICAL RESULTS

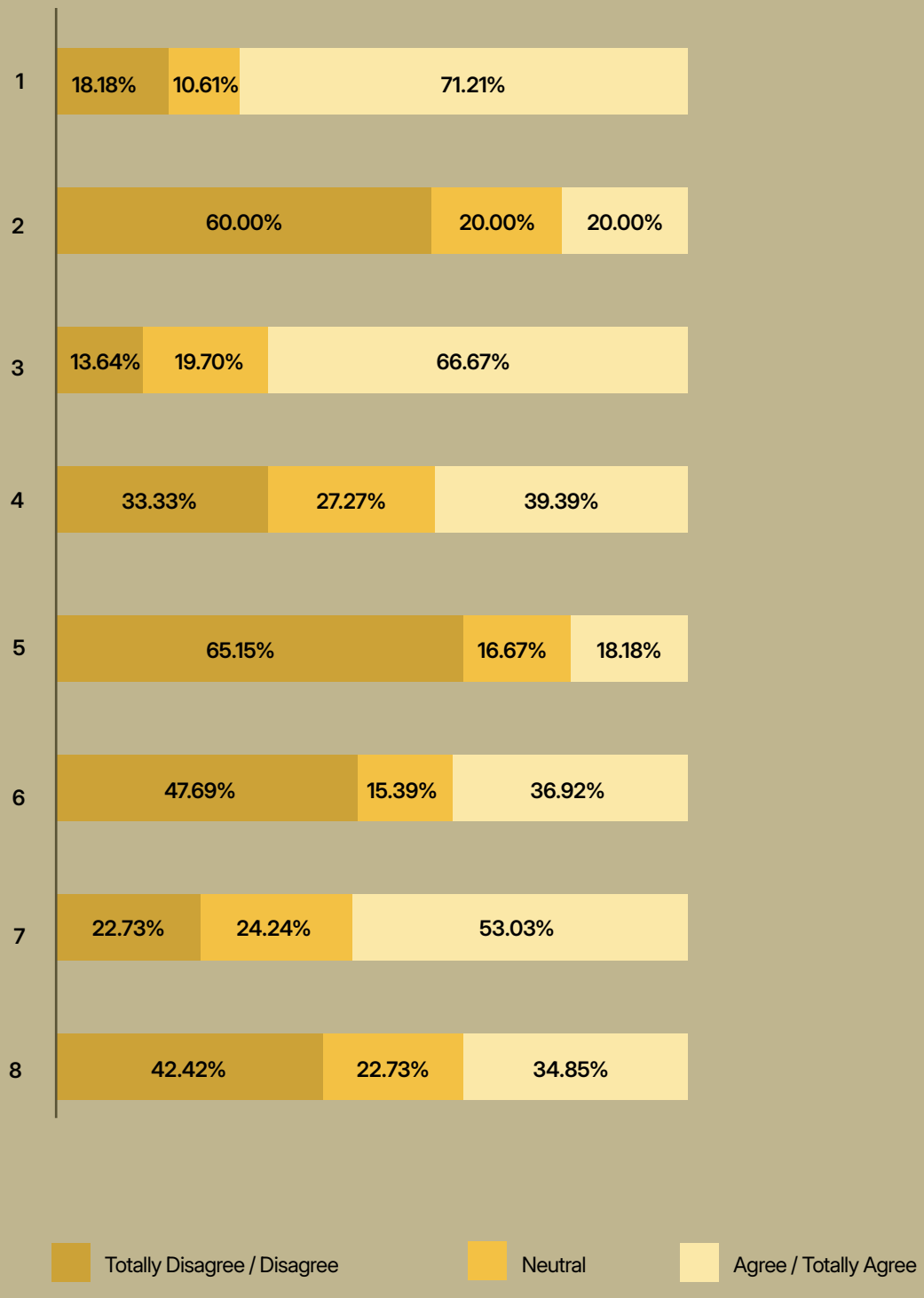
The section presented an average (3.40) at the threshold between the categories "point of attention" and "strengths". When evaluated individually:

- There is a perception that ANVISA provides regulations in line with international best practices. The proximity between mean and median, combined with the low standard deviation, reinforces this aspect as a strength of the institution.
- Regarding the clarity and objectivity of the regulations, although the mean score indicates this item as a point of attention, the median of 4 reveals that half of the participants perceive it as another strength of the institution. Predictability and security for companies to register products as well as the ability to update regulations to accommodate innovations were the points with the lowest average in the section. These results suggest that there is still a perception of uncertainties in these areas that are not considered critical, but require further progress to enhance regulatory certainty to companies.

Strengths - Clear and objective regulations; Regulations compatible with international best practices.

Points of attention - Predictability and security for companies seeking to register new products; Updating regulations to accommodate innovations.

C. THEMATIC SECTION - REGISTRATION PROCESS



REGISTRATION PROCESS	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. The SOLICITA system, used for the electronic submission of applications for the regularization of medical devices at ANVISA, is accessible and easy to navigate.	3.78	4.0	1.15	66
2. The DATAVISA System operates adequately and uninterrupted.	2.30	2.0	1.14	65
3. The documentation required for the regularization of medical devices at ANVISA is adequate and proportional to the risk of the product.	3,74	4.0	0.99	66
4. ANVISA's review of applications for the regularization of medical devices follows standardized protocols that ensure the quality of the analysis.	3,.03	3.0	1.13	66
5. The requirements formulated by ANVISA during product regularization processes are clearly justified and aligned with applicable regulations and standards.	2.86	3.0	1.10	66
6. The information provided by the regulated sector in medical device regularization processes is clear and compatible with the applicable regulations.	3.40	4.0	1.00	66
7. ANVISA analyzes compliance with requirements filed by the regulated sector within reasonable timeframes.	2.78	3.0	1.30	65
8. The average review time for medical devices registration applications at ANVISA is reasonable and compatible with the dynamism of the sector.	2.16	2.0	1.19	66
Thematic Section	3.01	3.1	1.1	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

71.21% of the respondents agreed that the SOLICITA system is accessible and easy to navigate, and only 10.61% expressed disagreement. On the other hand, the performance of the DATAVISA system generated the highest level of dissatisfaction among the items in the section, with 60% of respondents expressing disagreement and 20% expressing agreement.

The documentation required for product regularization received a predominantly positive evaluation: 66.67% of the participants agreed that the set of requirements is adequate and proportional to the product risk, while only 19.7% disagreed.

In the analysis of regularization requests, 39.39% of respondents agreed that the evaluation protocols are standardized and ensure quality, while 33.33% disagreed and 27.27% remained neutral.

The item referring to the average time for analysis of registration requests recorded the highest level of disagreement of the entire section: 65.15% of respondents indicated that review timelines are neither reasonable nor compatible with the dynamism of the sector, while only 18.18% agreed.

Regarding ANVISA's review of compliance with requirements, 47.69% of the participants disagreed that the timelines are reasonable, compared to 36.92% who agreed.

53.03% of respondents agreed that the information provided by the regulated sector is clear and compatible with regulation, while 22.73% disagreed.

The item concerning the clarity and justification of requirements formulated by ANVISA obtained a balanced distribution, with 42.42% of disagreement and 34.85% of agreement.

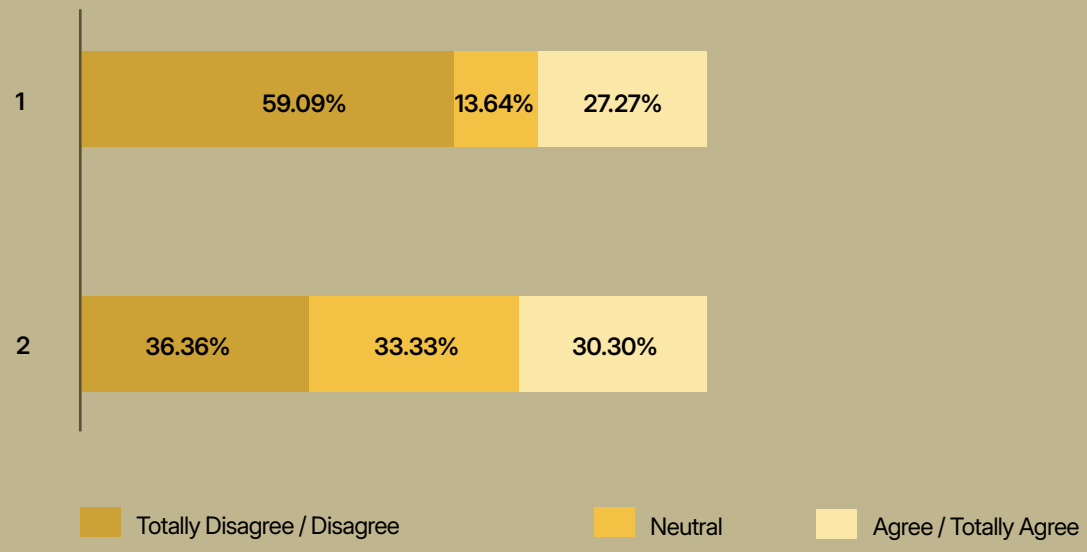
EVALUATION OF STATISTICAL RESULTS

Although the overall mean, median, and standard deviation for this section are broadly consistent and place the section within the "Point of Attention" category, this perception is not maintained when the data are analyzed individually.

- The electronic submission through the SOLICITA System, as well as the adequacy and proportionality of the required documentation, were highlighted by the survey as strengths of the process.
- The mean, median and standard deviation data indicate that the DATAVISA System is perceived as a bottleneck in terms of performance. The low scores suggest that the system is performing inadequately and unstable.
- On the other hand, the standardization of document reviews, the clarity and regulatory alignment of ANVISA's requirements, as well as the quality of information provided by the regulated sector fall within the "Point of Attention" category, based on their respective means and standard deviations.
- Regarding the analysis of compliance with requirements within reasonable timelines, the standard deviation of 1.30 indicates controversies and polarizations among the survey participants.
- Regarding the average review time for registration applications represent the most critical issue within this section (although, not classified as a bottleneck due to the high discrepancy of opinion). The low mean (2.16) and median (2.0) indicate dissatisfaction with the average analysis timelines. While the high standard deviation (1.18) reflects greater dispersion and variability in responses, the prevailing assessment remains negative, as half of the respondents rated this item at or below 2.

STRENGTHS	Strengths – The SOLICITA System for electronic filing and risk-based adequacy and proportionality of documentation for product regularization.
POINTS OF ATTENTION	Points of Attention – Standardized protocols for analyzing requests, clear reasoning compatible with regulations governing the requirements formulated, clarity of information, and compatibility with regulations governing the information provided by the regulated sector.
BOTTLENECK	DATAVISA System.
CONTROVERSIES	Controversies – Average time for analyzing registration applications and deadline for analyzing compliance with requirements.

D. THEMATIC SECTION - INTERACTION AND COMMUNICATION WITH ANVISA



INTERACTION AND COMMUNICATION WITH ANVISA	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. ANVISA's service channels are efficient and allow for the timely resolution of doubts and pending issues.	2.50	2.0	1.20	66
2. ANVISA's communication with companies in the medical device sector is transparent and predictable.	2.90	3.0	1.10	66
Thematic Section	2.7	2.5	1.15	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

The statement about the transparency and predictability of communication with companies obtained 36.36% of disagreement, against 30.30% of agreement, and 33.33% of neutral respondents.

Most participants (59.09%) disagreed that the service channels are efficient and capable of allowing the timely resolution of doubts and pending issues, while 27.27% indicated agreement with the standard.

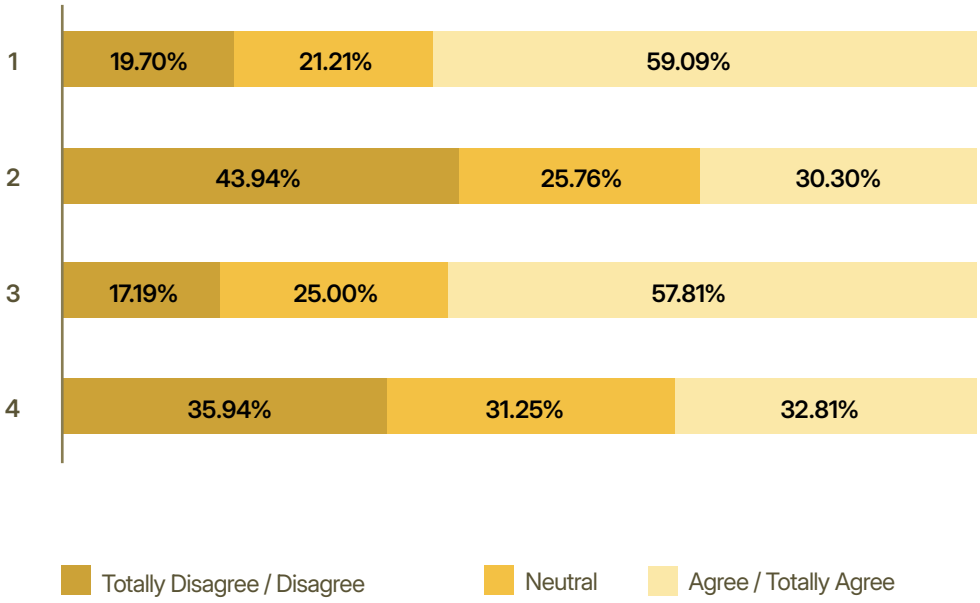
EVALUATION OF STATISTICAL RESULTS

The results of this section were negative (average 2.9), signaling problems in both service channels and the predictability of institutional communication. The regulated sector seems to consider that ANVISA does not provide sufficiently agile or clear answers. This perception weakens the relationship between regulator and regulated entities, reinforcing the need for greater transparency and structured dialogue.

POINTS OF ATTENTION

Points of Attention – Service channels are efficient and responsive in resolving queries, and communication with companies is transparent and predictable.

E. THEMATIC SECTION - EFFICIENCY AND CONTINUOUS IMPROVEMENT



EFFICIENCY AND CONTINUOUS IMPROVEMENT	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. ANVISA constantly seeks to improve its processes to make the regularization of medical devices more efficient.	3.60	4.0	1.16	66
2. There is an appropriate balance between health safety and agility in the approval of new medical devices.	2.80	3.0	1.12	66
3. ANVISA considers the opinion of the medical device sector when formulating and updating its regulations.	3.48	4.0	1.02	64
4. Brazil has a competitive regulatory environment for innovation and the launch of new medical devices.	2.85	3.0	1.13	64
Thematic Section	3.18	3.5	1.11	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

The statement with the highest level of agreement was that ANVISA constantly seeks to improve its processes to make the regularization of products more efficient, with 59.09% of agreement and only 19.70% of disagreement.

The second most favorable assessment related to ANVISA's consideration of the opinion of the medical device sector in the formulation and updating of regulations, with 57.81% of agreement and 25% of disagreement.

Responses regarding the balance between health security and agility in the approval of new devices reveal that 43.94% of the participants disagreed that such balance exists, while 30.30% agreed.

The statement assessing whether Brazil offers a competitive regulatory environment for innovation and the introduction of new medical devices presents balanced results, but slightly negative: 35.94% disagreement and 32.81% agreement.

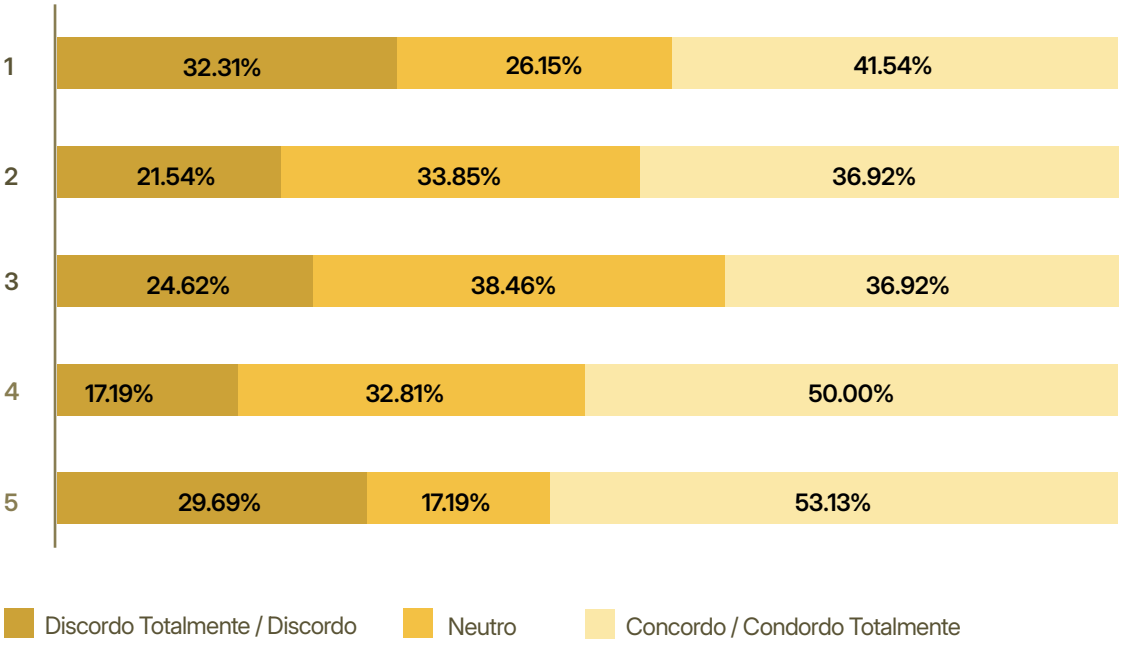
EVALUATION OF STATISTICAL RESULTS

The mean, median and standard deviation of the thematic section place it within the category of a "Point of Attention" in issues related to efficiency and continuous improvement.

- Two items were considered strengths by the respondents, ANVISA's constant effort to improve and streamline its processes and the Agency's willingness to consider input from the regulated sector in the construction or updating of regulations. The means and standard deviations indicate consistency and are translated as strengths of the institution.
- As for the balance between health security and agility, and a competitive regulatory environment for innovation, both were seen as "Points of Attention" by the respondents.

POINTS OF ATTENTION	Points of Attention – Appropriate balance between health safety and agility in the approval of new products.
STRENGTHS	Strengths – Constant pursuit of process improvement to make the regulation of medical devices more efficient and effective. The opinion of the medical device industry is considered in the formulation and updating of regulations.

F. THEMATIC SECTION - INTERACTION BETWEEN ANVISA AND INMETRO



INTERACTION BETWEEN ANVISA AND INMETRO	AVERAGE	MEDIAN	STANDARD DEVIATION	RESP.
1. Collaboration between ANVISA and INMETRO in the process of conformity assessment of medical devices is efficient.	3.03	3.0	1.18	65
2. INMETRO's requirements for conformity assessment of medical devices are aligned with ANVISA's requirements.	3.23	3.0	1.16	65
3. The certification process conducted by INMETRO is completed within reasonable timeframes, so not to avoid delays in the commercialization of medical devices.	3.06	3.0	1.17	65
4. The requirement for INMETRO certification for medical devices adds value to the regulatory process, enhancing safety and quality of products.	3.45	3.5	1.15	64
5. The requirement for laboratory tests by INMETRO for medical devices is in line with international standards and avoids duplication of regulatory requirements.	3.23	4.0	1.35	64
Thematic Section	3.2	3.3	1.20	

EVALUATION OF THE PERCENTAGE OF RESPONSES RECEIVED CONSIDERING "AGREE", "NEUTRAL" AND "DISAGREE".

The statement regarding the collaboration between ANVISA and INMETRO received 41.54% agreement, while 32.31% of the participants disagreed.

With respect to the alignment of INMETRO's requirements with those of ANVISA, 44.62% agreed and 21.54% disagreed.

The statement addressing the adequacy of the timelines in INMETRO's certification process recorded 36.92% agreement, against 24.62% disagreement and 38.46% neutrality. Thid indicates absence of a consistent perception among respondents about the adequacy of the certification timelines.

The item assessing whether INMETRO certification adds value to the regulatory process was the second most positively evaluated in the section: 50% agreement and only 17.19% disagreement.

Finally, the requirement of laboratory tests by INMETRO presented the highest level of agreement with 53.13% of the respondents, but also registers 29.69% of disagreement.

EVALUATION OF STATISTICAL RESULTS

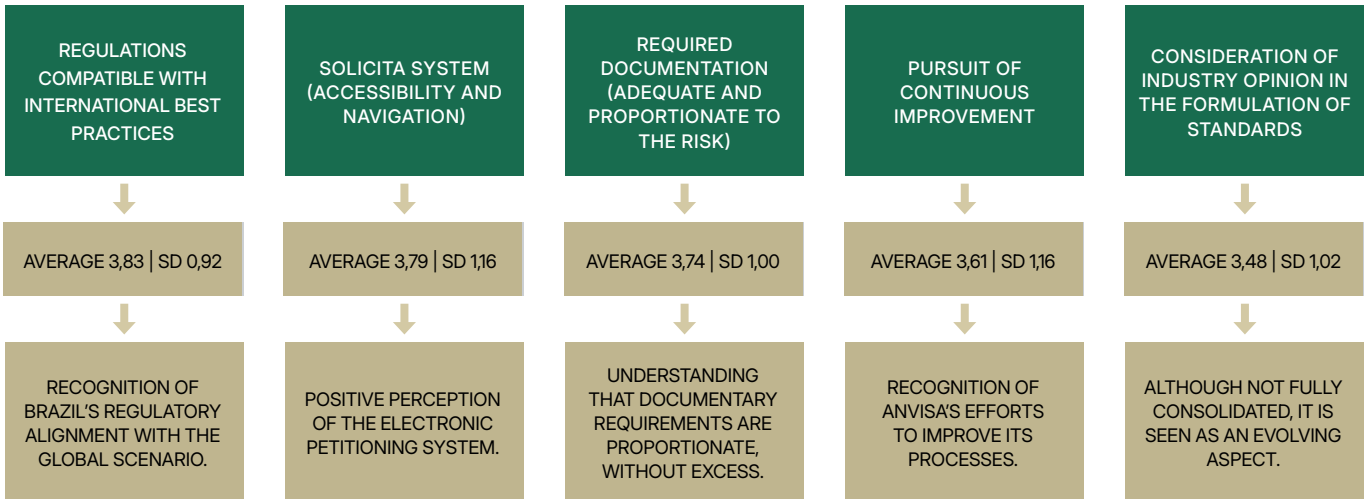
The overall evaluation of the thematic section, with an average of 3.2, indicates an intermediate position. The high standard deviation reveals a wide dispersion of the data around the mean, reflecting divergent perceptions among the respondents.

- The value added by INMETRO certification, in terms of ensuring the quality and safety of products, was recognized as a strength, with a mean score of 3.45. The low dispersion of the data indicates cohesion.
- The efficiency of the collaboration between ANVISA and INMETRO was classified as a point of attention, although the standard deviation indicates divergence in opinions.
- Other areas of attention include the alignment of INMETRO's requirements with those of ANVISA and the timelines applied in the certification process.
- The item "requirement of laboratory tests in line with international standards" presented a high standard deviation (1.35), with a discrepancy between the mean and the median. This reinforces the existence of asymmetric positions among the respondents.

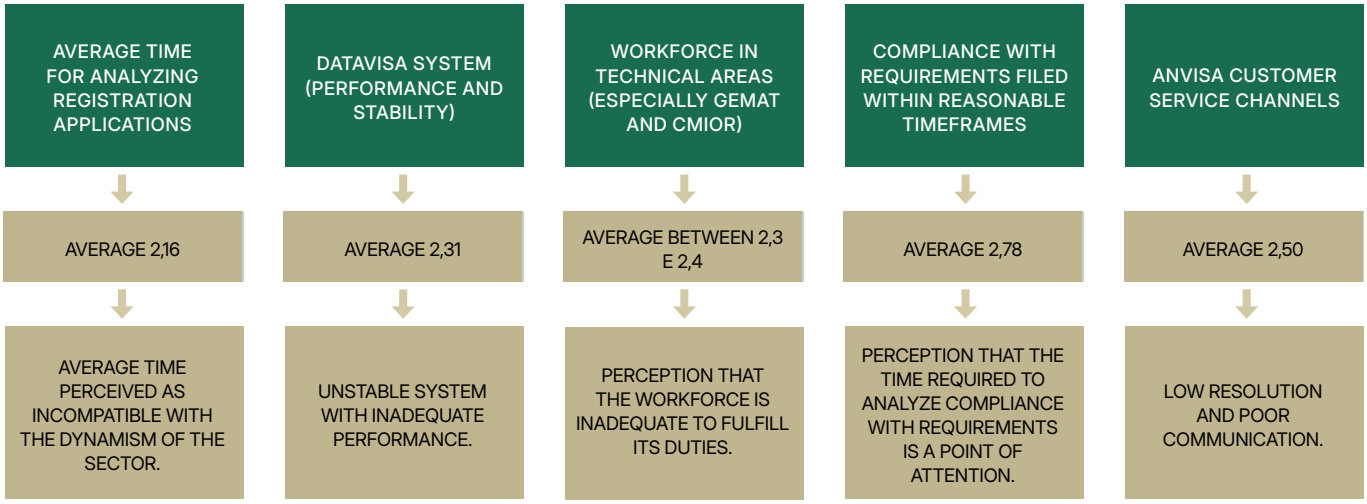
G. ITEMS WITH HIGHER AVERAGES AND LOWER AVERAGES

The figures below highlight items with higher and lower average scores, as well as those exhibiting greater level of disagreement, as discussed in the thematic sections.

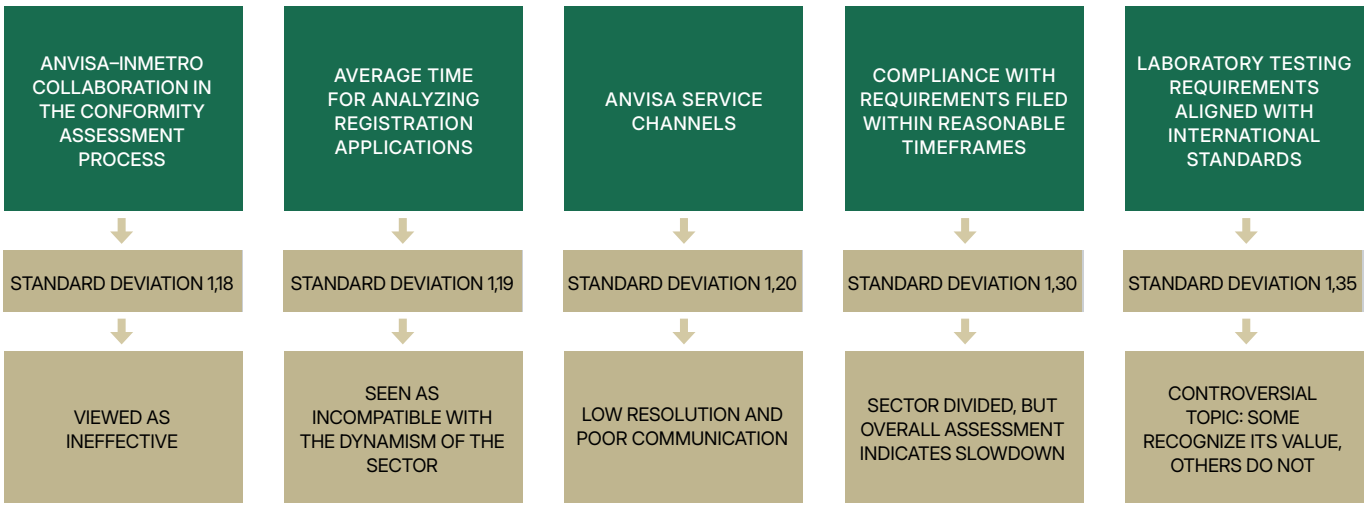
HIGHEST AVERAGES



LOWEST AVERAGES



H. CONTROVERSIAL ITEMS (HIGH STANDARD DEVIATION)



The divergences pointed out above show that the regulatory experience is not homogeneous.

I. DISCUSSION OF RESULTS – GENERAL CONTEXT

The analysis of the responses indicates that perceptions within the regulated sector regarding Brazil's regulatory environment of medical devices combine meaningful progress with persistent structural weaknesses. On the one hand, respondents recognize ANVISA's effort to improve its processes, reflected into relatively positive evaluations on digitalization through the SOLICITA system, which is viewed as accessible and efficient, and on the adequacy of the required documentation, considered proportional to product risk. Respondents also highlight the alignment of Brazilian regulations with international practices, an aspect perceived as a positive differential that enhances the legitimacy of the adopted standards.

On the other hand, significant bottlenecks persist and compromise the speed and predictability of the regulatory process. Among them, the insufficiency of human resources in ANVISA's strategic technical areas, the instability of the DATAVISA system and, above all, the length of review timelines. These timelines are widely perceived as incompatible with the dynamism of the medical devices sector. These constraints are combined with perceptions of insufficiency regarding the clarity and reasoning of certain complementary requirements, as well as the consistency of the review practices, suggesting room for improvement in objectivity and predictability in the processes.

Institutional interactions are also critically evaluated. ANVISA's service channels and communication with the regulated sector were perceived as fragile, with low averages and high dispersion, indicating heterogeneous experiences and a limited level of confidence in existing mechanisms for structured dialogue. While respondents acknowledge ongoing efforts toward continuous improvement and a degree of openness to consider the opinions of the sector, these advances have not been sufficient to generate a perception of an appropriate balance between security and agility, nor to consolidate a competitive regulatory environment for innovation.

The relationship between ANVISA and INMETRO emerges as a particularly ambivalent dimension. There are those who recognize that INMETRO's adds value to the regulatory process by reinforcing the safety and quality of the products. At the same time, recurring criticisms relate to procedural delays, overlapping requirements and the duplicity of laboratory tests. This last aspect stands out as the most controversial aspect of the survey, with sharply divided evaluations between those who view international alignment and those who perceive unnecessary obstacles.

Overall, the study reveals a regulatory system that advances in normative and technological aspects but which remains limited by institutional, technological and interinstitutional coordination barriers. Strengthening of human resources, modernizing electronic systems, reducing review timelines and improving communication with the regulated sector emerge as priorities for enabling Brazil's medical device regulatory environment to become more agile, predictable and competitive, while fully preserving the safety and high performance that underpin health regulation.

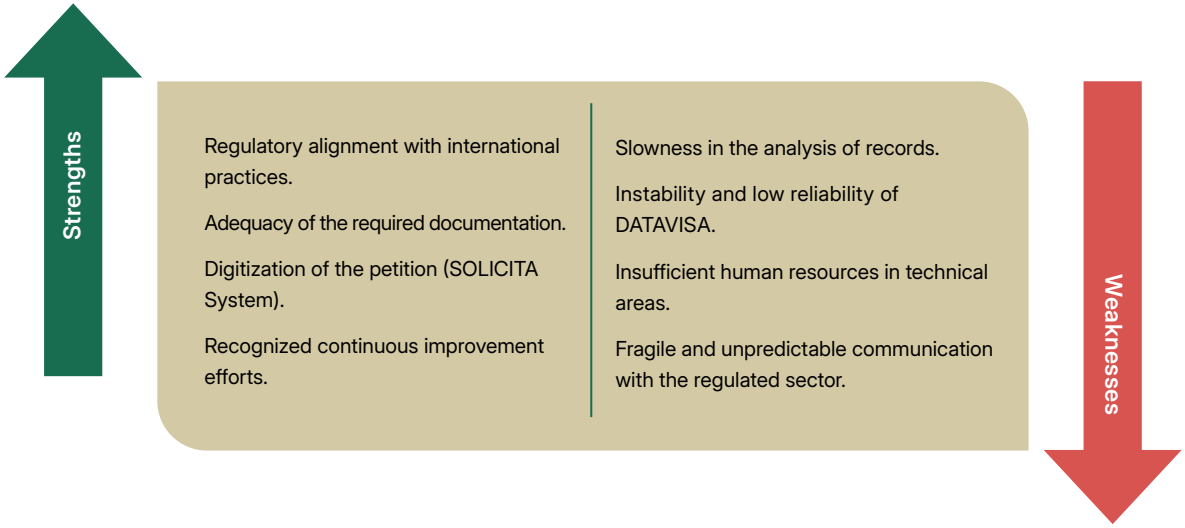
ORGAN	OVERALL AVERAGE	INTERPRETATION
ANVISA	3.31	Intermediate evaluation – considered reasonable, but with bottlenecks related to review timelines, service channels and predictability.
INMETRO	3.20	Intermediate evaluation – mixed perception: recognizing the added value of certification, highlighting criticism regarding delays and duplicities.

PERCEPTION OF ANVISA

ANVISA is perceived in an ambivalent way. On the one hand, respondents recognize important advances that reinforce the image of an agency that seeks modernization and continuous improvement.

On the other hand, the structural factors mentioned above, and especially the insufficiency of human resources, negatively affect the institution's public image. Although ANVISA is widely regarded as a technically robust and well-positioned authority on the international scene, the general perception is of an overloaded, slow, and insufficiently transparent agency in its daily interaction with the regulated sector.

In summary: ANVISA is viewed as a competent institution, but limited by structural obstacles, projecting regulatory strength, but operational fragility.



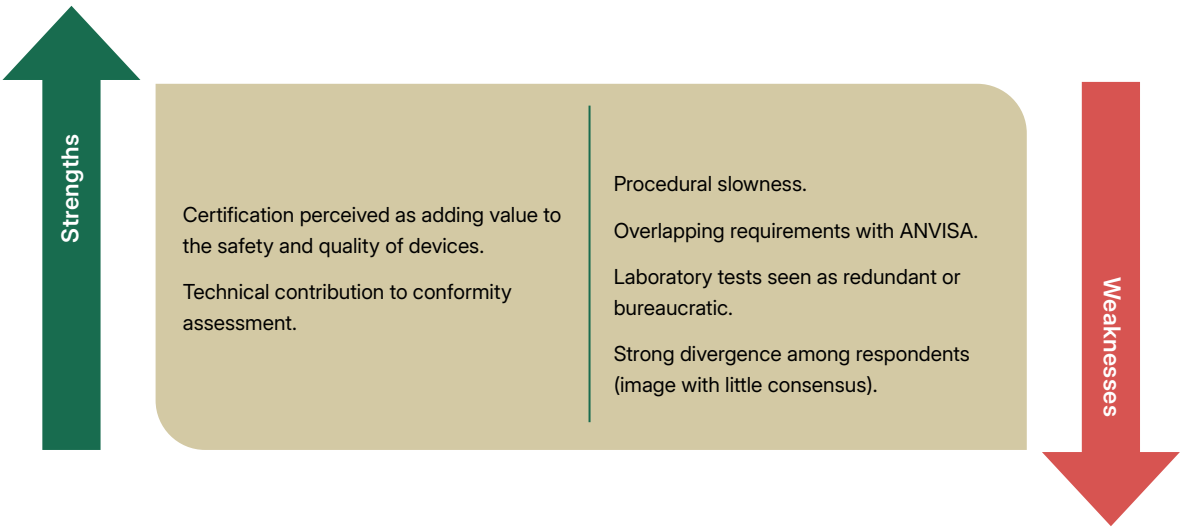
PERCEPTION OF INMETRO

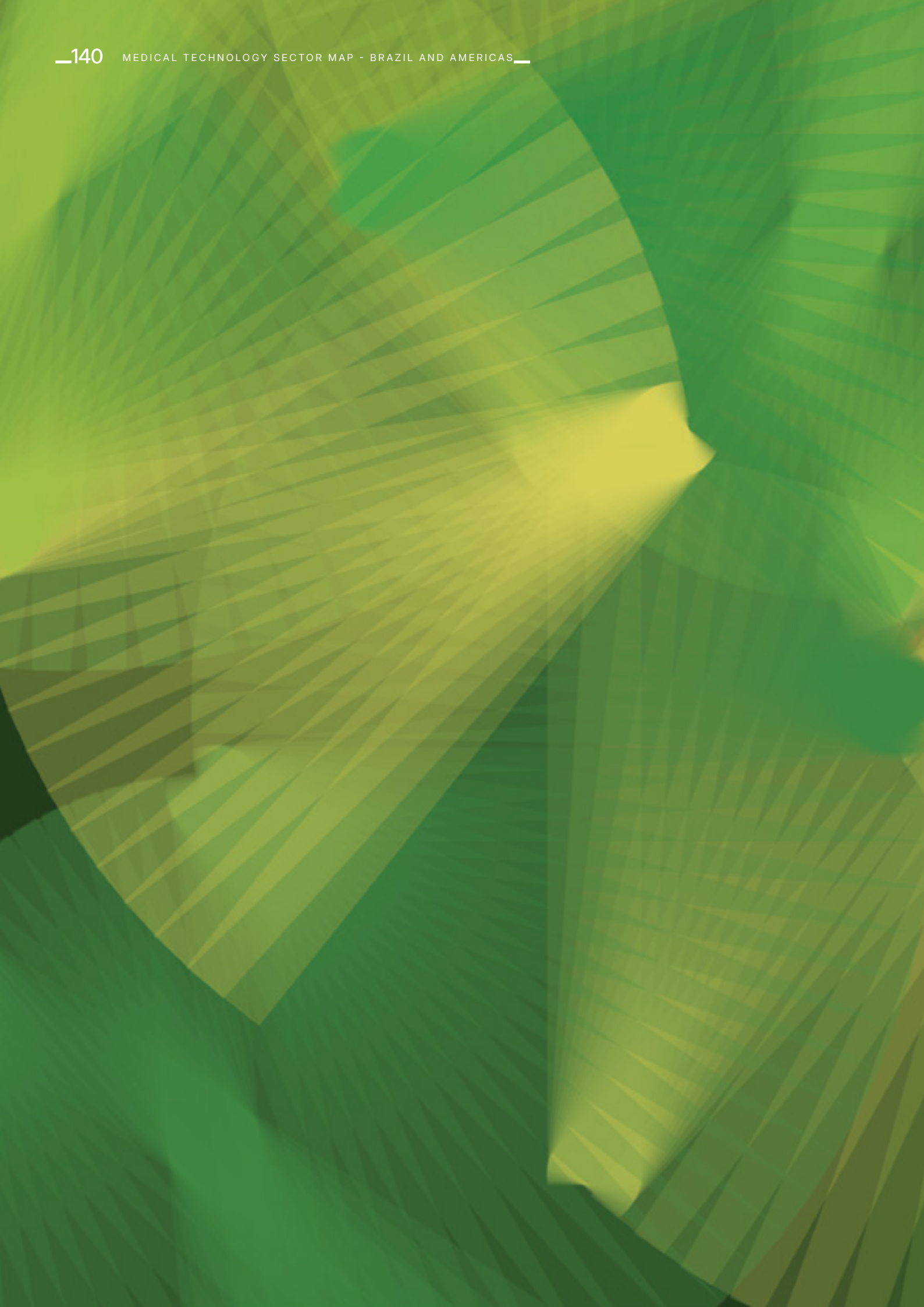
INMETRO, in turn, is perceived in an even more controversial way. There is a certain recognition that its certification activities add value to the regulatory process by ensuring greater safety and quality to products, thereby reinforcing its role as a technical guarantor of conformity.

However, the respondents also associate INMETRO with negative attributes, such as procedural delays, overlapping requirements with ANVISA and the perception that laboratory tests are often redundant and bureaucratic. The high dispersion of responses in this section suggests a lack of consensus in the sector: for some, INMETRO adds reliability; for others, it represents an unnecessary obstacle to regulatory efficiency.

In summary: INMETRO is viewed as an essential institution, whose role is not yet calibrated in its articulation with ANVISA, resulting in divided opinions between value added and excessive bureaucracy.

- ANVISA projects a more solid image, recognized for its technical competence and international alignment, but weakened by operational constraints.
- INMETRO is perceived as more unstable in its reputation, with polarized perceptions: valued for the security it provides but criticized for bureaucracy and lack of integration.





Final Notes and Suggestions

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8. Final Notes and Suggestions

This study set out to provide an overview of the medical technology sector in Brazil and in five countries in the Americas – Argentina, Canada, Colombia, the United States and Mexico – with the objective to identify regulatory bottlenecks and suggest proposals that may contribute to overcoming challenges faced by ANVISA, and especially GGTPS, as well as by the sector as a whole.

The motivation for ABIIS to undertake this study lies in the context currently faced by GGTPS, responsible for the pre-market control of medical devices, amid a sustained increase in demand for product regularization. This demand has been driven not only by the growing complexity of the regulated devices, but also by the continuous emergence of new technologies subject to regulation control. This scenario contrasts with the stagnation of the available workforce, imposing challenges not only for the regulatory authority, but also for the regulated sector and ultimately for the population's access to these devices.

By comparing regulatory frameworks across countries, the study seeks to identify not only similarities and differences between the regulatory models, but also alternatives and innovative solutions, which may serve as a reference, an example or an inspiration to address the challenges experienced by the GGTPS, while preserving the protection of the population's health and improving access to medical products.

Among the countries analyzed, Brazil has the second-largest population, totaling 211,140,729 inhabitants, behind only the United States. The country has the largest public health system in the world – free of charge and universal, with expenditures corresponding to approximately 9.89% of Brazilian GDP. Imports of medical devices registered a growth of 19.4% in 2024 compared to 2023, reaching the figure of 8 billion dollars. The number of authorizations for the commercialization of products (notifications and registrations) also increased by 5.44% over the same period, totaling 8,320 new authorizations in 2024.

Considering the annual population growth and demographic aging, which are reshaping the country's demographic composition, it is evident that the demand for services and products will continue to expand. Consequently, the demand for new registrations will continue to rise, requiring the government to be attentive and prepared for this scenario.

This scenario is also repeated in other countries, indicating a global trend of growth in the demand for health products and services. In view of this, it is imperative to adopt measures that promote regulatory convergence and strengthen international cooperation between countries, enabling faster and more reliable analysis and approval of registrations.

GLOBAL CONTEXT AND INDUSTRY TRENDS

The global medical technology market reached US$ 542.21 billion in 2024, and is projected to reach US$ 572.31 billion in 2025, maintaining an average annual growth of 6.5% until 2032. North America leads with 38% of the global market, followed by Europe (27%) and Asia-Pacific (23.5%), the latter being the fastest-growing region.

- The main technological trends are::
  - Artificial Intelligence (AI) and machine learning;
  - Wearable devices and remote monitoring;
  - Robotic surgery and 3D printing;
  - Digitization and interoperability of clinical data.

There is a convergence between engineering, biotechnology, and data science, with a strong emphasis on personalization of care and continuous innovation.

BRAZIL'S POSITION AND CHALLENGES

Brazil is the largest market in Latin America, with an estimated value of US$ 15.4 billion in 2024, representing 2.5% of the global market. Imports reached US$ 8.0 billion (+19.4%), and exports, US$ 852 million (+8.7%), with the US accounting for 22% of export destination. The country remains highly dependent on imports of advanced technologies (USA and Germany = 30% of the total). The In Vitro Diagnostics (IVD) segment was the main growth driver (+28.4%), well above the global average (8%).

Brazil has competitive potential in specific niches (IVD, prostheses, remote monitoring) but continues to face internal challenges that hinder its consolidation as an export and innovative hub.

REGULATORY CONVERGENCE

All countries examined participate in regulatory initiatives aimed at regulatory convergence, with emphasis on activities related to IMDRF and MDSAP:

- **Argentina –** Participates as an observer member of the IMDRF and an Affiliate Member of the MDSAP.
- **Colombia –** Participates as an Affiliate Member of the IMDRF.
- **Brazil, Canada and the United States** – Members of the IMDRF Steering Committee, jointly responsible with other countries for the supervision and decision-making for all IMDRF activities. As founding members of the Program, they participate in the MDSAP Council of Regulatory Authorities, supporting the development, maintenance and expansion of the program. They also actively participate in the process of recognition and monitoring of Auditing Organizations.
- **Mexico–** Participates in IMDRF and MDSAP as an Affiliate Member.

HUMAN RESOURCES

Human resources are a recurring indicator in different sections of the *WHO Global Benchmarking Tool Plus Medical Devices*[132], a tool developed by the World Health Organization to evaluate national regulatory systems in the different functions involving the life cycle of health products.

Among the indicators related to the Registration and Authorization for Marketing function, sub-indicator MA03.1 stands out: Sufficient competent personnel to conduct registration or marketing authorization activities, whose objective is "to ensure that the available human resources are sufficient, in terms of quantity, experience and specific skills to perform all the steps involved in the registration or authorization of marketing of products".

In other words, this is an essential area for the execution of regulatory activities, not only those related to pre-market control, but all those involving the life cycle of products.

In Brazil, the GGTPS workforce has remained largely unchanged since 2015, despite a significant increase in demand for regularization services and related activities. In the last ten years, the staff number has increased from 47 to 48, despite ANVISA's 2016 estimated assessment for the need for 112 professionals.

This gap directly impacts the performance of the technical areas, resulting in an increase in the review timeframes of product regularization submissions.

The ABIIS survey – *Mapping in the Health Sector* reinforces the perception that workforce shortages constitute one of the main challenges faced by GGTPS, especially by GEMAT (unit with the highest demand compared the other three areas) and by CMIOR (the area of orthopedic implants). On the other hand, GQUIP and GEVIT were better perceived, with more than 60% of the respondents being neutral or agreeing with the statement that the workforce is adequate to perform its statutory responsibilities. For comparison purposes, Health Canada's Medical Devices Directorate, responsible for pre-market control, employs 165 professionals.

On the other hand, the workforce figures focused on medical device control activities throughout their life cycle and involving other areas, such as post-market surveillance and inspection, indicate variations: ANVISA is composed of 113 professionals, ANMAT of 100, INVIMA of 65, while the FDA-CDRH has 2,260 servers dedicated to these activities.

Analyzing the simplification of regulatory processes, several measures have been adopted over the last ten years to mitigate the workforce constraint. Among them, ANVISA established simplified controls for the regularization of low-risk MD and IVD MD, currently called

132 Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)

"Notification", increased the validity period of records to ten years, and adopted the Reliance model, among other initiatives.

RISK CLASSIFICATION OF PRODUCTS

Product risk classification is directly related to the level of control required to ensure the safety and performance of the device, as well as the procedures established for conformity assessment.

These controls must be proportional to the degree of risk: the lower the risk, the lesser the need for control. This allows the regulator to allocate its resources more efficiently, prioritizing areas of greatest need.

There are variations across countries regarding the criteria used for product risk classification:

- **Argentina and Brazil** – Mercosur member countries – adopt risk classifications for MDM and MD IVD aligned, respectively, with Regulations No. 745/2017 and No. 746/2017 of the European Union. Products are classified into four risk classes for both medical devices and *in vitro diagnostics*.
- **Canada and Colombia** – Follow risk classifications for medical devices based on Directive No. 93/42/EEC of the European Union. For MD IVD, it was not possible to identify the normative of reference used for risk classification. In Canada, products are classified into four risk classes, for both MD and MD IVD. In Colombia, MDs are classified into four classes and MD IVD into three.
- **United States** – Have a database with approximately 1,700 generic types of medical devices, classified and grouped into 16 medical specialties.
- **Mexico** – Rules for risk classification of products are described in Appendix II of the Mexican Pharmacopoeia, available upon purchase.

Divergences in risk classification across countries may represent obstacles to international trade, creating unjustified regulatory barriers. These differences directly impact product entry strategies into new markets, raise operating costs, and may delay the population's access to secure devices with adequate performance.

CONFORMITY ASSESSMENT OF MDS AND MD IVDS AGAINST ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS

According to the *Principles of Conformity Assessment for Medical Devices SG1 Final Document GHTF/SG1/N78:2012*, conformity assessment is defined as the "systematic examination of the evidence generated the procedures undertaken by the manufacturer, under requirements established by the regulatory authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *essential principles of safety and performance for medical devices (SG1/N041)*."

In general, the regulatory pathways for assessing pre-market control vary according to the risk classification of the products. This study focuses on the procedures adopted by the selected regulatory authorities, with particular emphasis on the documentation required in the technical dossier to demonstrate compliance with essential safety and performance requirements.

In Argentina, proof of compliance is based on the submission of information related to the tests performed on the product, according to its risk classification.

- MD classes I and II – Locally manufactured – Submission of a declaration of conformity attesting to tests performed according to the EPSP.
- MD classes III and IV – Locally manufactured – Proof of compliance with the essential requirements through the presentation of original tests addressing the applicable requirements.

- MD IVD incorporating electrical equipment—Submission of test certificates according to IEC 61010 standards, issued by laboratories accredited by the Argentine Accreditation Body.
- MD IVD Group D – Certain MD IVD are subject to mandatory laboratory analysis, according to the test protocol previously approved by the INPM.

In Brazil, companies must prove compliance with essential safety and performance requirements according to the product risk classification.

- MD and MD IVD classes I and II – maintenance of a technical dossier at the company premises, containing the evidence of compliance with essential requirements and results of tests performed, as provided for in regulations.
- MD and MD IVD classes III and IV—submission of a technical dossier filed before ANVISA, containing the essential requirements and tests performed, accompanied by the other documents required by the authority.
- MD IVD class IV – certain MD IVD are subject to prior analysis at the INCQS..
- Some medical devices, regardless of the risk classification, are subject to compulsory third-party certification, as established in specific regulations issued by ANVISA. Certification is carried out under the scope of the Brazilian Conformity Assessment System, and the requirements for conformity assessment (RAC) are issued by INMETRO..

In Canada, compliance with essential requirements is demonstrated through the use of voluntary technical standards recognized by Health Canada, made publicly available through an official list, together with the submission of a declaration of conformity. The use of these standards is voluntary. Manufacturers may choose to comply with a standard equivalent to or more stringent than a recognized standard, or to submit alternative evidence demonstrating device conformity, which is then subject to evaluation.

In Colombia, MD compliance with essential requirements must be proven through the submission of scientific information, a list of standards applied in the conformity assessment process, and a description of solutions adopted to meet safety and performance requirements. For higher-risk products (classes IIb and III), clinical studies are also required.

For higher-risk IVD MDs (category III), manufacturers must obtain a "Specialized Technical Concept", issued by specialists who are part of the Specialized Chamber for Medical Devices and Reagents for *in vitro Diagnostics*. This opinion is based on the analysis of clinical and analytical studies, a review of scientific literature and, when necessary, laboratory analysis.

In the United States, compliance of MD and MD IVD may be demonstrated through the voluntary use of FDA-recognized consensus standards, with the issuance of a Declaration of Conformity (DOC) by the manufacturer as a prerequisite. Alternatively, manufacturers may choose to apply a standard, whether recognized or not, without issuing a DOC. In such cases, compliance is demonstrated through the submission of complete test reports. Another possibility is to join the "Accreditation Scheme for Conformity Assessment" Program, a voluntary initiative that allows testing to be conducted by laboratories accredited by the FDA.

In Mexico, conformity of MD classes II and III is demonstrated through the submission of complete test reports performed according to specifications of the Mexican Pharmacopoeia, Mexican Official Standards or applicable international standards. When no relevant reference standards exist in the documents, manufacturer may submit tests developed internally. Electromedical equipment must include specific tests conducted according to the IEC 60601 standard. For MD IVD, class III diagnostic agents for hepatitis B and C, HIV and products intended for blood typing are required to submit evaluation results issued by laboratories authorized by the Health Department.

REGULATORY DEADLINES

Legal deadlines for product regularization vary across countries. The table below presents the legal deadlines established by authorities for the regularization of high-risk MDs and MM IVDs.

The comparison of the statutory deadlines applied to product regularization in the different countries reveals significant differences, with a shorter legal deadline for Mexico and a longer one for Brazil.

Mexico	Colombia	Canada	Argentina	United States	
Class III	Class III	Class IV	Class IV Group D	Class III	Class IV
30 to 35 working days	90 days	90 days	110 working days	290 days	Equipment – 250 days
					Material – 320 days
					IVD – 365 days

AVERAGE DECISION TIMES FOR REGISTRATION APPLICATIONS - BRAZIL

An analysis of average review times (Classes III and IV) handled by GGTPS:

- Management of materials for use in health – Although the statutory deadline is 320 days, the average review time reached 411 days in the period from July 2024 to June 2025. For orthopedic implants, the average was even longer, reaching 427 days.
- Management of products for *in vitro diagnostics* – The average review time was 200 days in the period from July 2024 to June 2025, below the statutory deadline of 365 days.

- Equipment technology management—The average review time was 98 days in the period from July 2024 to June 2025, below the statutory deadline of 250 days.

Data from the sector survey indicates that 65.15% of the respondents totally or partially disagree with the statement "The average review time for registration applications is reasonable and compatible with the dynamism of the sector".

AVERAGE DECISION TIMES FOR PRODUCT LICENSE – CANADA

Analysis of average timelines of medical device licenses:

- Class II—Although the statutory timeline is 15 days, the average review time between July 2024 and June 2025 was 40 days..
- Class III—Although the statutory timeline is 75 days, the average review time between July 2024 and June 2025 was 217 days.
- Class IV—Although the statutory timeline is 75 days, the average review time between July 2024 and June 2025 was 240 days.

AVERAGE DECISION TIMES FOR REGULARIZATION OF PRODUCTS – UNITED STATES

- 510(k) pre-market notifications – Between July 2024 and June 2025, the MDUFA's timelines was 124 and 112 days for 2024 and 2025 respectively, while the average review time was 152 days.
- Pre-market approval—Between July 2024 and June 2025, MDUFA's timelines was 290 and 285 days for 2024 and 2025 respectively, while the average review time was 436 days.

AVERAGE DECISION TIMES FOR REGULARIZATION OF PRODUCTS – MEXICO

Data available for the period from January to September 2025.

- Class I products—statutory timeline of 30 days, while the average review time was 65 days.
- Class III products—statutory timeline of 60 days, while the average review time was 121 days..

Comparison of average review times across regulatory authorities for the regularization of MD and MD IVD are subject to a series of limitations that compromise the level of detail achievable. Among the limitations are:

- Heterogeneous risk classification: differences in risk classification directly affect technical and documentary requirements of each regulatory route.
- Differences in regulatory frameworks: National regulations vary in scope, flows, and controls applied.
- Procedures applied to conformity assessment: vary between countries, ranging from documentary evidence to mandatory third-party certification.
- Limited public data availability: The limitation of databases allowing to compare deadlines across countries is another challenge. Only ANVISA and the FDA provide databases that allow comparison between statutory deadlines and actual review times. Health Canada publishes performance data upon request. Other authorities provide data on regularized products and validity periods, but do not have sufficient information to calculate average timelines.
- Workforce: the available workforce directly influences regulatory response times.

SUGGESTIONS

The study highlights the challenges faced by different regulatory authorities and the medical device industry, especially in the context of the increasing market complexity. Despite ongoing efforts of different organizations to promote regulatory convergence and international cooperation, significant obstacles remain that directly impact the regulated sector.

One of the key challenges evidenced by this study is the lack of uniformity in product risk classification, an essential element for defining conformity assessment criteria. This gap can generate regulatory inconsistencies, hinder international trade, and reduce procedure predictability. Another recurring challenge is the limitation of human resources, which affects all stages of product control.

Based on these findings, the following suggestions are proposed as an inputs to promote dialogue and support stakeholders to advance and create innovative solutions capable of addressing the challenges imposed by technological dynamism and the growing flow of high-quality medical technologies to the Brazilian population.

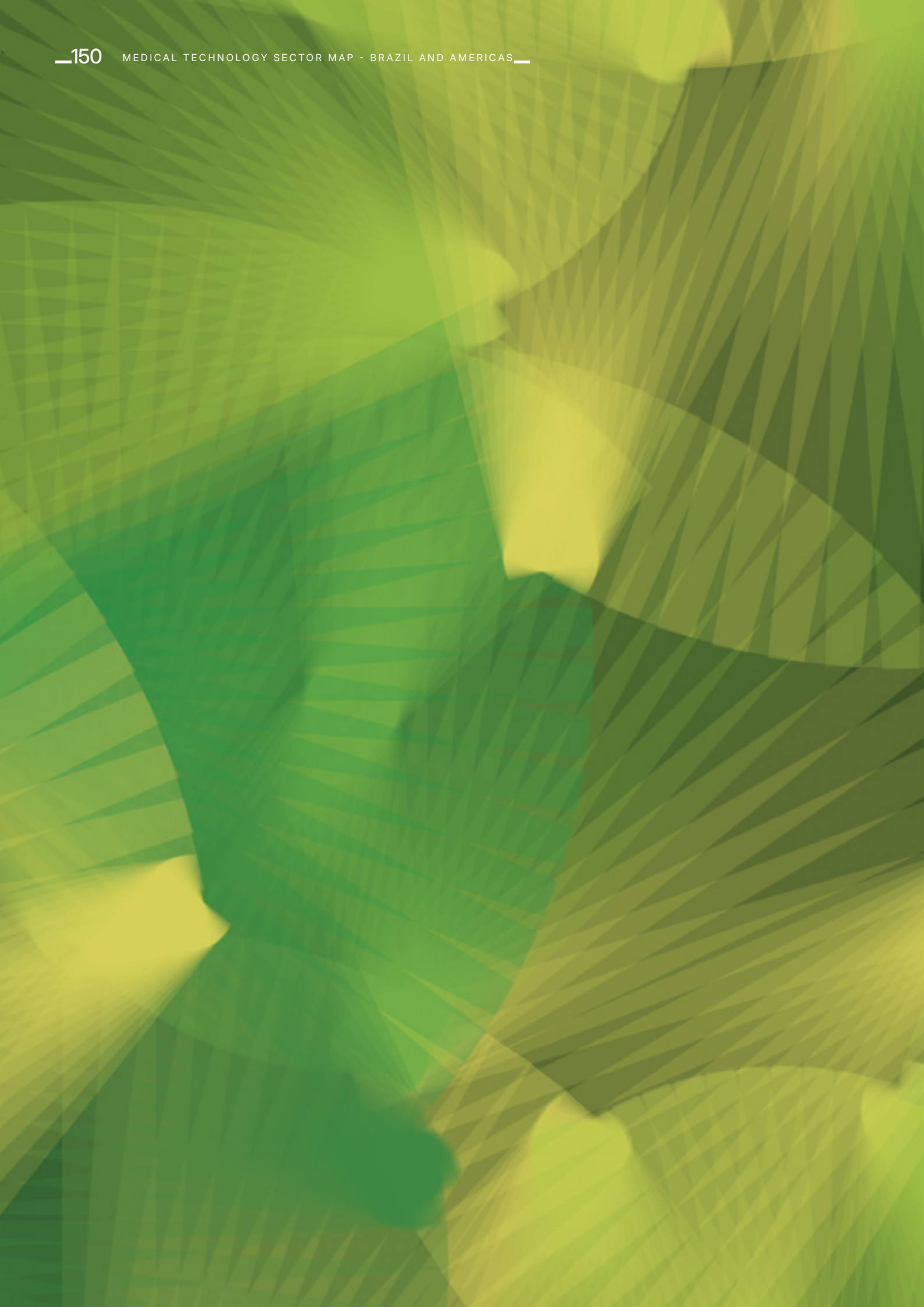
ANVISA

Increasing GGTPS workforce to the minimum estimate of 112 civil servants, as proposed in ANVISA's assessment of 2016, is an urgent and essential measure to ensure full compliance with its regimental responsibilities.

- **Formalization of Technical Committee**
  Establish a permanent Technical Committee composed of ANVISA, INMETRO and entities representing the sector, with bimonthly meetings focused on discussing proposals and regulatory improvements for the medical devices segment.
- **Modernization of DATAVISA**
  Implement system improvements focusing on correcting instabilities and optimizing system functionalities to support shorter review times of processes and submission.
- **Recognition of Technical Standards**
  Publish a list of technical standards recognized by ANVISA, which can be used voluntarily by manufacturers to assess conformity and prove compliance with essential safety and performance requirements in the regularization of products, following models adopted by Health Canada and the US FDA. While contributing to shorter review times, this mechanism increases predictability to the sector as to the requirements that can be used by companies to regularize their products.
- **Adoption of a Declaration of Conformity**
  Assess the feasibility of implementing a Declaration of Conformity, through which manufacturers may attest compliance with the Essential Principles of Safety and Performance, in line with *GHTF/SG1/N78:2012 Principles of Conformity Assessment for Medical Devices*.
- **Consolidation of the Reliance policy**
  Expand the list of Equivalent Foreign Regulatory Authorities (AREE) recognized by ANVISA for the adoption of the optimized analysis procedure..

INMETRO

- Establish joint INMETRO/ANVISA/regulated sector technical committees, with an advisory nature, to discuss issues related to the certification of conformity of medical devices.
- Adopt a mandatory protocol to assess the applicability of RIA for any new or significantly revised conformity assessment requirement, in coordination with ANVISA, and in line with the delegation of authority established under Interministerial Agreement No. 692/2009.
- Establishing procedures for the recognition of results issued by accredited international organizations and laboratories, as well as the adoption of practices such as remote audits and acceptance of international certifications (e.g., MDSAP) are pointed out as opportunities to gain efficiency and reduce technical barriers to trade.



Attachments

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9. Attachments

HEALTH INDICATORS

COUNTRY	ARGENTINA	BRAZIL	CANADA	COLOMBIA	UNITED STATES	MEXICO
Population (2023)[133]	45,538.401	211,140.729	39,299.155	52,321.152	343,477.335	129,739.759
Health expenditure (% of GDP) (2021)[134]	9.71	9.89	12.33	9.02	17.36	6.08
Income level – World Bank	Upper middle income	Upper middle income	High income	Upper middle income	High income	Upper middle income
Regulatory/Sanitary Authority	ANMAT	ANVISA	HEALTH CANADA	INVIMA	US FDA	COFEPRIS

RISK CLASSIFICATION

COUNTRY	REGULATION		RISK CLASS				REFERRAL ALIGNMENT INTERNATIONAL
ANMAT	MD	Disp. No. 64/2025	I	II	III	IV	Harmonized classification rules Mercosur with Regulation 745/2017 (European Union)
	MD IVD	Disp. No. 2198/2022	A	B	C	D	Harmonized classification rules Mercosur with Regulation 746/2017 (European Union)
ANVISA	MD	RDC No. 751/2022	I	II	III	IV	Harmonized classification rules Mercosur with Regulation 745/2017 (European Union)
	MD IVD	RDC No. 830/2023	I	II	III	IV	Harmonized classification rules Mercosur with Regulation 746/2017 (European Union)
HEALTH CANADA	MD	Medical Devices Regulations (SOR/98-282)	I	II	III	IV	Directive 93/42/EEC (European Union)
	MD IVD		I	II	III	IV	-
INVIMA	MD	Dec. No. 4725/2005	I	IIA	IIB	III	Directive 93/42/EEC (European Union)
	MD IVD	Dec. No. 3770/ 2004	I	II	III	-	-
FDA	MD (including MD IVD	21 Code of Federal Regulations (CFR) Parts 800-1050	I	II	III	-	They do not adopt classification rules. Database with 1,700 generic types classified and grouped into 16 medical specialties
COFEPRIS	MD (including MD IVD)	Regulation of Inputs for Health	I	II	III	-	Classification rules available in the Appendix II to the MD Supplement to the United Mexican Pharmacopeia upon acquisition

133 WHO Countries Accessed on 09/20/2025
134 WHO Countries Accessed on 09/20/2025

GOOD MANUFACTURING PRACTICES – QUALITY MANAGEMENT SYSTEM

ANMAT	Certification of Good Manufacturing Practices of MD and MD IVDs classes I, II, III and IV necessary for the Authorization of Operation and for the regularization of products. The criteria for GMP certification are in accordance with Provision No. 3266/2013 (Mercosur GMC Resolution No. 20/201). GMP Certification is valid for 5 years. ANMAT is an Affiliate Member of MDSAP.
ANVISA	Compulsory GMP certification for the registration of MD and MD IVD classes III and IV. The criteria for GMP certification are in accordance with GMC Resolution No. 20/2011. ANVISA is a member of the Council of Regulatory Authorities of the MDSAP. Validity of GMP Certificate: • ANVISA - 2 years • MDSAP - 4 years
HEALTH CANADA	Compulsory MDSAP certificate for regularization of products. Health Canada Founding member of MDSAP, member of MDSAP Board of Regulatory Authorities.
INVIMA	Until the Certification of Good Manufacturing Practices is regulated, the company must comply with requirements established by the "Technical Concept of Health Conditions" provided for in Decrees N. 4725/2005 and 3770/2004.
US FDA	Quality System (QS) Requirements (21 CFR Part 820), amended to incorporate by reference ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. Effective as of February 2, 2026[135] The FDA does not issue a Certificate of Good Manufacturing Practice.
COFEPRIS	Good Manufacturing Practices of compulsory observation (NOM – 241 – SSA1- 2025)

135 Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP) | FDA Accessed on 9/25/2025

GOOD MANUFACTURING PRACTICES
CONFORMITY ASSESSMENT – ESSENTIAL SAFETY AND PERFORMANCE PRINCIPLES

ANMAT	**MD produced locally:** Classes I and II – Declaration of tests performed. Classes III and IV – Presentation of tests carried out. MD IVD Electrical equipment – Test certificates – Argentine Accreditation Body Group D – Laboratory analysis
ANVISA	**MD** Classes I and II – Technical Dossier kept in the company – information on safety and performance requirements and tests performed. Classes III and IV – Technical Dossier in the registration process – information on safety and performance requirements and tests performed. Certain products listed in regulations must present the INMETRO Certificate of Conformity or prior analysis carried out at INCQS. **MD IVD** – Technical dossier with information on safety and performance requirements. Class IV – Certain products must undergo prior analysis at INCQS.
HEALTH CANADA	**MD and MD IVD** 1 - Declaration of Conformity – Use of recognized technical standards 2 – The manufacturer may choose to comply with a standard equivalent to a recognized standard 3 – The manufacturer may choose to provide alternative evidence of the safety or effectiveness of the device.
INVIMA	**MD** Presentation of information, including technical and analytical studies, and the list of standards applicable to the product. **MD IVD** – Category III (highest risk) – Clinical, analytical studies and, when necessary, laboratory analysis.
US FDA	**MD and MD IVD** 1 - Declaration of Conformity – Use of recognized technical standards 2- General Use of Consensus Standards – The manufacturer demonstrates compliance through a thorough test report. 3- Participation in the "Accreditation Scheme for Assessment of Conformity" Program (ASCA). The program provides for tests to be carried out by laboratories accredited by the FDA.
COFEPRIS	**MD and MD IVD** Submission of test reports performed by the manufacturer in accordance with specifications of the Mexican Pharmacopoeia, Mexican Official Standards or international standards.

LEGAL DEADLINE

ANMAT	Disp. No. 9688/2019	I and II - 15 working days	III and IV - 110 working days
	Disp. No. 9688/2019	A & B - 15 business days	C and D - 110 working days
ANVISA	RDC No. 743/2022	I and II - 30 days	III and IV Material - 320 days Equipment - 250 days MD DIV - 365 days
HEALTH CANADA	Health Canada Website – Review Process	I - Exempt from License	III - 75 Days
		II - 15 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 working days	III - 90 days
FDA	MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027	I and II not exempt from 510(k) – 124 days	III - 290 days
COFEPRIS	Agreements: 1- 11/07 and 22/08 - Simplification of Processes 2- 18/07/2025 - Abbreviated Copy	I – 20 to 30 working days*	III – 30 to 35 business days*
		II – 25 to 30 working days*	* depending on the route chosen (abbreviated or simplified

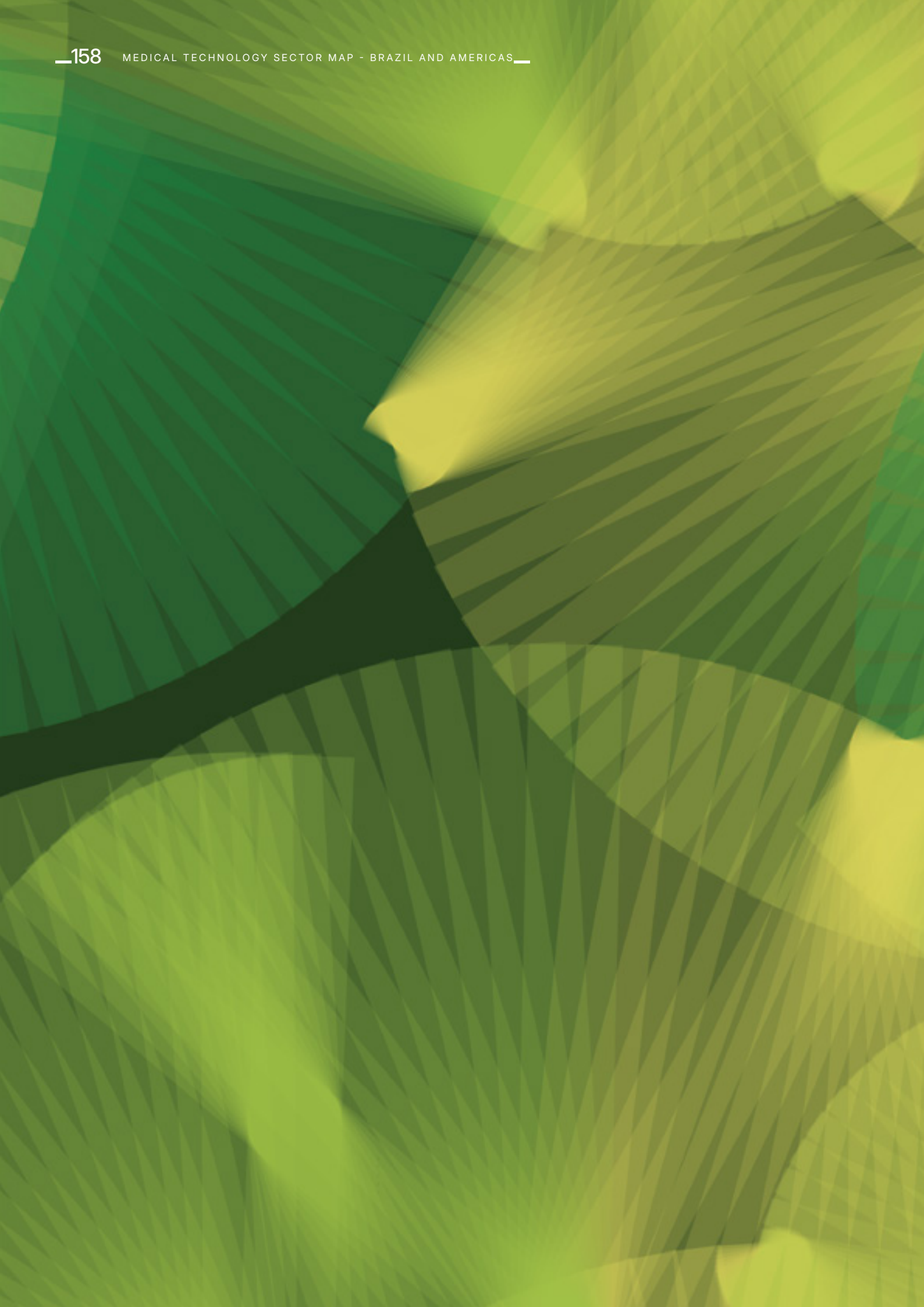
WORKFORCE – NO. OF PROFESSIONALS WORKING IN DIFFERENT ACTIVITIES RELATED TO THE LIFE CYCLE OF MEDICAL DEVICES

WORKFORCE	ANMAT	ANVISA	HEALTH CANADA	INVIMA	US FDA	COFEPRIS
	100	113	165	65	2,260	42

COSTS WITH FEES FOR REGULARIZATION OF MEDICAL DEVICES – AMOUNTS IN US DOLLARS

ANMAT	Provision No. 4058/2025	MD - I and II	MD - III and IV	MD IVD - A & B	MD IVD - C & D
		$166,57	$274,72	$148,43	$187,87
ANVISA	RDC No. 857/2024	I and II	III and IV	-	-
		$653,57	$8,949.84	-	-
HEALTH CANADA	Website Health Canada	II	III	III (MD DIV Near the Patient)	IV
		$450,39	$ 9,924.46	$ 21,140.25	$ 21,521.52
INVIMA	Resolution No. 202457944/2024	MD I and IIA	MD IIB and III	MD DIV I and II	MD DIV III
		$956,74	$1,082.91	$630,88	$841,16
FDA	Medical Device User Fee Amendments (MDUFA)User Fees for FY 2025	510(k)	PMA	510(k) (Small Businesses)	PMA (Small Business)
		$ 24,335.00	$540,783.00	$6,084.00	$ 135,196.00
COFEPRIS	Rates (Website)	I	II	III	-
		$846.36	$1,246.64	$1,612.22	-

Central Bank of Brazil – Currency Converter (10/20/2025)



List of Acronyms

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ABIIS – Aliança Brasileira da Indústria Inovadora em Saúde

ABNT – Brazilian Association of Technical Standards

ANMAT – National Administration of Medicines, Food and Medical Technology (Argentina)

ANVISA – National Health Surveillance Agency (Brazil)

ASCA – Accreditation Scheme for Conformity Assessment (FDA, USA)

BPR – Good Regulatory Practices

CDRH – Center for Devices and Radiological Health (FDA – USA)

CEE – European Economic Community

CMIOR – Coordination of Implantable, Orthopedic and Rehabilitation Materials (ANVISA)

CNI – National Confederation of Industry (cited in the sectoral data annexes)

CPCPS – Coordination of Clinical Research in Health Products (ANVISA)

COS – Sanitary Operation Commission (Mexico)

COFEPRIS – Comisión Federal para la Protección contra Riesgos Sanitarios (Mexico)

COPROSAL – Health Products Commission (Mercosur Subgroup 11)

DATAVISA – Information System on Regulatory Processes and Products (ANVISA)

DDMOT – Directorate of Medical Devices and Other Technologies (Colombia)

E-Health – Electronic Health (digital products and services category)

EPSP – Essential Principles of Safety and Performance

EU – EUROPEAN UNION

F&DA – Food and Drugs Act (Canada)

FDA – Food and Drug Administration (USA)

Fiocruz – Oswaldo Cruz Foundation (Brazil)

GGTPS – General Management of Health Products Technology (ANVISA)

GEMAT – Materials Management (ANVISA)

GEVIT – Management of Equipment and Products for Therapeutic Use (ANVISA)

GGPES – General Management of Personnel Management (ANVISA)

GHTF – Global Harmonization Task Force

GMC – Common Market Group (MERCOSUR)

GQUIP – Medical Equipment Management (ANVISA)

HELENA – ANMAT Electronic Registration System (Argentina)

HHS – U.S. Department of Health and Human Services (USA)

HIV – Human Immunodeficiency Virus

HSA – Health Sciences Authority (Singapore)

HTLV – Human T Lymphotropic Virus

IA – Artificial Intelligence

IBGE – Brazilian Institute of Geography and Statistics (*referred to in population analyses*)

IEC – International Electrotechnical Commission

IECEE – IEC System for Conformity Testing and Certification of Electrotechnical Equipment

IMDRF – International Medical Device Regulators Forum

INCQS – National Institute for Quality Control in Health (Fiocruz)

INMETRO – National Institute of Metrology, Quality and Technology (Brazil)

INPM – National Institute of Medical Products (Argentina)

INVIMA – National Institute of Drug and Food Surveillance (Colombia)

ISO – International Organization for Standardization

IVD – In Vitro Diagnostic (In Vitro Diagnosis)

MD – Medical Device

MD IVD – In Vitro Diagnostic Medical Device

MDALL – Medical Devices Active License Listing (Health Canada)

MDD – Medical Devices Directorate (Health Canada)

MDEL – Medical Device Establishment License (Health Canada)

MDL – Medical Device License (Health Canada)

MDSAP – Medical Device Single Audit Program

MDUFA – Medical Device User Fee Amendments (FDA – USA)

MHLW – Ministry of Health, Labour and Welfare (Japan)

NMPA – National Medical Products Administration (China)

OCP – Product Certification Body

OECD – Organization for Economic Co-operation and Development

Organization OPME – Orthotics, Prostheses and Special Materials

PAHO – Pan American Health

PMA – Premarket Approval (FDA – USA)

PMDA – Pharmaceuticals and Medical Devices Agency (Japan)

POP – Standard Operating Procedure

PPE – Personal Protective Equipment

RAC – Regulatory Authority Council (MDSAP)

RAC Council – Regulatory Authority Council (Governance) from MDSAP)

RDC – Resolution of the Collegiate Board (ANVISA)

RD&I – Research, Development and Innovation

RPS WG – Regulated Product Submission Working Group (IMDRF)

RPPTM – Registro Nacional de Productores y Productos de Tecnología Médica (Argentina)

SBAC – Brazilian Conformity Assessment System

SING – Health Sciences Authority – Singapore (*synonymous with HSA, appears in the tables*)

SOLICITA – ANVISA's Electronic Petitioning System

SOR/98-282 – Medical Devices Regulations (Canada)

TBT – Technical Barriers to Trade

TGA – Therapeutic Goods Administration (Australia)

US / USA – United States of America

WHO – World Health Organization

ABIIS | Aliança Brasileira da Indústria Inovadora em Saúde