CHALLENGES AND PROPOSALS 2026

ABIIS Brazilian Alliance of Innovative Health Industry

about us

BRAZILIAN INNOVATIVE HEALTH INDUSTRY ALLIANCE (ABIIS)

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table of contents

04 **1. MESSAGE FROM THE PRESIDENT**

06 **2. EXECUTIVE SUMMARY**

10 **3. THE BRAZILIAN ALLIANCE FOR INNOVATIVE HEALTHCARE INDUSTRY (ABIIS)**

- 12 About Us
- 13 Mission
- 13 Vision
- 13 Principles

14 **4. WHAT ARE MEDICAL DEVICES**

16 **5. DIFFERENCES BETWEEN MEDICAL DEVICES AND DRUGS**

20 **6. THE GLOBAL MEDICAL DEVICE MARKET**

22 **7. THE DOMESTIC MEDICAL DEVICE MARKET**

- 29 Profile of companies in the sector
- 30 Job creation
- 31 Direct jobs in the medical device sector in selected countries and in Brazil

34 **8. ABIIS'S PILLARS OF ACTION AND PROPOSALS FOR THE MEDICAL DEVICE SECTOR**

- 35 **8.1** Smart Regulation
- 37 Proposals for Smart Regulation
- 39 **8.2** Institutional Improvement of Regulators
- 41 Proposals for the institutional improvement of regulators
- 44 **8.3** Rational incorporation of technologies
- 44 Processes of technology adoption in healthcare in Brazil (public and private)
- 50 Proposals for the rational incorporation of technologies
- 53 **8.4** Improvement of the business environment
- 54 Proposals for Improving the Business Environment
- 61 **8.5** Ethics and compliance
- 64 Proposals for ethics and compliance

70 **9. CONSOLIDATED PROPOSALS**

01

MESSAGE FROM THE PRESIDENT

The medical device sector plays a strategic role in the health of the population and the country's development. In a scenario of growing demand for access, innovation, and economic sustainability, it is becoming increasingly important to strengthen the dialogue between the productive sector, government, and society.

This document provides an objective overview of the sector's main challenges and presents proposals aimed at improving the regulatory environment, expanding access to health technologies, and building a more efficient, ethical, and predictable business environment.

ABIIS thus reaffirms its commitment to knowledge generation, the formulation of technical proposals, and the advocacy of public policies that contribute to innovation, regulatory compliance, and the sustainability of the Brazilian healthcare system.

We hope this material will help enrich the debate and support the development of concrete solutions for the present and future of healthcare in Brazil.

Bruno Boldrin Bezerra
PRESIDENT

THIS DOCUMENT PRESENTS AN OBJECTIVE OVERVIEW OF THE SECTOR'S MAIN CHALLENGES AND OFFERS PROPOSALS AIMED AT IMPROVING THE REGULATORY ENVIRONMENT, EXPANDING ACCESS TO HEALTH TECHNOLOGIES, AND BUILDING A MORE EFFICIENT, ETHICAL, AND PREDICTABLE BUSINESS ENVIRONMENT

02

EXECUTIVE SUMMARY

The document Challenges and Proposals 2026, prepared by ABIIS, presents a strategic agenda for strengthening of the medical devices sector (MDs) in Brazil, combining market diagnostics, regulatory analysis, and institutional proposals aimed at expanding access to innovation, regulatory modernization, and improving the business environment.

ABIIS positions the MD sector as a strategic element for the sustainability of the healthcare system and for national economic development, advocating for greater alignment between the government, regulators, and industry to reduce barriers to technological access and increase regulatory predictability.

BRAZIL IS PRESENTED AS THE LEADING MARKET IN LATIN AMERICA AND A STRATEGIC REGIONAL HUB, PARTICULARLY IN HIGH-VALUE-ADDED SEGMENTS SUCH AS IN VITRO DIAGNOSTICS, ORTHOPEDIC IMPLANTS, AND CONNECTED DEVICES

SECTOR OVERVIEW

The document highlights that the global medical device market reached approximately US$542 billion in 2024, with an expected average annual growth rate of 6.5% through 2032, driven by an aging population, an increase in chronic diseases, and the digitization of healthcare.

Brazil is presented as the leading market in Latin America and a strategic regional hub, particularly in higher-value-added segments such as in vitro diagnostics, orthopedic implants, and connected devices.

In the domestic market, the document highlights the following data and characteristics of the sector:

- approximately 87,000 valid registrations and listings of medical devices with Anvisa;
- creation of approximately 153,000 direct jobs in the sector;
- predominance of small and medium-sized enterprises in the production and distribution chain;
- high dependence on imports, which reached US$6.6 billion in 2025, approximately six times the value of exports.

The text also emphasizes that medical devices operate under dynamics distinct from the pharmaceutical industry, characterized by shorter innovation cycles (18 to 24 months), strong technological incrementalism, weaker patent protection, and a need for greater regulatory agility and technological incorporation.

MAIN CHALLENGES IDENTIFIED

The document organizes the sector's challenges into five main areas:

1. Smart Regulation

ABIIS advocates for a regulatory model based on efficiency, proportionality to risk, and international convergence. The document criticizes bureaucratic excesses, redundant documentation, and regulatory delays, noting that these factors hinder patients' access to innovations and reduce the country's competitiveness.

Among the main proposals are the consolidation of Good Regulatory Practices, the expansion of AIR and ARR, the streamlining of documentation, the improvement of regulatory queue management, the expansion of reliance strategies, and greater coordination among regulatory agencies.

2. Institutional strengthening of regulators

The document argues that technological advancements in the sector require technical and operational strengthening of Anvisa and ANS. To this end, the proposals include measures such as expanding the GGTPS/Anvisa workforce, the creation of permanent forums for technical dialogue, the modernization of DATAVISA, the adoption of AI and automation, the formal recognition of technical standards, and the implementation of Declaration of Conformity mechanisms.

This document also places high importance on expanding regulatory reliance as a tool to accelerate access to innovative technologies without compromising public health protection.

3. Rational Incorporation of Technologies

ABIIS acknowledges institutional advances at Conitec and ANS/Cosaúde, but identifies bottlenecks related to procedural delays, low predictability, the absence of specific methodologies for medical devices, and limitations in transparency. In addition to these obstacles, it highlights the inadequacy of traditional HTA models for the characteristics of the sector.

The document emphasizes that medical devices have unique characteristics that make it difficult to apply the same methodological models used for pharmaceuticals, mainly due to rapid technological obsolescence, the difficulty of conducting traditional randomized studies, and the indirect impact on healthcare efficiency and systemic cost reduction.

The main proposals include the creation of specific HTA guidelines for medical devices, the reduction of review timelines to up to 120 days, and the

expanded use of real-world data (RWD), greater public participation, transparency in decision--making, and a specific budget allocation for technology adoption within the SUS.

4. Business environment and tax reform

The document devotes significant attention to the impacts of tax reform on the healthcare sector, advocating for legal certainty and tax neutrality during the transition to the IBS/CBS model.

The main risks identified include interpretive conflicts involving NCMs; exclusion of essential products from tax benefit lists; accumulation of tax credits; indirect increase in healthcare costs; and logistical uncertainty in consignment and OPME operations.

Among the measures advocated are the maintenance of the benefits of ICMS Agreement No. 01/1999 throughout the transition, tax recognition of non-onerous transactions, technical alignment between tax legislation and ANVISA's regulatory definitions, and the creation of joint technical bodies between tax authorities and health authorities.

5. Ethics and Compliance

This document also highlights the need for the continuous strengthening of ethics, transparency, and compliance practices as foundational elements of the sector's institutional legitimacy.

Strategic Conclusion

The medical device industry is positioned as an innovation-intensive sector, strategic for economic competitiveness, and fundamental to the sustainability of the Brazilian healthcare system.

On the one hand, public policies that are excessively bureaucratic or misaligned with the specificities of medical devices can widen the country's technological gap, reduce investments, and compromise Brazilian patients' access to modern and efficient solutions. On the other hand, the adoption of a more agile, predictable regulatory environment that is technically aligned with international best practices can create opportunities to strengthen the Health Economic-Industrial Complex by increasing competitiveness, stimulating innovation, reducing systemic costs, and, consequently, improving healthcare outcomes and the sustainability of the health sector in Brazil.

In short, ABIIS's main institutional message is that Brazil needs to make simultaneous progress in regulatory modernization, institutional strengthening of agencies, improvement of the HTA, tax predictability, and expanding access to innovation.

03

THE BRAZILIAN ALLIANCE FOR INNOVATIVE HEALTHCARE INDUSTRY (ABIIS)

The ABIIS brings together the entire medical device sector in Brazil, encompassing industry—both domestic and international—as well as suppliers and distributors who operate in all areas of this sector, including equipment, orthotics, prosthetics, and special materials (OPME), consumables, and in vitro diagnostics (IVD).

Founded in 2011, ABIIS aims to generate and disseminate knowledge, as well as develop proposals that contribute to the creation of a social, economic, and regulatory environment conducive to the development of innovation in health in Brazil.

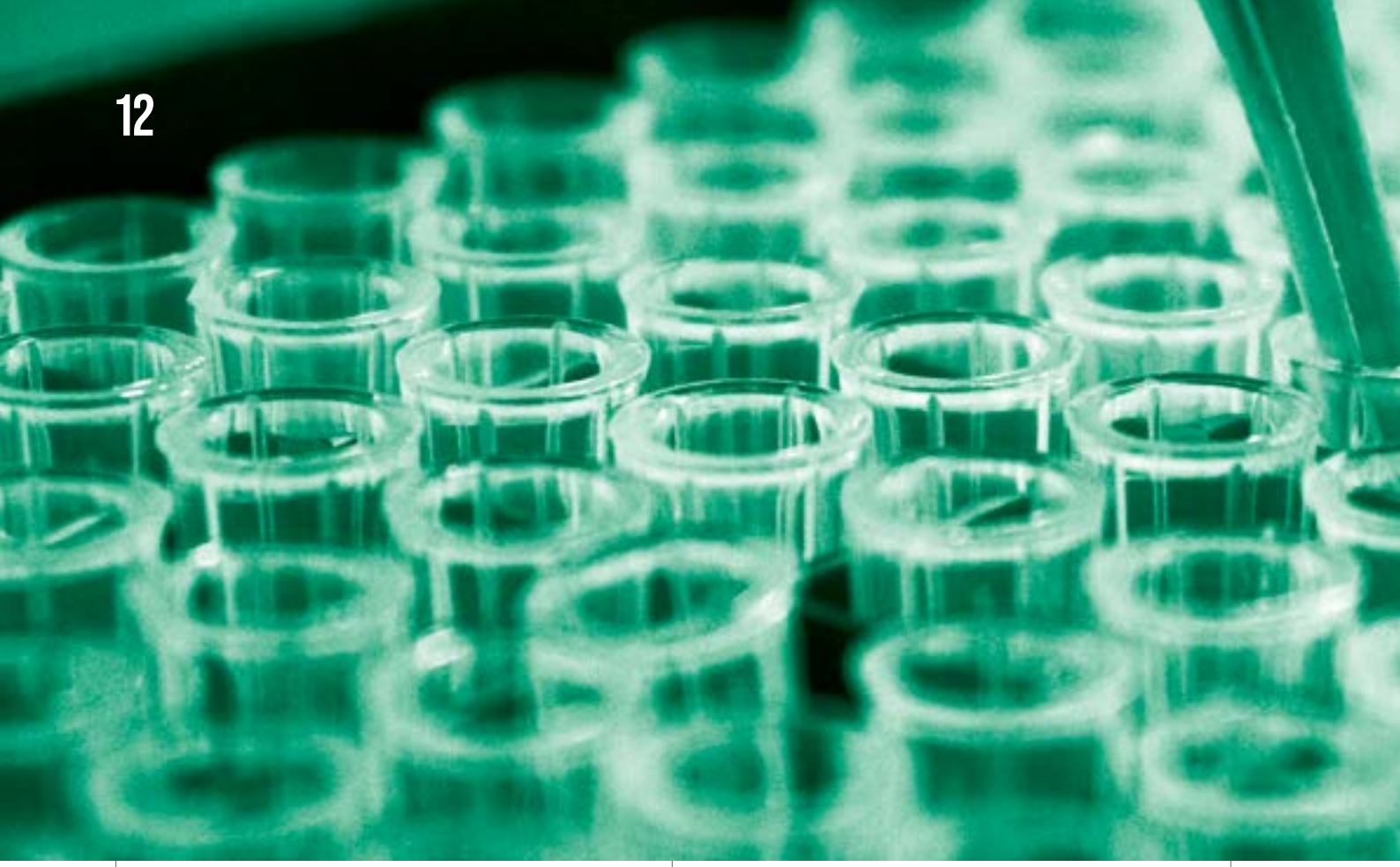
Through the production and dissemination of relevant content, data, and information, ABIIS contributes to the improvement of public policies aimed at expanding the population's access to modern, effective, and safe technologies. At the same time, it seeks to foster broad and lasting sustainability for the healthcare system and society.

ABIIS has also played an important role in debates and in the formulation of proposals related to key issues for the medical device sector, such as price regulation, technology adoption, issues associated with ports, airports, and borders, reliance, ethical and compliance aspects, among others.

Healthcare occupies a prominent position in the contemporary landscape due to its relevance, complexity, and the multiple challenges it presents in both the health and economic spheres. Currently, healthcare managers, specialists, and other stakeholders in various countries, including Brazil, are seeking options capable of balancing limited financial resources with the growing demand for specialized and high-cost care, driven primarily by the aging of the global population.

Faced with this landscape of numerous and ever-expanding challenges, ABIIS aims to serve as an active and responsible partner to the Brazilian government in the search for solutions that meet the needs of the state and deliver the best outcomes for patients, who are at the heart of the entire healthcare system.

THROUGH THE PRODUCTION AND DISSEMINATION OF CONTENT, DATA, AND RELEVANT INFORMATION, ABIIS CONTRIBUTES TO THE IMPROVEMENT OF PUBLIC POLICIES AIMED AT EXPANDING THE POPULATION'S ACCESS TO MODERN, EFFECTIVE, AND SAFE TECHNOLOGIES



About Us

ABIIS is an alliance of entities formed by the Brazilian Association of Importers and **Distributors of Healthcare Products (ABRAIDI)**, **the Brazilian Chamber of Laboratory Diagnostics (CBDL)**, and the **Advanced Medical Technology Association (AdvaMed)** of the United States.

ABRAIDI comprises approximately 300 companies nationwide that manufacture, import, and distribute products, equipment, medical and hospital supplies, implantable devices, and other items used in healthcare. The association maintains strong ties with government agencies and other entities in the healthcare sector. Founded in 1992, it is headquartered in São Paulo (SP).

The CBDL represents industries operating in the in vitro diagnostics sector and has 65 members, including both domestic and multinational companies.

One of its main goals is to promote the exchange of information aimed at improving the technical foundations of the sector. It has been working in partnership with entities in Brazil and abroad. It was established in 1991 and is headquartered in São Paulo (SP).

AdvaMed is the world's largest association in the advanced medical technology sector. It has over 400 members and maintains a global presence in countries across Europe, India, China, Brazil, and Japan. It represents innovative companies of all sizes—from the largest to the smallest—in the fields of medical devices, diagnostic products, and digital medical technology. Founded in 1974, it is headquartered in Washington, D.C. (USA).

In addition to the global representation provided by the entities that make up ABIIS, it is also present at key industry forums, serving as a member of the

Executive Group of the Health Industrial Complex (Geceis), coordinated by the Ministry of Health, and

the Inter-American Coalition of Business Ethics in the Medical Device Sector and holding a seat on the Advisory Board of the Health Ethics Institute (IES). It is also one of Brazil's representatives in the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector, which seeks to achieve regulatory convergence among member countries and implement Good Regulatory Practices in the Americas.

Mission

Develop and disseminate proposals for public policies, legal frameworks, and regulatory instruments, engaging stakeholders from the public and private sectors with the aim of making the business environment in Brazil increasingly conducive to investment in research, development, local production, and the commercialization of innovative medical technologies.

Vision

To remain the Brazilian government's primary partner in the debate and implementation of public policies that ensure and expand the population's access to innovative medical technologies, contributing to the country's socioeconomic development.

Principles

Ethics, loyalty, perseverance, efficiency, and technical rigor.

04

WHAT ARE MEDICAL DEVICES

A medical device is the term used to designate any equipment, apparatus, material, item or system used in medical, dental, or laboratory applications, intended for prevention, diagnosis, treatment, rehabilitation, and contraception in humans. The Agency classifies these items under the category of "Health Products."

The following are considered medical devices:

ORTHOSES, PROSTHESES, AND MEDICAL MATERIALS

IN VITRO DIAGNOSTICS

E-HEALTH

MEDICAL EQUIPMENT

Medical devices range from simple everyday consumables, such as gauzes or syringes, to more complex products, such as orthopedic implants, heart valves, HIV diagnostic kits, or magnetic resonance imaging equipment and software for medical purposes.

These devices can be used in various settings, including hospitals, clinics, homes, and even hard-to-reach locations, depending on their purpose and characteristics. Additionally, their use may be intended for both healthcare professionals and the general public, depending on the type of device.

Estimates from the World Health Organization (WHO) indicate the existence of more than 2 million different types of medical devices on the global market, categorized into more than 7,000 generic device groups[1]. These products are essential for healthcare.

Brazil currently has approximately 87,000 valid registrations and listings for medical devices, including equipment, medical and hospital supplies, implants, reagents, and other materials for in vitro diagnostics, according to Anvisa.

1. MEDICAL devices. World Health Organization. Available at: https://www.who.int/health-topics/medical-devices#tab=tab_1. Accessed on: May 22, 2026.

05

DIFFERENCES BETWEEN MEDICAL DEVICES AND DRUGS

Over time, a misconception has taken hold that treats medical devices and drugs as if they were equivalents. Although regulation clearly treats these products as distinct categories, it is still common— especially among the public, legislators, policymakers, and technical experts responsible for evaluating technologies for incorporation into the Unified Health System (SUS) — to interpret that both belong to the same category.

In practice, the similarities between them are limited to the fact that they are fundamental to promoting the health and well-being of the population and are subject to Health Surveillance regulations.

The medical device industry is characterized by a constant pace of innovation, with new products launched on the market, on average, every 18 to 24 months. This process results from high investments and the convergence of advances in different areas of knowledge. It is, therefore, a sector marked by rapid technological cycles, which require similar agility on the part of regulators, managers, and technology evaluators, particularly in decisions regarding the incorporation of new solutions into the public and private health systems. Otherwise, there is a risk of widening the technological gap between Brazilian patients and those in other countries.

Therefore, it is essential to distinguish medical devices from medicines, due to their different characteristics. The table below compares the differences between medical devices and medicines[2].

THE MEDICAL DEVICE INDUSTRY IS CHARACTERIZED BY A CONSTANT PACE OF INNOVATION, WITH THE LAUNCH OF NEW PRODUCTS ON THE MARKET, ON AVERAGE, EVERY 18 TO 24 MONTHS

2. ABIIS. Medical Technology Sector Map: Brazil and the Americas 2026. Available at: https://abiis.org.br/wp-content/uploads/2026/02/AF.83.21-Mapa--Tecnologia-Medica-Brasil-e-Americas-2026_DESKTOP.pdf. Accessed on: May 22, 2026.

	MEDICAL DEVICES	MEDICINES
INDUSTRY	Predominance of small and medium-sized companies.	Predominance of multinational companies.
CHARACTERISTICS OF THE TECHNOLOGIES	Generally 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 encompassing biotechnology, genetic engineering, among others.
INNOVATION	Continuous innovation, driven by scientific and technological advances and the development of new materials. This ongoing evolution enables the delivery of greater clinical value to patients, strengthens the industry's competitiveness, and demands an increasingly agile and effective regulatory environment.	A long process involving years of research.
LIFECYCLE	Short (on average, two years on the market). Most new products offer additional features and clinical value based on incremental improvements; this generally results in a range of related models for the user to choose from based on the patient's needs. General lack of patent protection. Dynamic market with multiple competitors.	Extensive, intensive patent protection.
ACTION	Generally act through physical interaction with the body or, in the case of in vitro products, do not come into contact with the body.	Generally act systemically throughout the body.

06

THE GLOBAL MEDICAL DEVICE MARKET

The medical device market remains one of the most dynamic segments of the global economy. The sector has an accelerated cycle of innovation, which generally ranges from 18 to 24 months, and continues to be characterized by the hiring and continuous training of a highly qualified workforce.

The global medical device market reached $542.21 billion in 2024, driven by structural factors such as an aging population, the rise in chronic diseases, and the digitization of healthcare. The sector is projected to grow continuously, at an average rate of 6.5% per year through 2032, driven by the gradual demand for advanced technologies, increased access in emerging markets, and advances in minimally invasive medical procedures.

Regionally, North America remains the sector's main hub, accounting for 38.17% of the global market, bolstered by a well-established innovation ecosystem, a robust industrial base, and, through 2024, a relatively stable regulatory environment. Asia-Pacific is emerging as the fastest-growing region, driven by expanding investments in healthcare infrastructure and the growth of the middle classes in China, India, and Southeast Asia. Europe, despite being a mature market, remains significant, particularly in the diagnostic imaging and robotic surgery segments.

In the context of Latin America, Brazil reaffirms its position as the largest regional market and as a strategic export hub, with the United States as its main destination, accounting for 22% of Brazilian exports in the sector. The domestic supply chain has sought to strengthen its competitiveness in higher-value-added segments—such as in vitro diagnostics, orthopedic implants, and connected devices—while adapting to the pressures of a global commercial environment increasingly influenced by new tariff policies and the reorganization of supply chains.

THE SECTOR IS PROJECTED TO EXPERIENCE CONTINUOUS GROWTH, WITH AN AVERAGE RATE OF 6.5% PER YEAR THROUGH 2032

07

THE NATIONAL MARKET FOR MEDICAL DEVICES

The domestic medical device market maintains unique characteristics that influence business dynamics and set it apart from others sectors. Among them, the extended payment cycle, which is expected of reaching, on average, about four months between product delivery and actual receipt. Another distinctive feature concerns the fact that, in addition to the supply of products, in certain situations there is the provision of services, the conduct of training, the delivery of additional materials on consignment, and even the loan of equipment. This context is largely explained by the fact that healthcare professionals often determine the products to be used only at the time of surgery.

Due to its innovative and technology-intensive nature, the sector continues to demand a highly specialized workforce, with ongoing training for the development and use of the advanced technologies that define it.

In 2025, companies in the sector employed approximately 153,000 workers - a skilled and continuously improving workforce - contributing to raising the level of human resources in the country.

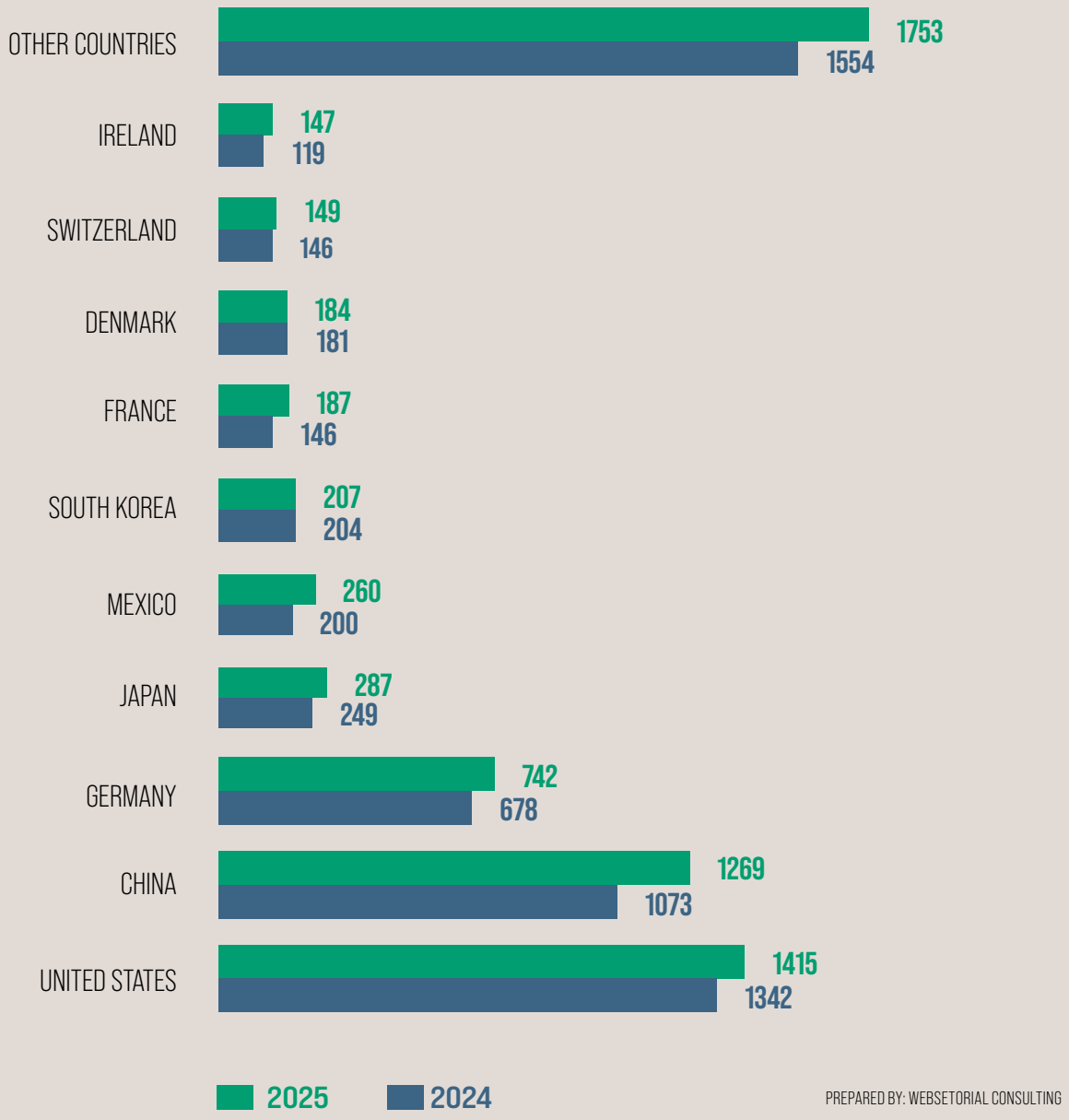
Nevertheless, despite the innovative and technological nature of the medical device industry, most research and development (R&D) activities continue to be conducted outside Brazil.

Historically, imports have exceeded exports in the Brazilian medical device market. This trend continued in 2025, when imports totaled US$6.6 billion—about six times the value of exports.

IN 2025, COMPANIES IN THE SECTOR EMPLOYED APPROXIMATELY 153,000 WORKERS — A SKILLED AND CONTINUOUSLY IMPROVING WORKFORCE —, CONTRIBUTING TO RAISING THE LEVEL OF HUMAN RESOURCES IN THE COUNTRY

CHART 01

Main countries of origin for medical device imports – In millions of dollars[3]



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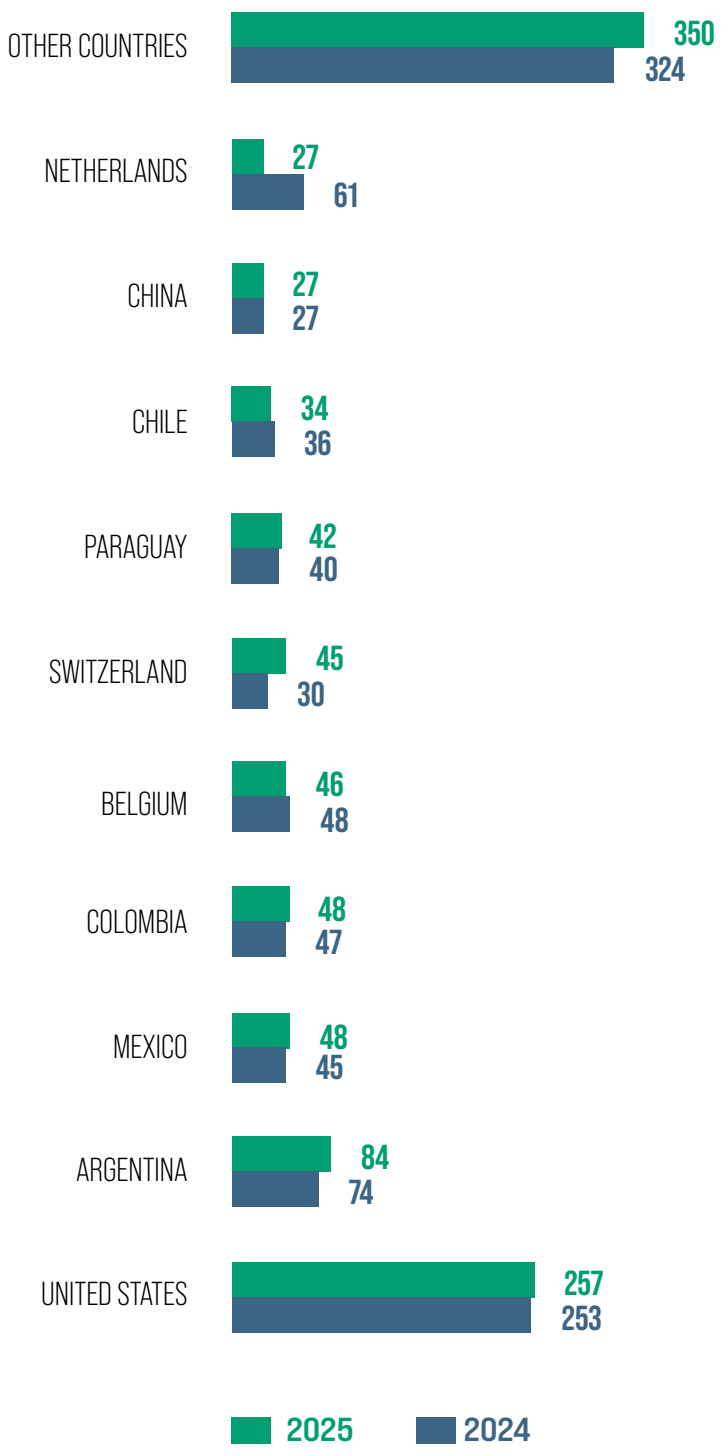
Exports, on the other hand, are mainly directed to the United States, which reached a value of US$ 256 million, or 25.5% of Brazilian exports.

Argentina came in second with an 8.1% share of this market and US$ 81 million in value, followed by Colombia with 4.9%.

3. Source: Comex Stat. Available at: https://comexstat.mdic.gov.br/pt/home. Accessed on: May 24, 2026.

CHART 02

Main destination countries for medical device exports – In millions of dollars[4]



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4. Source: Comex Stat. Available at: https://comexstat.mdic.gov.br/pt/home. Accessed on: May 24, 2026.

CHART 03

Market share of medical devices by segment – Brazil[5]

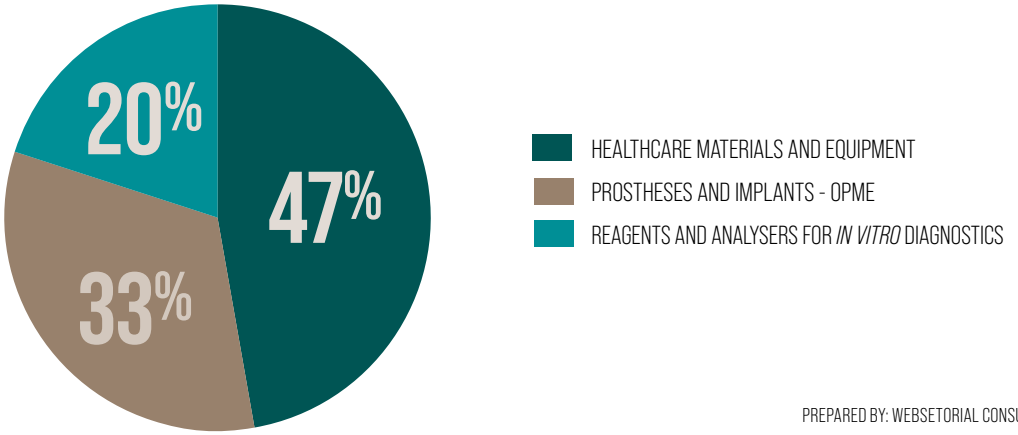

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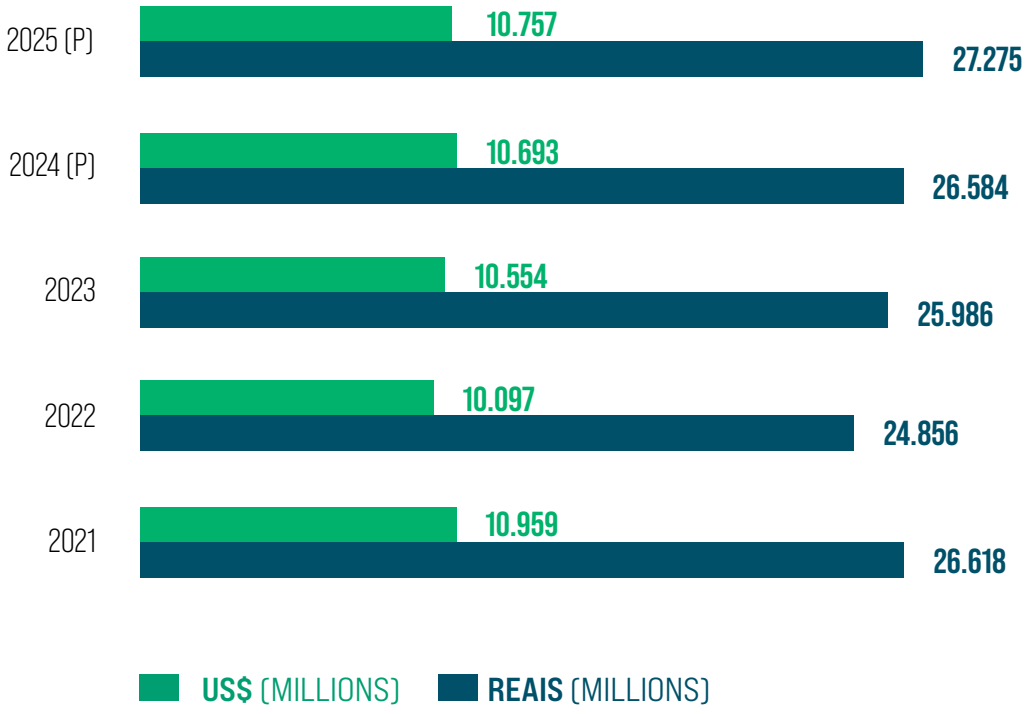
CHART 04

Brazilian production of medical devices.
In millions of dollars converted at the Purchasing Power Parity (PPP) rate



PREPARED BY: WEBSETORIAL CONSULTING

5. Source: ABIIS. Economic Bulletin: Data from January to December 2025, 52nd ed. Available at://efaidnbmnnnibpcajpcglclefindmkaj/https://abiis.org.br/wpcontent/uploads/2026/03/ABIIS-Boletim-53-jan-a-dez-25.pdf. Accessed on: May 25, 2026.

CHART 05

Apparent consumption of medical devices and percentage share of imports. In millions of dollars

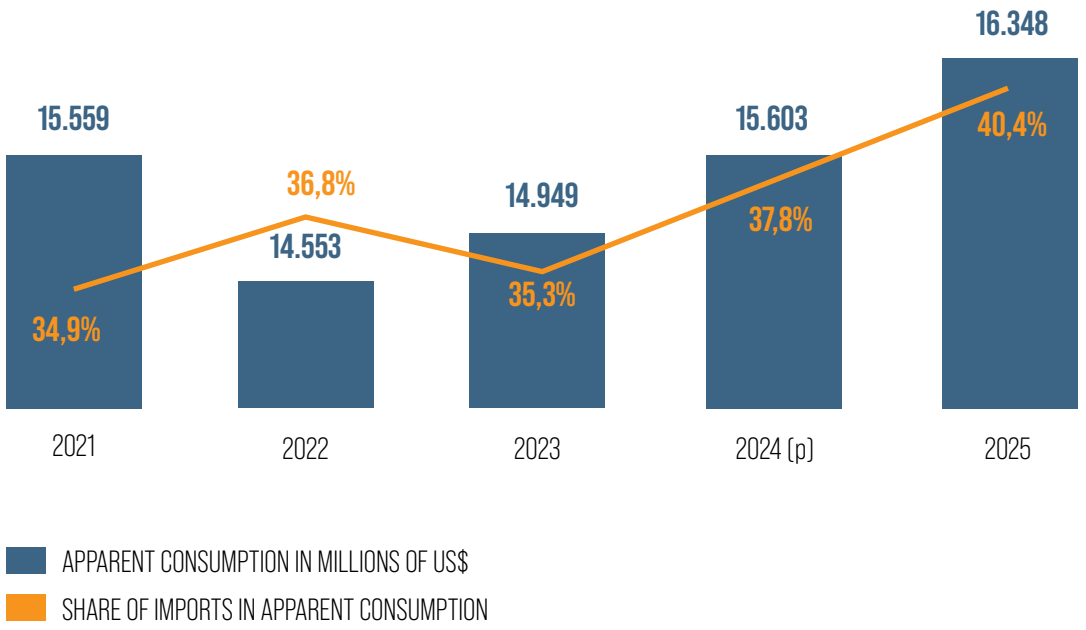


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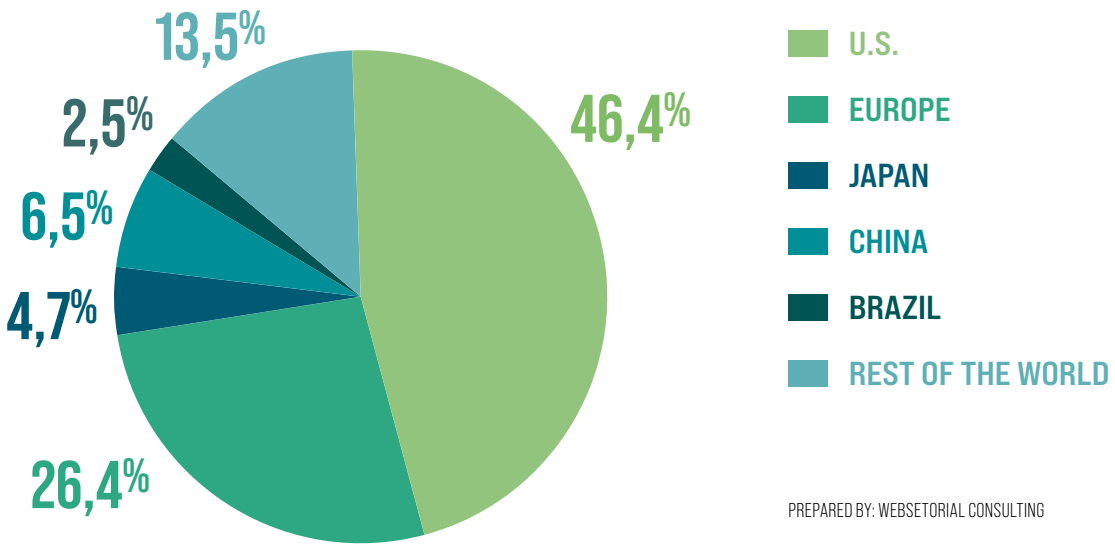
CHART 06

Brazil's share of the global market[6]



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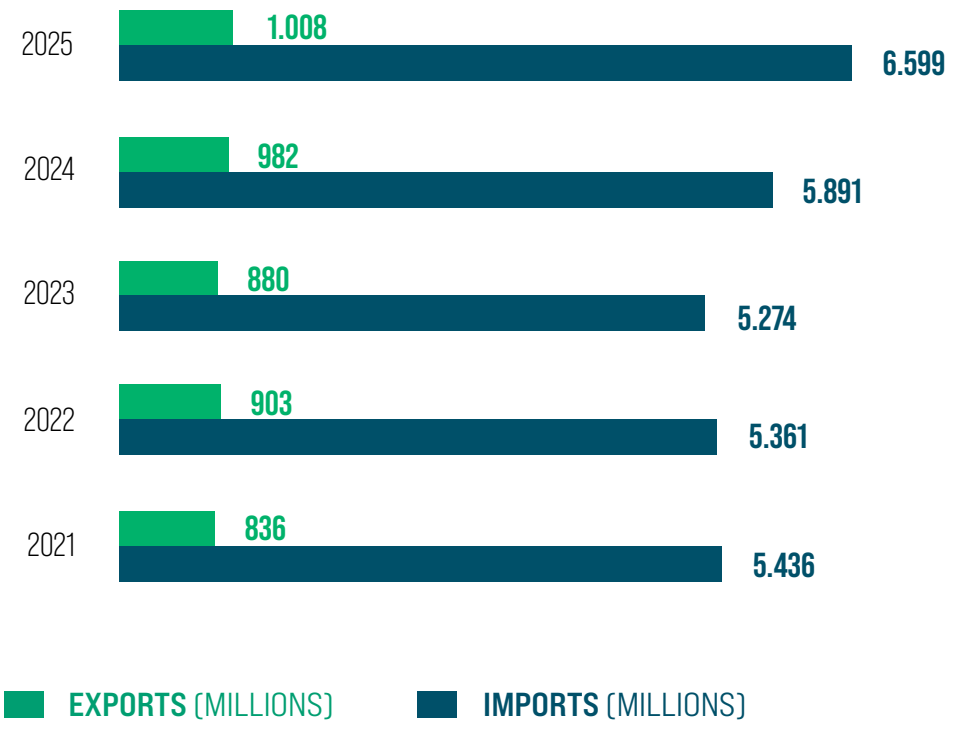
6. Source: MEDTECH EUROPE. Facts and figures 2025. [S.l.]: MedTech Europe, 2025. Available at: medtech-europe-facts-and-figures--2025-digital-1.pdf. Accessed on: Apr. 22, 2026.

CHART 07

Trade balance of Medical Devices[7]



PREPARED BY: WEBSETORIAL CONSULTING

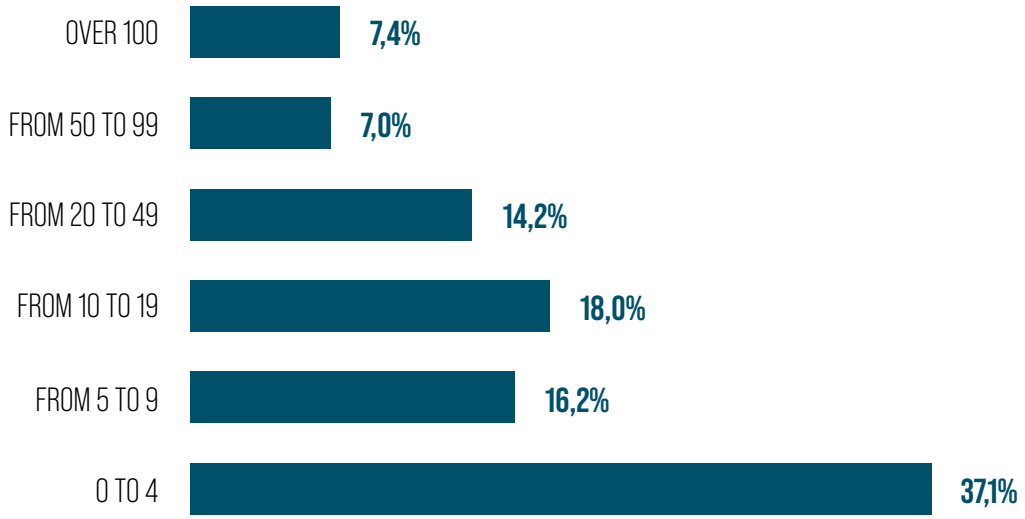
7. Source: Comex Stat. Available at: https://comexstat.mdic.gov.br/pt/home. Accessed on: May 24, 2026.

Profile of companies in the sector

There are 1,638 medical technology manufacturing companies in Brazil, and 13,995 are involved in the distribution and sale of these products. Small businesses (SMEs with up to 19 employees) account for about 71% of industrial companies and 94% of Brazilian medical device distributors, and most of them employ fewer than 20 people (small and microenterprises).

CHART 08

Brazil – Distribution of industrial companies in the medical device sector by size: in percentages, by employee count range[8]



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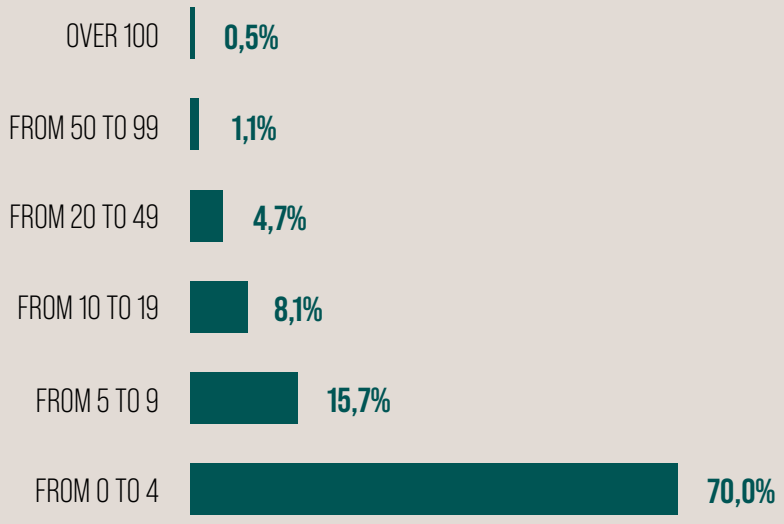
8. Source: BRAZIL. Ministry of Labor and Employment. RAIS 2024. Available at: https://www.gov.br/trabalho-e-emprego/pt-br/assuntos/estatisticas--trabalho/rais/rais-2024. Accessed on: May 20, 2026.

Job Creation

The Brazilian medical technology industry directly employs 61,000 people, and the trade sector—that is, product distributors—employs 91,000 workers, representing the creation of 153,000 direct jobs.

CHART 09

Brazil – Distribution of commercial companies in the medical device sector by size[9]



PREPARED BY: WEBSETORIAL CONSULTING

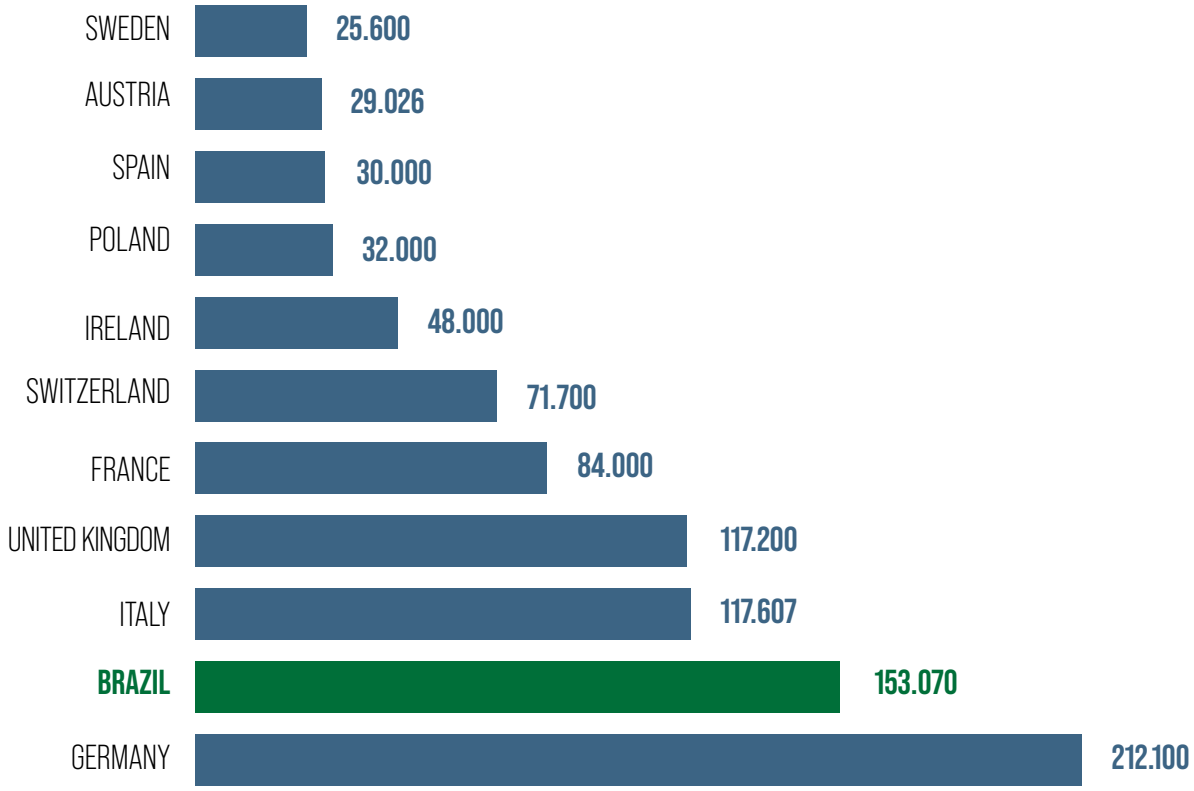
9. Source: BRAZIL. Ministry of Labor and Employment. RAIS 2024. Available at: https://www.gov.br/trabalho-e-emprego/pt-br/assuntos/estatisticas--trabalho/rais/rais-2024. Accessed on: May 20, 2026.

Direct jobs in the medical device sector in selected countries and in Brazil

The number of people employed in the manufacture and distribution of medical devices per capita is 7 per 10,000 inhabitants, a figure similar to that of Finland, according to MedTech Europe, the industry's representative body in Europe.

CHART 10

Direct employment in the medical device sector in selected countries and Brazil: number of workers[10]

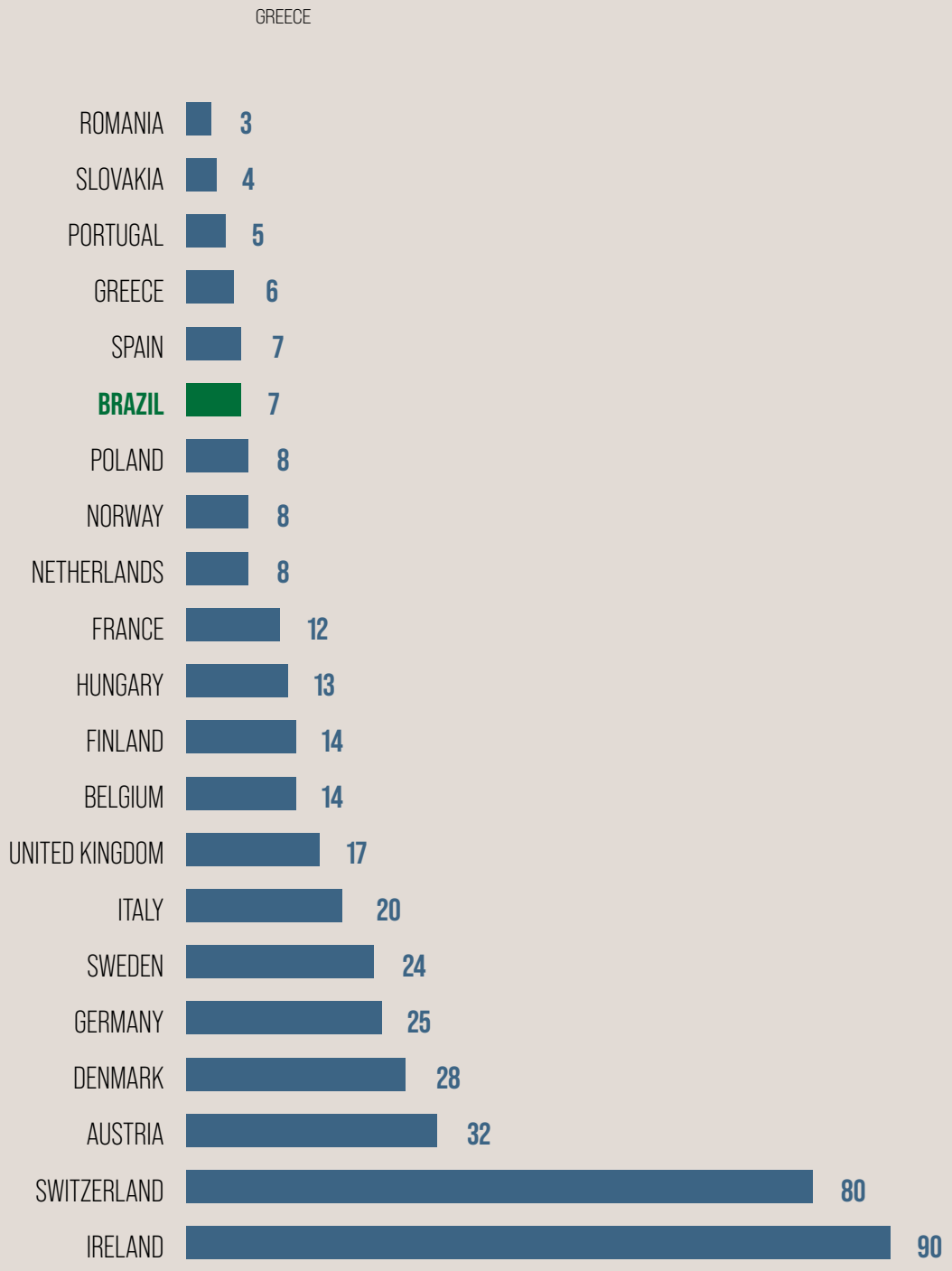


PREPARED BY: WEBSETORIAL CONSULTING

10. Sources: BRAZIL. Ministry of Labor and Employment. RAIS 2024. Available at: https://www.gov.br/trabalho-e-emprego/pt-br/assuntos/estatisticas--trabalho/rais/rais-2024. Accessed on: May 20, 2026.
MEDTECH EUROPE. Facts and figures 2025. [S.l.]: MedTech Europe, 2025. Available at: medtech-europe-facts-and-figures-2025-digital-1.pdf. Accessed on: Apr. 22, 2026.

CHART 11

Direct employment in the medical device sector in selected countries and in Brazil: number of workers per 10,000 inhabitants[11]



PREPARED BY: WEBSETORIAL CONSULTING

11. Sources: BRAZIL. Ministry of Labor and Employment. RAIS 2024. Available at: https://www.gov.br/trabalho-e-emprego/pt-br/assuntos/estatisticas--trabalho/rais/rais-2024. Accessed on: May 20, 2026.
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08

ABIIS'S KEY AREAS OF FOCUS AND PROPOSALS FOR THE MEDICAL DEVICES SECTOR

8.1 SMART REGULATION

The healthcare sector is among the most heavily regulated both in Brazil and internationally. This high level of regulation is not only understandable but essential, especially when considering products aimed at the prevention, diagnosis, treatment, and rehabilitation of patients, such as medicines and medical devices. This is a field in which safety and performance must be continuously ensured, as any failures can have significant consequences for people's health, as well as broader impacts on the functioning of and trust in the healthcare system.

When exercised responsibly, regulation plays a fundamental role in mitigating and preventing health risks. By establishing rigorous criteria for the approval, marketing, and monitoring of products, it helps ensure that only safe technologies with proven quality and performance are available on the market.

This process benefits the entire healthcare chain, protecting patients and offering greater safety to professionals who use these technologies in their clinical routines, while simultaneously strengthening trust in the healthcare system as a whole.

However, responsibility alone is not enough. Regulation must also be guided by efficiency. This means it must act as a balancing mechanism between different dimensions: on one hand, the needs of patients and healthcare professionals for rapid access to innovative solutions, and on the other, the economic and operational sustainability of the healthcare system. Smart regulation is capable of avoiding bureaucratic excesses, reducing redundancies, and eliminating unnecessary barriers that could delay the arrival of new technologies or discourage investment and development in the country.

In this context, the pursuit of more effective regulation is directly linked to the adoption of so-called Good Regulatory Practices. This concept refers to the quality, predictability, and consistency of regulatory processes, reflecting the need for well-organized structures and well-founded decisions. It involves the implementation of institutional mechanisms for coordination, evaluation, and regulatory review with the aim of ensuring that rules are developed in a transpa-

rent, participatory manner and based on scientific evidence. Furthermore, it requires the conduct of risk and regulatory impact analyses, ensuring that the decisions adopted are proportionate, duly justified, and aligned with international best practices.

In fact, adopting Good Regulatory Practices means building a regulatory environment that combines robustness and agility. This environment must be tailored to the specificities of the Brazilian context, but also connected to trends and global benchmarks, enabling greater regulatory convergence and facilitating the country's integration into international innovation chains.

THIS HIGH REGULATORY INTENSITY IS NOT ONLY UNDERSTANDABLE BUT ESSENTIAL, ESPECIALLY WHEN CONSIDERING PRODUCTS AIMED AT PREVENTION, DIAGNOSIS, TREATMENT, AND REHABILITATION OF PATIENTS

A well-structured system must be capable of keeping pace with rapid technological evolution, particularly in areas such as medical devices, digital health, and advanced therapies, without compromising safety standards.

Furthermore, it is essential that regulation does not become a factor restricting development. Excessive barriers can limit the entry of new players into the market, reduce competitiveness, and discourage investment, in addition to contributing to an unjustified increase in the costs of essential products and technologies. Conversely, a predictable and efficient regulatory environment tends to stimulate innovation, expand the range of available solutions, and promote public access to more modern and effective treatments.

A notable example of an initiative aimed at promoting these best practices in the Americas is the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector, in which ABIIS participates. This coalition brings together various stakeholders—including industry representatives, government authorities, healthcare professionals, patients, and service providers—in a collaborative effort to harmonize standards and promote greater regulatory alignment among countries. By reducing asymmetries and promoting the convergence of requirements, the initiative seeks to facilitate the flow of technologies between markets and, above all, expand patients' access to safe and effective medical innovations.

Proposals for **smart regulation**

1 GOOD REGULATORY PRACTICES

The consolidation and continuous maturation of Good Regulatory Practices are essential for improving the regulatory system. This includes the systematic adoption of tools, such as Regulatory Impact Assessment (RIA) and Regulatory Outcome Assessment (ROA), which promote decisions that are increasingly evidence-based and proportionate to the health risk. It is essential to ensure continuous monitoring of the results of current regulations, so that existing regulations are maintained only when they remain necessary and effective. This process must occur with transparency and structured public participation, strengthening the legitimacy and quality of regulatory decisions.

2 COORDINATION AMONG AUTHORITIES IN CONTEXTS OF DUAL REGULATORY ACTION

In contexts where a single product is subject to the oversight of different authorities, it is essential **to ensure effective institutional coordination among the agencies involved**. A lack of alignment can lead to overlaps, interpretive differences, and increased regulatory complexity, without a proportional gain in terms of public heath protection. Coordinated action, with a clear definition of responsibilities and formal mechanisms for technical dialogue, contributes to greater predictability, regulatory consistency, and efficiency in the implementation of requirements.

Proposals for
smart regulation

3 EFFICIENT MANAGEMENT OF QUEUES AND REGULATORY TIMELINES

Efficient management of regulatory timelines is a critical factor in expanding and accelerating access to health technologies. In this context, it is important to **advance strategies that optimize the use of regulatory authorities' resources through the streamlining of processes, as well as the adoption of agile management methodologies, accompanied by performance indicators**. Initiatives such as optimizing the grouping of product families with the same technical basis, reducing redundant change requests by reusing common documentation across different dossiers, and expanding the scope of lower-risk changes to include those that are non-reportable or eligible for immediate implementation can help reduce redundancies, ensure greater proportionality to risk, and increase the efficiency of analyses.

4 STREAMLINING DOCUMENTATION REQUIREMENTS

It is proposed that **requirements be directly related to the demonstration of product safety and performance**, avoiding the submission of documents that do not add equivalent technical value.

In this context, the requirement for documents such as the Free Sale Certificate could be re-evaluated in light of its actual contribution to the health review, especially considering that ANVISA conducts a complete technical evaluation of products during the regulatory approval process, in addition to requiring Good Manufacturing Practice certification for manufacturing facilities. It is worth noting that, for in vitro diagnostic devices, the regulatory framework already dispenses with this type of requirement, highlighting the viability of approaches based on direct technical evaluation and allowing for a reduction in reliance on evidence linked to prior marketing in other markets, in line with Anvisa's regulatory autonomy.

8.2 INSTITUTIONAL IMPROVEMENT OF REGULATORY AGENCIES

Just as regulatory frameworks are constantly evolving — being periodically reviewed, updated, and refined — it has become an essential requirement for regulatory action. The effective implementation of Good Regulatory Practices also requires that regulators themselves keep pace with this transformation. This means that regulatory action cannot be static: it must continually adapt to technological, scientific, and market changes, incorporating new knowledge and tools that enable more informed, agile, and evidence-based decisions.

This need for constant updating is even more evident in the medical device sector, which stands out for its high dynamism. This is a segment marked by increasingly shorter innovation cycles, in which new technologies emerge, evolve, and are replaced within a short timeframe. Furthermore, products are becoming progressively more complex, often integrating digital solutions, artificial intelligence, and connectivity. Given this scenario, keeping pace with these innovations is no longer a competitive advantage and in this context, the continuous training of professionals involved in the regulatory process becomes indispensable. Technicians and specialists responsible for analyzing and approving technologies must be in a constant process of learning and updating their knowledge so that they understand not only how new products work but also their potential risks, benefits, and impacts on the healthcare system. This process of continuous professional development contributes to safer, more consistent decisions that are aligned with international best practices.

In addition to technical expertise, another fundamental aspect highlighted by ABIIS concerns the institutional structure of regulatory agencies. **In order to adequately fulfill their mission, these institutions must have operational conditions commensurate with the complexity of their responsibilities**. This includes not only the existence of well-defined and efficient processes but also the availability of sufficient human resources with appropriate training. Overburdened teams or a shortage of professionals can compromise the quality of analyses, extend deadlines, and, consequently, impact the public's access to innovative technologies.

Therefore, the consolidation of a modern, efficient regulatory environment aligned with Good Regulatory Practices depends on a continuous effort to update both technical and institutional aspects. This is a process that involves investing in people, improving structures, and being open to dialogue with the private sector and society, always with the goal of balancing safety, innovation, and access to the healthcare system.

IN ORDER TO ADEQUATELY FULFILL THEIR MISSION, THESE INSTITUTIONS MUST HAVE OPERATIONAL CONDITIONS COMPATIBLE WITH THE COMPLEXITY OF THEIR RESPONSIBILITIES

Proposals for the **institutional strengthening of regulatory agencies**

In line with the need for continuous strengthening of the technical and institutional capacity of regulatory authorities—an essential condition for the consolidation of a modern, efficient regulatory environment aligned with Good Regulatory Practices—several structural measures can be highlighted:

1 STRENGTHENING THE WORKFORCE AT GGTPS/ ANVISA AND ANS

Bringing the staffing levels of the General Directorate of Health Product Technology (GGTPS) up to the minimum estimated requirement of 112 employees is a measure to ensure the operational capacity of the department, as well as to replenish the staff at ANS. Adequate staffing levels are essential to address the complexity and growing volume of regulatory demands, contributing to greater speed, quality of analysis, and predictability of processes.

2 INSTITUTIONALIZATION OF FORUMS FOR TECHNICAL DIALOGUE

The creation of a **permanent Technical Committee, with the participation of Anvisa, Inmetro, and sector representative entities**, holding periodic meetings, can strengthen information exchange and the joint development of regulatory solutions. This forum for dialogue contributes to greater transparency, alignment of expectations, and continuous improvement of the standards applicable to the medical device sector.

Proposals for the **institutional strengthening of regulatory agencies**

3 MODERNIZATION AND IMPROVEMENT OF SYSTEMS

The enhancement of the DATAVISA system, focused on reducing instability and optimizing functionality, combined with **the incorporation of data analysis tools, automation, and artificial intelligence**, represents a significant step toward increasing operational efficiency and identifying redundancies in regulatory processes. More robust systems enable the improvement of process handling and analysis, promoting regulatory predictability and enhancing the experience of both users and the regulatory authorities themselves.

4 RECOGNITION OF TECHNICAL STANDARDS

The publication of a list of technical standards recognized by Anvisa, which manufacturers may voluntarily adopt, contributes to greater clarity regarding the requirements applicable to product regulation. This approach, aligned with international practices, promotes regulatory convergence, reduces uncertainty, and increases predictability, while preserving technical flexibility for demonstrating compliance with applicable requirements.

Proposals for the **institutional strengthening of regulatory agencies**

5 ADOPTION OF A DECLARATION OF CONFORMITY

The possibility **of implementing a Declaration of Conformity**, through which the manufacturer itself certifies compliance with essential safety and performance principles, represents an option to make processes more agile and proportionate to risk. This model, already provided for in international guidelines, can help optimize regulatory resources and focus efforts on more complex analyses.

6 CONSOLIDATION AND EXPANSION OF RELIANCE STRATEGIES

Strengthening the reliance policy—by expanding the recognition of Equivalent Foreign Regulatory Authorities and extending it to post-registration petitions—allows for greater use of evaluations already conducted by other jurisdictions. This approach also helps reduce redundancies, optimize resources, and accelerate access to innovative technologies, while maintaining high safety standards.

Together, these measures reinforce the importance of aligning technical expertise, institutional structure, and more modern regulatory instruments, creating conditions for the regulatory system to keep pace with technological evolution and respond more efficiently to society's demands.

8.3 RATIONAL INCORPORATION OF TECHNOLOGIES

TECHNOLOGICAL INCORPORATION PROCESSES IN HEALTHCARE IN BRAZIL (PUBLIC AND PRIVATE)

Technology adoption processes in healthcare in Brazil, both in the SUS and in private health insurance, have advanced in terms of institutionalization and transparency, but still face procedural challenges related to predictability, methodological adequacy, speed of decision-making, and implementation of access, particularly for innovative technologies and medical devices, requiring regulatory improvements to expand patient access to innovation while ensuring the system's sustainability.

1 Context

The incorporation of health technologies is a technical-scientific process of evaluating and adopting new medications, medical devices, procedures, vaccines, therapeutic protocols and guidelines, or organizational systems, including digital tools (such as AI and electronic health records) within the healthcare system. It aims to enhance the technological arsenal of health systems with increasingly safe, effective, and efficient technologies, and to promote rational use based on clinical scientific evidence and economic analyses.

In Brazil, the health technology assessment process begins with the registration of the technology with Anvisa, which authorizes its commercialization from the perspective of safety and efficacy. Subsequently, to ensure broad access to the technology for the population, there is a need to incorporate it into the SUS reimbursement schedule (Conitec process) and the list of mandatory procedures for supplementary health (Cosaúde/ANS).

The incorporation of health technologies in Brazil is one of the most challenging issues for both the SUS and Supplementary Health, especially regarding the medical device sector due to its highly innovative nature and the specific characteristics inherent to these devices.

Over the past few years, significant progress has been made in health technology assessment within the SUS and supplementary health, such as the consolidation of the National Commission for the Incorporation of Technologies in the SUS (Conitec), within the SUS framework, and the creation of the Commission for Updating the List of Procedures and Events in Supplementary Health (Cosaúde) by

the ANS; however, both processes still present some challenges, in which the bureaucracy, delays (often failing to meet established legal deadlines), and a lack of transparency in decision making are just some of the aspects that require improvement within the framework of guidelines and legal frameworks governing technology incorporation processes in healthcare in Brazil.

These issues pose major obstacles to Brazilian patients benefiting from technological advances in products and procedures that are proven to be safe and effective, already available to the populations of various countries, and with great potential to generate savings and greater efficiency in the public and supplementary health systems.

Among some stakeholders in the healthcare sector, there is a mistaken belief that more innovation means higher costs for the system, leading to decisions based solely on purchase prices, without considering the patient's journey as a whole. In this scenario, the evaluation of technologies to be incorporated must be thorough and consider both the context of use within the healthcare system (public or private) and the specific characteristics of each technology. This analysis must go beyond the acquisition cost and include potential costs avoided over time, such as reductions in length of hospital stay, hospital infection rates, and adverse events, as well as enabling a faster return to professional activities, more accurate and earlier diagnoses, among many other benefits. Recognizing this need to find ways to balance society's demands for health technologies with the economic sustainability of the system, ABIIS presents proposals for improvements to the processes of technology adoption in healthcare in Brazil.

1.1. MAIN ASPECTS

The scope of the concept of health technology is quite broad, encompassing medications, medical devices, procedures, vaccines, therapeutic protocols and guidelines, organizational systems, information systems, and digital tools such as software.

Among health technologies, Medical Devices constitute the most heterogeneous and complex group for the evaluation process, given their wide variety and unique characteristics. Among these characteristics, the following stand out: i) an accelerated innovation lifecycle of 1.5 to 2 years; ii) the impossibility of conducting controlled, blinded studies; iii) high potential to generate savings for healthcare systems given their ability to alter care pathways and reduce costs related to adverse events.

Health Technology Assessment (HTA) is a systematic process that uses scientific evidence and economic analyses to inform decisions regarding the incorporation of new health technologies, such as medications, medical devices, procedures, vaccines, protocols, and therapeutic guidelines, as well as organizational systems and digital tools. The objective of HTA is to ensure that the technologies adopted are safe, effective, and contribute to the sustainability of the health system, promoting choices based on efficiency and rationality, always aligned with patients' needs and available resources. Anvisa is the agency responsible for HTA, with a focus on safety and efficacy for the approval of technology on the market, establishing maximum retail prices for certain medications. Anvisa does not conduct economic evaluations to determine

the cost-effectiveness and efficiency of the technology for the market. Conitec is the commission responsible for evaluating health technologies within the SUS. The process it conducts is structured and follows clear guidelines, prioritizing efficacy, safety, cost-effectiveness, and budgetary impact on the SUS. Furthermore, its methodology allows for broad transparency and public participation through public consultations and hearings. Interim and final decisions are publicly disclosed in the form of recordings of the meetings held and technical reports. Decisions are made through a voting process by the committee members, with a clear explanation of the reasons leading to that outcome. CONITEC is an advisory body linked to the Ministry of Health (MS), to which it issues a recommendation. It is the MS that has the prerogative to decide whether or not to incorporate the technology into the SUS.

The National Supplementary Health Agency (ANS) is the body responsible for evaluating and deciding on the inclusion of procedures in the List of Mandatory Procedures for health plans. ANS's advisory body for the HTA process is Cosaúde, composed of representatives from the Chamber of Supplementary Health (CAMSS), with final decisions made by the Collegiate Board (Dicol). The incorporation of new technologies into the list of procedures covered by health plans follows principles of **evidence-based health care, economic and financial balance in the sector, and social participation**; however, its methodology exhibits variations and less standardization than the Conitec model. Cosaúde meetings are also public, with broad participation by sector stakeholders and guests; however, **there is no voting mechanism to support the final decision** made by Dicol.

Finally, the methods to be applied in the preparation of submission dossiers are the same for Conitec and ANS. These are methodological guidelines published by the Ministry of Health (MS) for the preparation of Systematic Literature Reviews, Technical-Scientific Reports- (PTC), Economic Evaluations, and Budget Impact Studies, among others.

2 Incorporation of technologies into the SUS

The incorporation of technologies into the SUS is a technical-scientific process established and structured by Law No. 12,401/2011 (which created Conitec) and regulated by Decree No. 7,646/2011. It is based on the use of scientific evidence of efficacy and safety, as well as economic studies of cost-effectiveness and budgetary impact.

The process involves submitting a dossier that includes a technical-scientific opinion, a cost-effectiveness analysis, and a budget impact assessment, which must be reviewed by Conitec within 180 days (extendable by an additional 90 days) and referred to one of its committees (medicines, products and procedures, or clinical protocols) for a recommendation. The final recommendation decided by the Conitec committee is sent to the Secretariat of Science, Technology, and Innovation in Health (SCTIE) of the Ministry of Health (MS) for publication of the decision in an Ordinance in the Federal Official Gazette (DOU). Following publication, the Ministry of Health has up to 180 days to ensure the availability of the technology within the SUS. In 2022, Conitec established an efficiency benchmark called the cost-effectiveness threshold, adopting the value of 1 GDP per capita per QALY (Quality-Adjusted Life Years), currently set at R$ 40,000/QALY as a reference, also taking into account the national GDP for 2022. In exceptional cases, such as rare and pediatric diseases, the threshold may be relaxed to up to 3 GDPs/QALY.

Therefore, the main stages of the incorporation process into the SUS are, initially, the submission, which occurs through the presentation of a dossier. Any person or entity may request the incorporation of new medications, products, or procedures, provided that the technology is already registered with Anvisa. After submission, the Department of Health Technology Management and Incorporation (DGITS) of the Ministry

THESE ISSUES REPRESENT MAJOR OBSTACLES FOR BRAZILIAN PATIENTS TO BENEFIT FROM TECHNOLOGICAL ADVANCES IN PRODUCTS AND PROCEDURES PROVEN TO BE SAFE AND EFFECTIVE

of Health (MS), which serves as the Executive Secretariat of Conitec, conducts a compliance analysis in the dossier to verify that all necessary requirements for the analysis are present.

If compliant, the DGITS forwards the dossier for expert analysis, often relying on the participation and support of Health Technology Assessment Centers (NATS) to prepare the Recommendation Report to be presented to the Conitec Committee related to the technology. Through one of its three committees (medicines, products and procedures, or clinical protocols and therapeutic guidelines), Conitec deliberates and issues a **preliminary recommendation**, favorable or otherwise, regarding the incorporation of the technology into the SUS.

The recommendation report is made available for public consultation and **public participation** for 10 to 20 days, allowing for comments on the preliminary decision. Conitec then analyzes the contributions from the public consultation and presents the **final recommendation** and decision in a consolidated form to the respective committee, which deliberates again on the incorporation of the technology and forwards the **final decision** to the SCTIE of the Ministry of Health (MS). The committees are composed of one representative from each of the eight departments of the Ministry of Health (MS), namely Anvisa, ANS, AMB, CFM, CNS, Conass, Conasems, and a civil society organization active in the field of the respective technology under evaluation. Finally, following approval, the SUS has up to 180 days to make the technology available in the public health system.

3 INCORPORATION OF TECHNOLOGIES INTO SUPPLEMENTARY HEALTH

The incorporation of technologies into the Brazilian supplementary health system is a process regulated by ANS, also focused on evidence of efficacy, safety, and economic studies of cost-effectiveness and budgetary impact for updating the List of Mandatory Procedures. Since the enactment of Law No. 14,307/2022, technologies approved by Conitec (SUS) must be incorporated into the ANS List within 180 days, ensuring faster access to new treatments, medications, and procedures, including advanced therapies and personalized diagnostics. Unlike the situation at Conitec/SUS, there is no cost-effectiveness threshold in supplementary health.

THE INCORPORATION OF NEW TECHNOLOGIES INTO THE HEALTH PLANS' LIST OF PROCEDURES FOLLOWS PRINCIPLES OF EVIDENCE-BASED HEALTHCARE, ECONOMIC AND FINANCIAL BALANCE OF THE SECTOR, AND SOCIAL PARTICIPATION

3.1. MAIN STAGES OF THE INCORPORATION PROCESS AT ANS

As with Conitec/SUS, any person or entity may request the incorporation of new drugs, products, or procedures, provided they are registered with Anvisa, by submitting a dossier containing a PTC, economic evaluation, and budget impact analysis.

The General Directorate for Healthcare Regulation (GGRAS), which is part of the Directorate for Product Standards and Licensing (DIPRO), is responsible for the technical review of proposals to update the List, verifying whether the submitted dossier meets all the minimum eligibility requirements. Once deemed eligible, the proposal to update the List (PAR) containing the dossier is forwarded by GGRAS to an HTA specialist, typically a member of a NATS, for the preparation of the Critical Analysis Report (RAC), which must be presented at the Cosaúde technical meeting within 180 days of the eligibility review date.

A preliminary recommendation is drafted by GGRAS following the first Cosaúde technical meeting at which the applicant presents the PAR; next, a representative of the Health Operators presents arguments and counterarguments regarding the request; and finally, ANS presents the contents of the RAC. The GGRAS preliminary recommendation is presented by DIPRO at the ANS collegiate board meeting (DICOL) to ratify the preliminary decision and determine the opening of public consultation (and a public hearing when the decision is not to incorporate).

All material related to the incorporation process (dossier, RAC, presentations made at Cosaúde) is made available to the public during the 20-day public consultation period. When the decision is unfavorable to incorporation, ANS schedules a public hearing in which any interested citizen may register and participate with guaranteed speaking time.

After the consultation period and the public hearing, ANS schedules a new technical meeting of Cosaúde to present the contributions, ensuring speaking time for all interested parties, including the petitioner.

Following the post-consultation Cosaúde meeting, GGRAS issues a new recommendation regarding the inclusion of the technology in the list, which will be deliberated by Dicol regarding the final decision to be subsequently published in the Official Gazette (DOU), stipulating a deadline—generally 30 days—for health plans to begin offering mandatory coverage (when the decision is in favor of inclusion). In the case of ANS, inclusion may be linked to a Utilization Guideline (DUT) that specifies which cases are eligible for the use of the technology.

Proposals for the **rational incorporation of technologies**

In light of the above, it is evident that there are differences between the two **processes**. In terms of **transparency** and **public participation**, Conitec conducts regular public consultations and publishes detailed reports, which promote predictability, the traceability of discussions, and public engagement; ANS also provides for public participation, but with less detail and predictability regarding procedures and decision-making rationale. With regard **to methodology** and **guidelines**, Conitec follows clear, standardized guidelines supported by scientific evidence and robust economic analyses, whereas at ANS, despite being based on a similar scientific foundation, the process tends to be less structured and may vary depending on the regulatory context of supplementary health. Finally, the **economic scenarios** differ: Conitec's evaluations prioritize the impact on the SUS budget, whereas ANS considers the economic and financial sustainability of the providers, reflecting distinct realities and requiring specific approaches.

1 IMPROVEMENT OF THE HTA PROCESSES

Supplementary health insurance and the SUS operate on different principles, which is why we advocate for **distinct processes**, given that the target population is diverse, the comparator in the PICO question is often different, and, above all, the economic perspective differs. We need to find more agile ways to provide patients with access to health innovations in a rational and effective manner, taking into account the cost-benefit ratio of the technologies compared to existing ones in each of the systems (public and private), as well as adopting a more pragmatic approach by expanding and improving HTA processes, utilizing the

Best practices from each of the established agencies, Conitec and ANS (Cosaúde).

Process agility and the financial sustainability of health plans resulting from automatic incorporations through Conitec approvals are constant challenges in supplemental health care, given that Conitec's analysis occurs from a public sector perspective—which, in many cases, involves a nationwide acquisition carried out by the Ministry of Health (MS)—whereas in supplemental health care, acquisitions are dispersed individually by health plan operators.

The use of real-world data (RWD), such as patient records and electronic health records, is important to complement clinical studies, particularly for innovative technologies and medical devices due to the lack of randomized clinical trials.

Proposals for the **rational incorporation of technologies**

2 TRANSPARENCY, PUBLIC PARTICIPATION, AND REDUCED WAIT TIMES

The GGRAS deliberation, which currently takes place internally, should be made public, thereby ensuring **transparency** and taking into account the views of Cosaúde members who currently do not have voting power.

Social participation and that of the petitioner contribute to greater engagement by patients and society at large, in addition to promoting greater equality and a platform for the petitioner to speak, in the case of ANS. In the case of Conitec, the petitioner and society should have the same opportunities for input promoted by ANS, such as public hearings and broader participation by the petitioner in discussions, particularly throughout the entire committee meeting, which currently conducts discussions without the petitioner's presence.

The medical devices sector operates quite differently from the pharmaceuticals sector, as previously explained. Innovations or even product updates occur at a rapid pace. Given this fact, it is of the utmost importance that the deadlines for the HTA be equally expedited. The **proposal** is to establish shorter deadlines for analysis in specific regulations (laws, decrees, ordinances, and resolutions), which should not exceed 120 days.

3 EVELOPMENT OF SPECIFIC HTA EVALUATION GUIDELINES FOR MEDICAL DEVICE ATS

Considering the differences between medical devices and drugs, the **logic used for technology incorporation analyses of the two product categories must also differ**, in accordance with the specific characteristics of each. The benefits that a new medical device technology can bring to a patient's life have impacts that extend beyond the user and encompass the entire healthcare system, such as the reduction of hospital costs. For this reason, it is essential that these products be evaluated from a specific perspective that is better suited to their characteristics.

Therefore, it is essential to develop specific guidelines for the HTA of medical devices under the coordination of the Ministry of Health, with the participation of industry and academia, modifying the way clinical evidence is evaluated in light of the barriers to conducting studies according to the nature of the technology.

Proposals for the
rational incorporation of technologies

4 SUS BUDGET – INCLUSION IN MINISTRY OF HEALTH ANNUAL BUDGET FOR SPECIFIC ALLOCATION OF FUNDS FOR THE INCORPORATION OF NEW TECHNOLOGIES

The Annual Budget Law (LOA) establishes the federal budget. In its preparation, it is up to the National Congress to evaluate and adjust the proposal that the Executive Branch submits to Parliament. However, the Ministry of Health's budget established in the LOA does not have a specific line item for the incorporation of new technologies. Considering that the benefits innovation can bring to the health sector are not immediate, it is necessary to create a programmatic initiative to invest in the incorporation of technologies considered most efficient for the population so that the benefits can be reaped over the long term. Above all, this measure will have a positive impact on investments in research and innovation in the medical device sector in the country.

One possible action would be to propose to the Ministry of Health and the National Congress that the LOA include a specific line item for the incorporation of new health technologies with a dedicated budget allocation for this purpose.

8.4 IMPROVING THE BUSINESS ENVIRONMENT

The medical device sector encompasses a wide range of life-essential technologies, from basic consumer items to highly complex equipment and implantable devices, serving as a pillar of support for public and private healthcare networks in Brazil. In the context of sectoral development, taxation, infrastructure, and regulation are central elements. A healthy business environment is defined by predictability, legal certainty, and the mitigation of uncertainties that could compromise investment in innovation and the maintenance of strategic inventories.

The improvement of this ecosystem is inseparable from public policies that recognize the essential nature of healthcare in line with OECD guidelines. The modernization of the system represents a historic opportunity to replace the current operational complexity with a model grounded in technical objectivity, budgetary sustainability, and adequate infrastructure, ensuring that structural bottlenecks do not become barriers to the population's access to innovative medical technologies.

THE IMPROVEMENT OF THIS ECOSYSTEM IS INSEPARABLE FROM PUBLIC POLICIES THAT RECOGNIZE THE ESSENTIAL NATURE OF HEALTH CARE IN LINE WITH OECD GUIDELINES

Proposals for **improving the business environment**

1 TAXATION: LEGAL CERTAINTY AND MANAGEMENT OF THE TRANSITION IN THE VAT MODEL

1.1. CONTEXT

The transition to the new consumption taxation paradigm (IBS and CBS) aims to simplify the system, reduce litigation, and uphold the principle of non-cumulative taxation. For these objectives to be realized in the healthcare sector, objectivity and predictability in the classification of goods and services are indispensable. Historically, interpretive discrepancies between the NCM and commercial descriptions have generated costly tax disputes.

Furthermore, data cross-referencing errors in the formulation of the new tax exemption lists by the Special Secretariat for Tax Reform excluded NCM codes whose essential characteristics had already been previously recognized by the tax administration.

At the same time, the dynamics of medical device supply require specific operational frameworks. Established instruments, such as ICMS Agreement No. 01/1999, which exempts healthcare supplies and equipment from tax, must be preserved on an equal footing throughout the transition to avoid tax gaps.

Proposals for **improving the business environment**

Similarly, non-onerous interstate transit operations—such as the prior submission of OPME for surgeries, regulated by Sinief Adjustment No. 02/2024—require full recognition to ensure that the tax is levied only at the time of actual consumption, shielding the logistics flow of hospitals.

1.2. PROPOSALS FOR STRATEGIC ACTION

The interpretation and application of the lists of tax benefits (Reduced Rate Regime and Zero Rate Regime) must strictly adhere to ANVISA's regulatory definitions, using consistent technical terminology to mitigate interpretive conflicts between the NCM and the product description.

It is important to conduct an **immediate review of the IBS and CBS regulatory lists to correct technical omissions, including, specifically, the NCM codes that appeared simultaneously in ICMS Agreement No. 01/1999 and in the PIS and Cofins exemptions**, but which were omitted from the final text of the legislation.

The effectiveness and scope of the aforementioned ICMS Agreement must be fully maintained until the end of the transition period for subnational taxes, set for December 31, 2032, safeguarding the stability of costs for critical supplies.

It is proposed that, as the ICMS is phased out and gradually replaced by the IBS between 2029 and 2032, the Management Committee ensure the replication and automatic conversion of the exemption benefit under ICMS Agreement No. 01/1999 to the proportional IBS rate, preventing the emergence of partial tax charges.

Another proposal is that the **general Dual VAT regulation ensure full recognition of the non--onerous transactions involving the shipment and movement of goods provided for in Sinief Agreement No. 02/2024**, deferring the taxable event for the IBS and CBS exclusively to the moment of the medical device's actual consumption. The objective is to ensure by law that physical shipments and transfers of medical devices on a consignment basis to hospitals retain the character of non-onerous transactions, shielded from immediate taxation.

It is also proposed that a **technical appeals body** be established, shared between the Tax Authority and the health sector, stipulating that any challenge to tax classification brought by the IBS Management Committee or the CBS Secretariat must be supported by a binding technical opinion issued jointly by the Ministry of Health and Anvisa.

Proposals for
improving the business environment

2 GOVERNANCE AND BUDGETARY-FINANCIAL EFFICIENCY

2.1. CONTEXT

The competitiveness and financial viability of the medical device sector depend on integrated government decisions, preventing fiscal and trade policies from operating in isolation from healthcare needs. One of the main financial risks of the VAT model in sectors with preferential rates or exemptions is the systemic accumulation of tax credits in the procurement and supply chain. Without agile monetization tools, these credit balances become invisible financial costs that stifle companies' cash flow.

Similarly, foreign trade policy plays a regulatory role in the healthcare supply chain. Unilateral changes in import tariffs on capital goods and technological components without domestic equivalents generate immediate cost shocks for medical service providers, making advanced diagnostics and procedures more expensive.

2.2. PROPOSED STRATEGIC ACTIONS

It is recommended that the Legislative Branch **approve Complementary Bills PLP No. 36/2023 and PLP No. 16/2025**, definitively integrating their guidelines on simplified reimbursement and mandatory deadlines for the refund of credit balances into the general regulations of the IBS and CBS.

It is proposed to the Legislative Branch **that a maximum period of 30 days be established in the Complementary Law for the approval and physical return of credits accumulated** in healthcare transactions, providing for authorization of automatic offsetting against other taxes in the event of tax authority default.

To the Executive Branch, it is recommended **that a permanent technical representative from the Ministry of Health be included in the deliberations of Camex and Gecex**, ensuring health and epidemiological alignment prior to any changes in import tax rates on medical technologies.

Proposals for
improving the business environment

3 PUBLIC POLICIES AND BUDGETARY SUSTAINABILITY OF THE SUS

3.1. CONTEXT

Sustainability in the provision of medical devices within the SUS requires financing mechanisms aligned with the economic reality of the manufacturing sector. The SUS Price List for OPME faces a substantial historical shortfall that limits supplier participation and compromises the reach of care in the most vulnerable regions.

Integrated financing models, such as the federal "Agora Tem Especialistas" program and the state cofinancing initiative of the São Paulo SUS Table, have proven that budgetary supplementation by care pathways is a viable path to restoring the economic balance of service delivery.

Furthermore, the incorporation of disruptive innovations into the SUS is hindered by budgetary constraints. Currently, new medical devices compete directly for resources with the funding of hospitals' daily routine supplies, creating an environment of competitive scarcity. Technologies that reduce hospital stays, optimize surgical procedures, and mitigate complications generate systemic savings for the state in the long term, requiring transparent budget governance focused on results and clinical efficiency.

INTEGRATED FINANCING MODELS, SUCH AS THE FEDERAL "AGORA TEM ESPECIALISTAS" PROGRAM AND THE STATE COFINANCING INITIATIVE STATE-LEVEL SUS PAULISTA TABLE, HAVE PROVEN THAT BUDGETARY SUPPLEMENTATION BY CARE PATHWAYS IS A VIABLE PATH TO RESTORING THE ECONOMIC BALANCE OF SERVICE DELIVERY

3.2. PROPOSALS FOR STRATEGIC ACTION

Initially, it is proposed that the Ministry of Health adopt a funding methodology for the Agora Tem Especialistas program to **establish a national policy for supplementing funding for high-complexity OPMEs in the SUS Table**, mitigating the risks of regional shortages.

It is recommended to encourage the replication of state programs for co-financing medical devices along the lines of the São Paulo SUS Table, establishing rules so that local treasuries supplement federal transfers and equalize regional cost disparities.

It is proposed that the prioritization criteria for updating budget allocations incorporate epidemiological indicators and measures of disease burden, directing financial revisions toward medical devices targeting clinical conditions with high prevalence and greater social impact.

Finally, it is proposed that **a budget line item dedicated exclusively to innovation in medical devices** be **established within the public health budget**, ensuring an independent funding stream for technological modernization, without competing with funds for routine hospital supplies.

4 TECHNOLOGICAL INFRASTRUCTURE AND LEGAL METROLOGY

4.1. CONTEXT

The introduction and constant updating of highly complex medical devices in Brazil face serious operational obstacles due to the scarcity of accredited laboratory infrastructure for critical performance and safety testing.

The limited capacity of the national network creates critical bottlenecks for conducting tests used for product development and validation, such as the ISO 5840 series (focused on cardiac valve prostheses), ISO 25539 (focused on catheters and stents for endoprostheses and similar products), and ISO 14242 and 14243 (focused on wear of hip and knee prostheses), these being just a few examples of fundamental and highly complex tests for building national capability regarding the development and provision of high-value-added technologies to the SUS.

The saturation of the few accredited facilities results in waiting lists and longer turnaround times for regulatory validation that often exceed 12 months, frequently just to obtain a result, which

Proposals for **improving the business environment**

still needs to be analyzed and, in many cases, can lead to rework by project teams.

The high capital investment (Capex) required to purchase state-of-the-art machinery, such as pulse duplicators and multi-axis workbenches, prevents developers from establishing dedicated laboratories. This scenario significantly increases the cost of innovations in the local market, reduces the speed of updating technological portfolios, and delays the delivery of new therapies to hospitals and healthcare providers.

The expansion of this infrastructure through technical centers that already hold ISO 17025 accreditation is urgent to optimize the country's compliance processes, but, more than that, a distinction must be made between obtaining laboratory accreditation based on this standard and what adds the most value to its service portfolio—that is, obtaining the appropriate scope of accreditation to perform the tests mentioned at the beginning of this argument, beyond the capacity to acquire the equipment.

This is possible only through two systems that involve human capital and must function side by side: first, greater agility is needed in obtaining the appropriate scope of accreditation, which is achieved through on-site audits by CGCRE/Inmetro at service providers, but secondarily alongside the training and provision of qualified personnel for both the government bodies that grant accreditation and the laboratory facilities that conduct the tests based on that accreditation. These components add to the pressing need for operational investment (OPEX), bringing with them the fair counterpart to this challenging reality: highly trained personnel are required to operate high-tech equipment, delivering high-value-added services.

THE EXPANSION OF THIS INFRASTRUCTURE THROUGH CENTERS THAT ALREADY HOLD ISO 17025 ACCREDITATION IS URGENT TO OPTIMIZE THE COUNTRY'S COMPLIANCE PROCESSES

4.2. CONTEXT

It is proposed that the federal government, in coordination with FINEP, the BNDES, and the Ministry of Science, Technology, and Innovation, **establish funding lines and calls for subsidized credit dedicated to the acquisition of** highly complex **laboratory** and computational simulation **equipment** for technical centers that are already accredited in accordance with ISO 17025, that are already authorized by the Brazilian Network of Health Analytical Laboratories (Reblas) and that already include within their scope of accreditation the tests for which this equipment will be used, or that present a clear and feasible plan—which must be monitored—for incorporating these testing methodologies into their scope of accreditation.

It is also recommended that the federal government, in coordination with the aforementioned institutions, establish **funding programs and subsidized credit initiatives dedicated to training and hiring specialized personnel** who are demonstrably capable of operating the equipment to be acquired, in line with the accreditation objectives already achieved or intended to be achieved.

In this context, public funding for state-of-the--art metrological and laboratory infrastructure should be contingent upon the implementation of the "Open Laboratory" model, in order to make testing and certification capacity available to the entire healthcare market on a competitive basis.

It is also proposed **to create technical incentive programs aimed at the specialized training and capacity building of engineers** in international methodologies recognized as the gold standard for demonstrating the preclinical safety and performance of complex products (ISO 5840 series, ISO 25539, ISO 14242, ISO 14243, among others to be indicated by experts) and in advanced computational simulation methods applicable to health technologies.

Finally, **it is proposed that Inmetro and Anvisa establish a joint fast-track procedure (simplified summary process) for scope-expansion audits in laboratories qualified** by the program, streamlining the acceptance of the generated documents, both domestically and internationally, through multilateral mutual recognition agreements, and the integration of technical reports into national and international regulatory processes for Brazilian medical devices.

8.5 ETHICS AND COMPLIANCE

Ethics and integrity are inseparable elements that must form the foundation of all structures of a Nation state. In this regard, ABIIS, as a member of the Advisory Board of the Health Ethics Institute (IES), is aligned with the role of promoting best practices in the medical device sector.

In this context, the general objectives of the IES also form the core of ABIIS's purposes, whose intention is to promote dialogue on common issues among public and private actors, aiming for transparency and more ethical actions in the health sector, fostering fair and efficient regulation, control, and oversight, as well as private self-regulation. This also includes fostering critical thinking among all stakeholders, including patients, to create environments of fair competition, with the aim of safeguarding legal certainty, legitimate trust in economic relations, and citizens' quality of life.

In a survey conducted in 2025, the IES estimated that corruption in the Brazilian healthcare sector has increased by 79% over the past five years. What stands out, even through a simplified calculation, is the urgent need to conduct a more in-depth study to quantify, in figures, public and private corruption in the sector in Brazil.

The estimate is concerning and highlights a problem that the market has identified as growing in recent years: corruption in healthcare increases mortality, as it delays care, worsens the quality of services, and can, literally, cost lives. It means fewer resources for treatments, dilapidated hospitals, unequal access, loss of trust, and economic impact.

Acts of corruption in both the public and private sectors undermine everyone's right to universal and equal access to healthcare actions and services in the country, as mandated by Article 196 of the 1988 Federal Constitution.

The fact is that the medical device sector mobilized in 2015 with the creation of the so-called Health Ethics Medical Devices, evolving and gaining institutional robustness, thus giving rise to the IES. Through private self-regulation, now spearheaded by the IES itself, the medical device sector can point to clear results in the perpetuation of

THE INSTITUTIONAL ENVIRONMENTS IN WHICH ABIIS OPERATES, SUCH AS THE MENTIONED IES, THE INTER-AMERICAN COALITION FOR BUSINESS ETHICS, AND THE GLOBAL MEDICAL TECHNOLOGY ALLIANCE (GMTA), AMONG OTHERS, DEMONSTRATE A SERENE AND EFFECTIVE PATH TOWARD BUILDING A TRANSPARENT VALUE CHAIN

best practices, identified in companies that have remained faithful to self-regulatory standards (Normative Instructions and the Brazilian Consensus Framework for Multisectoral Collaboration in the Health Sector).

The members' maturity report, based on a self--assessment questionnaire monitored over nine years, from 2017 to 2025, indicates that, given adherence to self-regulatory standards among peers in the value chain—which also directly impacts public sector procurement—a realistic path, complementing state regulations, is feasible. This development should represent a natural opening for the sustainability of the healthcare sector to be built in a balanced manner and on solid foundations for its perpetuation.

The medical device sector constitutes a highly significant segment within the Brazilian healthcare market, with apparent consumption in 2025 projected to exceed US$10 billion. This scale demands, above all, clear and rigorous rules in the field of integrity to demonstrate the ethical maturity achieved by the sector over the past decade., clear and rigorous rules in the field of integrity.

In this context, the institutional environments in which ABIIS operates, such as the aforementioned IES, the Inter-American Coalition for Business Ethics, and the Global Medical Technology Alliance (GMTA), among others, demonstrate a steady and effective path toward building a transparent value chain, in which unethical practices can literally be mitigated and, in some cases, even eliminated from economic and financial relations.

According to the reports presented by the IES to its Advisory Board, there are **four key pillars in the construction of the business ethics ecosystem**: 1) *Identification* of unethical practices; 2) Constant *monitoring* of unethical practices; 3) *Solution* through the application, review, and innovation of state regulation, with fair and enforceable guidelines for the market, complemented by private self-regulation with faithful compliance by

the signatories; and 4) *Solution* through the development of critical thinking among professionals (and future professionals) in the healthcare sector, through education.

Thus, it is essential to have an exhaustive discussion within the private sector regarding state regulations that require revision and/or innovation, the strengthening of private self-regulation, the constant monitoring of unethical practices—both public and private—and the implementation of a concrete educational process, the results of which can be perceived across generations.

ABIIS, in partnership with IES, committed to the economic and financial sustainability of the healthcare sector in Brazil, particularly in the medical device segment, and in line with the concrete results that translate into access and the qualitative and quantitative outcomes for Brazilian patients, with regard to the promotion of ethics and integrity, presents the following proposals as an institutional commitment to assist the branches of the Federal Republic of Brazil in the upcoming legislative session.

Proposals for **Ethics and Compliance**

1 STATE RECOGNITION OF PRIVATE SELF-REGULATION

Structure business operations within Brazil's healthcare value chain through existing **private self-regulation**, whose guidelines are set forth in the Normative Instructions and the Brazilian Consensus Framework for Multisectoral Ethical Collaboration in the Health Sector, both structured, implemented, and monitored by the Instituto Ética Saúde, in partnership with its Advisory Board.

This framework should be consolidated around three pillars:

1. mandatory implementation and ongoing monitoring of signatories to verify compliance with self-regulatory standards within the entire private sector;

2. formalization of the State's endorsement of the IES's self-regulatory standards through the relevant government agencies (Federal Court of Accounts – TCU | Office of the Comptroller General – CGU), so that they serve as guidelines applicable to economic and financial relations in the public and private health sector markets;

3. In areas requiring legal enforcement for compliance by market actors, formalize the model of disciplined self-regulation through the legislative process before the National Congress.

JUSTIFICATION

Private self-regulation rules prove to be far more effective and aligned with the reality of healthcare market practices, as they are produced by the active stakeholders themselves and feature a faster process of development and modification, should adaptation to changing market practices be necessary. This brings much greater legal certainty and legitimate trust to organizational structures.

Proposals for
Ethics and Compliance

2 BROADER DISCUSSION AND APPROVAL OF BILLS THAT DIRECTLY IMPACT THE PROMOTION OF ETHICS AND INTEGRITY IN THE MEDICAL DEVICES SECTOR

National legislation regarding ethics and integrity that requires innovation and/or revision is currently under discussion among stakeholders in the value chain. This study was developed by the IES, and the proposals will be presented throughout 2026, in line with the needs observed by the market. However, the following stand out as priorities:

1. May—Month of Ethics in Health—Bill No. 2,899/2024: establishes the month of May as Ethics in Healthcare Month, as well as creating obligations for the Federal Government to establish guidelines and implement actions, with the support of state governments, in order to promote transparency in economic and financial relations among private actors. The bill has already been approved by the Chamber of Deputies (in three committees: Taxation, Health, and Constitution and Justice) and has been sent to the Senate for a vote;

2. transparency in private relations – Bill No. 4,864/2024 and others (Brazilian Sunshine Act): a bill that establishes transparency requirements in commercial relations between healthcare professionals and suppliers of medical devices and medications. There are bills currently under consideration in the Chamber of Deputies and the Federal Senate, all of which have been amended. In this regard, there is a need for a thorough review by the private sector, with suggestions for changes regarding practical feasibility upon their approval;

3. corporate liability for unethical practices – Bill No. 686/2025 (exclusion of criminal liability and liability for administrative impropriety for legal entities that adopt effective integrity and compliance measures): suggests the inclusion, in Article 2, of a provision establishing as a criterion for the exclusion of criminal liability and liability for administrative impropriety of the legal entity the requirement for compliance certifications through independent external audits and assessments, fostering mutual oversight among companies that maintain economic and financial relationships;

4. criminalization of private corruption in healthcare – Bill No. 221/2015 and others: propose an amendment to the text aimed at ensuring that the criminalization of corruption in the healthcare sector is equitable and can cover the maximum number of possibilities and segments in which such practices may occur (draft already prepared by the IES, based on technical studies aimed at expanding, in an equitable manner, the criminalization of unethical practices of private corruption among actors in the healthcare sector);

5. *Consumer (beneficiary) compliance:* propose a bill that guarantees maximum protection for consumers regarding the use of medical devices, imposing mandatory compliance rules on health plan operators, with a focus on efficiency and transparency in relations with beneficiaries. Primarily, but not limited to, authorizations for procedures, requests for documents, external audits of authorizations and/or post-procedure reviews by professionals not affiliated with the providers, full transparency in health plan rate indices and adjustment methods, as well as mandatory compliance certifications to serve as a tool for monitoring and overseeing these entities.

JUSTIFICATION

National legislation affecting ethics and integrity in the healthcare sector lacks greater assertiveness, highlighting the need for revision and innovation. Thus, considering ABIIS's institutional scope regarding the medical device segment, we propose a focused effort on initiatives that will directly result in beneficial impacts, strengthening transparency throughout the value chain and ensuring better outcomes for patients.

3 CHANGES TO THE NATIONAL CURRICULUM GUIDELINES FOR HEALTH-RELATED COURSES HEALTH FIELD FOR THE CROSS-CUTTING INCLUSION OF THE TOPIC OF ETHICS AND INTEGRITY (TRAINING OF FUTURE PROFESSIONALS)

Proposal submitted to the Ministry of Education (MEC) and the National Education Council (CNE) by the entities comprising the IES Advisory Council, including ABIIS, aiming at **the cross-cutting implementation, in higher education programs in the health field, of content on Ethics and Integrity in Economic Relations in the training of health professionals**. The proposal consists of a suggestion for the CNE to issue a Resolution.

We propose moving forward with discussions with the government regarding this proposal, given that addressing the root cause of unethical practices— namely, the education of future professionals— must be considered a priority in order for the solution to be definitive and its impacts lasting.

Proposals for
Ethics and Compliance

JUSTIFICATION

There is talk of cross-cutting themes in the presentation of content to students in health-related courses, with guiding principles common to all disciplines throughout the training period. These are themes that address the possibility of establishing an effective relationship between the acquisition of theoretical knowledge and the concrete issues of real-life situations.

In the proposal presented here, we address how economic and financial relationships should be established among those who work professionally in the health field, for example, among professionals in Medicine, Nursing, Physical Therapy, Biomedical Sciences, Pharmacy, Dentistry, Nutrition, Speech Therapy, Psychology, Physical Edutacion, as well as suppliers, hospitals, health insurance providers, among others. Always aiming for honest economic and financial relationships, without prejudice or unfair burden on the healthcare sector's value chain, with a focus on patient safety.

4 STRENGTHENING MUTUAL ACCOUNTABILITY IN PRIVATE-PRIVATE AND PUBLIC-PRIVATE RELATIONSHIPS THROUGH CERTIFICATIONS AND TRANSPARENCY PORTALS

Mutual control is a system in which all links in the value chain that interact in economic and financial relationships develop robust and thorough oversight of one another, primarily requiring compliance certifications and other documentary evidence demonstrating the integrity of the established relationships.

The model aims to create a history within the medical device value chain, in which all parties involved—from the product's release by the manufacturer and/or import procedures through to its use by the patient, as well as in the case of service provision—can contribute to a process (product and service record) so that the entire cycle has ethical traceability.

Proposals for **Ethics and Compliance**

Ethical traceability will be achieved through the electronic record of the product or service, hosted on an internet platform, where certifications and other documents necessary to prove the complete integrity of all operations can be verified (control of the product or service cycle).

It is therefore proposed that:

1. the State recognize the need to maintain a platform that hosts the product and service registry to consolidate ethical traceability;

2. compliance certifications in the healthcare sector for companies across the entire value chain, both public and private, be recognized as a tool demonstrating transparency and operational credibility;

3. the QUALIES certification, from the Instituto Ética Saúde, be recognized for its isonomic nature in the health sector, as an effective tool for generating real and transparent indicators for the concrete operability of mutual control in private relations, as well as an indicator of corporate integrity for public health procurement.

JUSTIFICATION

Trust is something that must be rebuilt throughout the entire healthcare value chain. When we foster mutual control among the links in the chain, the transparency process becomes comprehensive, no longer restricted to operations within an individualized contractual relationship, but extended to the entire product or service cycle.

Once all parties maintaining economic and financial relationships establish a chain of reciprocal oversight over their dealings—at every stage of the product and/or service lifecycle—this so-called mutual oversight and these phase-by-phase assessments come to form a process that allows, from the outset, for the tracking of all parties involved in the cycle and the operational model. With the appropriate certifications of integrity, trust will naturally be restored and demonstrated through transparency grounded in "Sustainable Ethical Procurement (SEP)."

09

CONSOLIDATED PROPOSALS

9.1 PROPOSALS FOR SMART REGULATION

Consolidation and Expansion of Good Regulatory Practices

Promote the continuous maturation of the regulatory system through the systematic adoption of Regulatory Impact Assessment (RIA) and Regulatory Outcome Assessment (ROA), ensuring evidence-based decisions and constant monitoring of the effectiveness of current regulations.

Coordination among authorities in contexts of dual regulatory oversight

Establish mechanisms for effective institutional coordination and formal technical dialogues between agencies that regulate the same product, aiming to eliminate overlaps and interpretive discrepancies and increase predictability in the sector.

Efficient management of regulatory queues and timelines

Implement agile management methodologies and performance indicators to optimize regulatory analysis, including the technical grouping of product families and the reduction of redundant applications through the use of common documentation.

Streamlining of documentary requirements

Focus document requirements strictly on demonstrating safety and performance, reassessing the need for documents such as the Free Sale Certificate to avoid technical redundancies.

9.2 PROPOSALS FOR THE INSTITUTIONAL IMPROVEMENT OF REGULATORS

Strengthening the workforce at GGTPS/ANVISA and ANS

Adjust the agencies' staffing levels—providing for a minimum of 112 staff members for the GGTPS—and make structural investments to ensure the speed and technical quality of regulatory analyses.

Institutionalization of technical dialogue forums

Create a permanent Technical Committee with representatives from Anvisa, Inmetro, and the productive sector to promote transparency and the joint development of regulatory solutions.

Modernization and improvement of systems

Update the DATAVISA system with a focus on reducing instability and integrating artificial intelligence and automation tools to eliminate operational redundancies.

Recognition of technical standards

Publish an official list of recognized technical standards that can be voluntarily adopted, promoting international regulatory convergence and clarity for manufacturers.

Adoption of Declaration of Conformity

Implement the Declaration of Conformity model, allowing manufacturers to attest to compliance with essential safety principles, making the regulatory process more proportionate to the risk.

Consolidation and Expansion of Reliance Strategies

Expand the recognition of Equivalent Foreign Regulatory Authorities, extending this practice to post-registration petitions as well, with the aim of accelerating access to innovations.

9.3 PROPOSALS FOR THE RATIONAL INCORPORATION OF TECHNOLOGIES

Improvement of HTA processes

Maintain separate Health Technology Assessment processes for the SUS and for supplementary health, respecting their distinct budgetary frameworks and diverse target audiences, while integrating the use of Real-World Data (RWD) to complement clinical analyses.

Transparency, public participation, and shorter timelines

Ensure the public disclosure of ANS deliberations and guarantee that applicants and the public have equal opportunities to speak at Conitec and the ANS, with strict review deadlines not exceeding 120 days.

Creation of specific evaluation guidelines for medical devices

Develop, under the coordination of the Ministry of Health, evaluation guidelines that take into account the specific characteristics of medical devices (such as the reduction of hospital costs), distinguishing them from the logic applied to medications.

SUS Budget

Establish in the Annual Budget Law (LOA) a specific budget line item and programmatic action dedicated exclusively to the incorporation of new health technologies.

9.4 PROPOSALS FOR IMPROVING THE BUSINESS ENVIRONMENT

Taxation (Legal certainty and VAT)

The interpretation and application of tax benefit lists (Reduced Rate Regime and Zero Rate Regime) must strictly adhere to ANVISA's regulatory definitions, using consistent technical terminology to mitigate interpretive conflicts between the NCM and the product description.

Governance and Budgetary-Financial Efficiency

It is recommended that the Legislative Branch swiftly approve Complementary Law Bills PLP No. 36/2023 and PLP No. 16/2025, definitively integrating their guidelines on simplified reimbursement and mandatory deadlines for the refund of credit balances into the general regulations of the IBS and CBS. It is recommended to set a maximum deadline of 30 days for the refund of accumulated tax credits and to permanently include the Ministry of Health in Camex/Gecex deliberations on import rates.

Public Policies and SUS Sustainability

Create national policies to supplement funding for highly complex OPMEs in the SUS Table and establish exclusive budget lines for innovation, independent of routine funding.

Technological infrastructure and legal metrology

Establish subsidized credit lines for accredited laboratories (ISO 17025/Reblas), make public funding contingent on the "Open Laboratory" model, and create a fast-track procedure for audits to expand laboratory scope.

9.5 PROPOSALS FOR ETHICS AND COMPLIANCE

State recognition of private self-regulation

Formalize the self-regulatory standards of the Institute of Health Ethics (IES) before bodies such as the TCU and CGU, transforming them into guidelines applicable to both the public and private sectors.

Approval of integrity bills

Prioritize the approval of Bill 2,899/2024 (Health Ethics Month), Bill 4,864/2024 (Brazilian Sunshine Act), Bill 686/2025 (corporate responsibility), and the criminalization of private corruption (Bill 221/2015).

Consumer (beneficiary) compliance

Propose legislation that imposes compliance rules on healthcare providers, with a focus on transparency in rate adjustments and independent external audits.

Amendment of the National Curriculum Guidelines

Implement the teaching of Ethics and Integrity in Economic and Financial Relations across all higher education courses in the health field.

Strengthening mutual oversight

Establish a platform for "product records," enabling ethical traceability throughout the entire cycle (from industry to patient) and recognize certifications such as QUALIES as indicators of integrity in public procurement.

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