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SWITZERLAND GLOBAL ENTERPRISE

Brazil

Medtech Market Factsheet

Compiled by:

Swiss Business Hub Brazil

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Official Program

Switzerland. Trade & Investment Promotion.

INTRODUCTION

The Brazilian Medtech market is the largest in Latin America with 213 million inhabitants. The market outlook for Medtech is promising and expected to grow at a 2021-2026 CAGR of 8.0%, adding up to a value of **USD 5.9bn** according to a forecast by Fitch Solutions (2022). This growth is enabled by an increasing demand for high quality medical devices and services, especially from the private health insurance market and an increase in government expenditure.

The Brazilian Medtech market is divided into public and private segment. Due to the country's polarized socio-demographic situation and the fact that Swiss companies often export premium products, they either choose to address the private and premium segment, or implement a multi-brand strategy (manufacturing in Brazil) to address both, the premium and the price sensitive value segment.

Depending on the chosen strategy, Swiss companies can enter the market by working with partners and distributors, opening a subsidiary in Brazil, operating through a joint venture or through M&A. In any case, Medtech products must go through the product registration process of Brazilian Health Surveillance Agency ANVISA (more in the regulatory chapter).

YOUR ADDRESSABLE MARKET

Where to play and how to win

The Brazilian healthcare market is mainly divided into two segments:

Healthcare	Public Health Sector	Private Health Sector
Population Coverage in %	78 %	22 %
Demand	Low- and middle priced products	High price products
Market	Price-sensitive	Premium quality
Number of Hospitals (2023)	2'457	4'184

While 100% have access, 78% of the population is assisted by the public healthcare program SUS (*Sistema Único de Saúde*) that is financed by taxpayers. The market segment is price-sensitive and demands low- and middle price products, although there are reference hospitals and health units in the public sector too. On the other hand, 22% of the population additionally pays for private healthcare plans, which are the main drivers for innovative and high technology solutions, as they demand premium products.

According to Fitch Solutions' Medical Devices Report 2020-2024, the market for medical devices was expected to grow at a 2019-2024 CAGR of 6.2% and 0.3% in USD terms, which will take the value back to USD 5.31bn (with fluctuations in 2020 and 2021 due to the Covid-19 pandemic), and then to register low double-digit growth y-o-y between 2022 and 2024.

Medtech Market Outlook by Sub-Sector

Medtech is an umbrella term for technologies in various medical sub-sectors, ranging from Odontology, Orthopedics, Ophthalmology, Dermatology, Oncology Ear, Heart and Lung specialists, among others. For each sector the trends, opportunities and challenges differ. The table below gives an overview of key sectors for Swiss companies.

	Odontology	Orthopedics and Traumatology	Ophthalmology	In-Vitro Diagnostics	Otolaryngology	Digital Health
Providers	240,000 Dentists	7,191 Hospitals	170,200 Ophthalmologists	15,000 Diagnostic Units	7,000 Otolaryngologists	7,191 Hospitals
Trends	- Intra oral scanner, - 3D printer for plaster models	- Robotics - AR and VR - Wearables - 3D printing	- Laser-assisted cataract surgery - Micro-invasive glaucoma surgery	- Point-of-care testing - Automation - Digitization	- Patient-centered care - Computer tomography	- Telemedicine - Data analytics and interoperable health - Wearables
Examples of Swiss companies active in Brazil	straumann, CURAPROX SWISS PREMIUM ORAL CARE, Geistlich Biomaterials	medartis® PRECISION IN FIXATION, medacta International	HAAG-STREIT SCHWEIZ Look closer. See further.	Roche	sonova HEAR THE WORLD	SOPHiA GENETICS, CLINERION clinical research solutions

Overview of the top 10 Hospitals and Diagnostics Centers

- **Top 10 Hospitals:** Hospital Israelita Albert Einstein (663 beds), Hospital Sirio Libanês (461 beds), Hospital das Clínicas da Universidade de São Paulo (2,972 beds), Hospital Moinhos de Vento (382 beds), São Luiz unidade Morumbi (203 beds), São Luiz unidade Anália Franco (259 beds), Hospital Mae de Deus (346 beds), IMIP (2,132 beds), Hospital Santa Paula (198 beds)
- **Top 10 Diagnosticas Centers:** Fleury Medicina e Saúde, Dasa, Delboni Auriemo, Lavoisier Diagnóstico e Medicina, Salomão Zoppi Diagnósticos, CDB Medicina Diagnóstica **in São Paulo**. Alta Excelência Diagnóstica e Multi-Imagem in **Rio de Janeiro**. Hermes Pardini em Belo Horizonte e Sabin Medicina Diagnóstica in **Brasília**.

Besides individual hospitals, who often have their own innovation departments, healthcare conglomerates would also be interesting customers for medical devices, digital health and biotech. The biggest chains are **HAPVIDA, Rede D'Or** and **AMIL.**

REGULATORY FRAMEWORK

Operating in Brazil requires Medtech companies (national and foreign players) to register the medical devices with **ANVISA**, the Brazilian Health Surveillance Agency, equivalent to the FDA or Swissmedic and an autonomous arm of the Ministry of Health. It is mandatory that a Brazilian based company is the owner of the registration towards ANVISA. For Swiss companies that do not have a subsidiary in Brazil, a **Brazilian registration holder** can act as a liaison between your product and ANVISA. As the registration is valid for 10 years or more, the strategy of hiring a registration holder is highly recommended in order to separate the commercial contract with partners and distributors from the regulatory aspect.

Risk Classification

ANVISA differentiates between **four risk classes** that are comparable with the European medical device directive.

Class I+II cover low and moderate non-invasive or superficial professional tools. The time to register varies slightly depending on the materiality of the products.

Class III+IV cover high and maximum risk products for diagnosis, monitoring of life-threatening diseases and long-term use implants like fillers or artificial bones. All class III+IV products must have a **GMP certification** (Good Manufacturing Practice) for health device's manufacturing, which requires a manufacturing site inspection from ANVISA. It can take up to 18 months to schedule an inspection, but it is possible to reduce this timeline. For companies that already have a certificate from other MDSAP member countries, no inspection is necessary and the issuance takes only 3 months. For members of **Abimed**, Brazilian Association of the Health Technology Industry, it is also possible to use a legal injunction to approve a registration based on the GMP submission protocol after 6 months of submission.

The tables below summarize the regulatory aspects and respective fees per risk class:

Class	Risk	Examples	Registration	Product	Timeframe (Months)	Validity
I	Low	Non-invasive or superficial professional tools	**Notification**	Software	1	No expiration
				Materials	1-1.5	
				IVD	1	
II	Moderate			Cosmetics	3-6	
III	High	Diagnosis of life-threatening disease, monitoring and long-term use implants	**Registration** and **GMP manufacturing**	Software	1.5	10 years
				Materials	6-10	
				IVD	4-6	
IV	Max			Software	1.5	
				Materials	8-12	
				IVD	6-12	

ANVISA Process	Estimated fees from Vera Rosas Consulting	Estimated fees from ANVISA
Notification Software	USD 1,200 to USD 1,800	Varies according to the company size: the notification of a single product or a family of products can vary from BRL 175.72 for companies with gross turnover up to BRL 360 thousand/year, up to BRL 3'514.32 for companies with gross turnover greater than BRL 50 MM/year).
Notification Material	USD 1,350 to USD 1,850	
Notification IVD	USD 1,300 to USD 1,600	
Registration Software	USD 1,800 to USD 2,600	Varies according to the company size: a single product registration can vary from BRL 780.96 for companies with gross turnover up to BRL 360 thousand/year, up to BRL 15'619.20 for companies with gross turnover greater than BRL 50 MM/year). Different fees apply to a family of products or to the registration of large equipment.
Registration Material	USD 1,350 to USD 2,000	
Registration IVD	USD 1,550 to USD 1,950	
GMP Request	USD 2,000	Varies according to the company size: for a GMP inspection outside of Brazil or the Mercosur region, the fees can vary from BRL 72'804.90 for companies with gross turnover up to BRL 360 thousand/year, up to BRL 72'804.90 for companies with gross turnover greater than BRL 50 MM/year).

Source: *Vera Rosas Registro e Legalização. Vera Rosas is a consulting company specialized in the products approval before ANVISA, legalization of companies before the Sanitary Surveillance agencies and implementation of Good Practices related to the manufacturing, storage, importation and distribution of products, and is a trusted expert of the S-GE expert network in Brazil.*

IMPORTANT: *The tables are a estimative only and we reinforce that each product's technical dossier should be individually analyzed by Vera Rosas' technical team for a more precise classification and quotation.*

Note: *The exchange rate is of 1 USD = 4.85 BRL on Aug 4th, 2023.*

Latest changes in the product registration

According to the regulatory consultancy Vera Rosas, ANVISA has recently made the following simplifications in the registration process:

- ANVISA has **formally recognized the Medical Device Single Audit Programme (MDSAP)**, under which the agency will accept quality system certifications from foreign regulators of the following countries, which are members of the MDSAP Programme together with Brazil: USA, Canada, Australia and Japan.
- **Registration of product families** are possible for products with the same composition, indications, contraindication, cautions etc.
- The term **Medical Devices** now summarizes consumables, equipment, software and implants.
- The format to present the **submissions** is now harmonized in line with international standards.
- For more details: RDC No. 751/2022, RDC 751/23.

HOW TO ENTER THE BRAZILIAN MEDTECH MARKET

The regulatory framework requires foreign companies to have a Brazilian subsidiary, a local distributor or a Brazilian Registration Holder (BRH). The main aspects of each scenario are explained below. Additionally, we recommend Swiss companies interested in the Brazilian market to participate at the leading trade shows of the sector (CIOSP for the dental industry and HOSPITALAR for medical devices and hospital supplies).

Subsidiary

- Setting up of a licensed entity
- Requires maintenance of a warehouse
- Hiring minimum required staff, including a technical responsible professional
- Sanitary licenses that cover the class risk of products lies within subsidiary

Aspects to consider

- Takes time (around 1 year) and is costly, for this reason it is usually a second step after the Swiss company has already experienced the market through a local partnership.

Distributor

- Submission of ANVISA registration through a distributor
- Distributor must have all sanitary licenses that cover the class risk of products

Aspects to consider

- Finding the right partner in Brazil requires extensive research, negotiation efforts and personal contacts (not only e-mail/phone).
- Check regional/national coverage, products portfolio, structural organization, language, etc. To reach national coverage, it may be necessary to have more than one local partner.
- Registering products through a distributor can create dependency because the partner will be the registration owner for 10 years or more. ANVISA allows the transferring of a registration through a commercial contract between the parties, though.
- It is important to coordinate the work of distributors and provide support from the headquarters in terms of marketing and business development.

Brazilian Registration Holder

It means outsourcing the registration to a **licensed consulting firm**, often referred to as a hosting company or a BRH. The BRH submits registrations on behalf of the exporter and issues Letters of Importation for each shipment, authorizing importers (distributors or end clients) to import the medical device.

Aspects to consider

- The hosting option is the Swiss Business Hub Brazil recommendation for companies that do not have a subsidiary in Brazil yet.
- This allows the Swiss company to nominate one or more distributors in Brazil, providing more freedom to negotiate.
- The registration is under the hosting company's name, but the Swiss company has the control of the situation.
- Once the Swiss company is ready to open a local subsidiary, it is possible to transfer the product registration.

EVENTS

CIOSP (Congresso Internacional de Odontologia de São Paulo) is the largest dental conference in Latin America, bringing together dental professionals from around the world to share knowledge and expertise.

- **Date:** 24 – 27 January 2024
- **Attendance 2023**: > 200 exhibitors and > 100'000 professionals
- **Swiss Pavilion confirmed**
- Watch Testimonials of Swiss Companies and advice from the Swiss Business Hub Brazil and SWISSCAM about the fair and the dental industry in Brazil.

HOSPITALAR is the largest healthcare event in Latin America, featuring a diverse range of medical products, equipment, and services, as well as educational opportunities and networking events for healthcare professionals.

- **Date:** 21 – 41 May 2024
- **Attendance 2023:** More than 1'000 exhibitors and 80'000 visitors (record year in terms of brands and attendance)
- **Swiss Pavilion confirmed**

Please note that products not registered at ANVISA need a special temporary importation license in order to be exhibited at the trade shows. You can find more information about temporary admission licenses for trade shows in this article from our experts Novatrade.

If you are a Swiss company not active in the Brazilian market yet, we recommend that you visit the fairs and take advantage of **our special trade fair services** to prepare your market entry, such as partner search; business meetings; legal, regulatory or tax advice; and others (see our conditions for CIOSP 2024 here).

If you are already present in Brazil, we highly recommend that you exhibit at the fairs with the **Swiss Pavilion**, organized by our partners from SWISSCAM, the Swiss-Brazilian Chamber of Commerce.

NEXT STEPS: HOW CAN WE HELP YOU?

Now that you know about the opportunities in Brazil, the regulatory aspects and the different strategies how to enter the market, it is time to plan your next steps. S-GE, together with its Swiss Business Hub Brazil (based in São Paulo) and our network of trusted experts, provides services across the internationalization of your company: Information and consulting, Export Workshops, Market Analysis, Legal, Tax & Regulatory, Business Partner Search, Trade Fair Services (Swiss Pavilion), Business Trip, and other Services in the Target Market.

Do not miss the opportunity to be active in one of the largest Medtech markets in the world and count on our support for a successful entry.

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