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State of the Art



# THE MEDICAL EQUIPMENT MARKET IN BRAZIL

FLANDERS INVESTMENT & TRADE MARKET SURVEY

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**MEDICAL EQUIPMENT**  
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## INTRODUCTION

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The Medical equipment market has been on the rise in Brazil for the past few years now and will only continue to do so. Technology is developing rapidly and has a positive influence on the medical market, helping the people in need.

With more than 210 million inhabitants, Brazil needs to deal with a lot of healthcare. It is also essential to provide the right health care to the people. Health care represents 8.3% of the GDP of Brazil.

With the Covid-19 pandemic going on, now, more than ever, it's crucial to have the right amount of medical equipment available not only for present needs but also in case this virus returns with mutations.





## 1.1 DIAGNOSIS, PREVENTION, MONITORING, TREATMENT

Diagnostic equipment is equipment that is made to help doctors and patients to come with a diagnosis. This can range from monitoring blood pressure, body temperature, weight, etc. What is also included in this category are the scales, dopplers, ultrasound, X-ray, and imaging. This category is very diverse, which means that the target market can range from the patient to doctor<sup>4</sup>.

This category has been on the rise in the last few years. People tend to take more care of their health by eating healthy food and going to the gym, but they as well look at their vitals.

Preventing diseases and making sure they do not spread viruses is very important. The situation in the world can contribute just how important it is to prevent another pandemic from happening. Just like healthy nutrition and working out prevents obesity. Preventive health care also needs preventive barrier devices such as condoms to stop spreading HIV/AIDS.

The treatment equipment is also a very widespread category. Most of the time this is used in hospitals. From determining the diagnosis to being hospitalized and going into surgery to post-operation care. Treatment equipment can include life support equipment to maintain the body function of the patient but also medical ventilators, incubators, heart-lung machines, and dialysis machines<sup>5</sup>.

Right now, with the Covid-19 taking overhand in many countries, there is a threat of shortcomings of alcohol gel, masks, protective clothing, goggles, and breathing machines. All this equipment is also a way of preventing the disease from spreading or at least to prevent doctors and nursing staff from getting the virus itself.

## 1.2 COMPENSATION FOR INJURY OR DISABILITY

Most of the time is this category is meant for people to help them with their mobility: elderly and people with a congenital anomaly or someone who was in an accident causing them to break something or amputate a limb. Another specific target group can be the army: the soldiers who come back from war can have problems with mobility. Those are the people who most need this equipment.

The equipment can range from wheelchairs, crutches, walkers adapted shoes to more comfortable hospital beds to make it easier to get out of bed. There is also another category called transfer equipment, which helps the patient and the caregiver to move the patient easier from place to place, this includes transfer lifts, benches, and boards<sup>6</sup>

The disability category can range from a hearing device for the elderly but can also be a device to help you speak better or also a program for dyslexic people. They can invoke on technology to help them read and understand better. Scientists believe that there is a correlation between disability and poverty. The relationship between disability and poverty is a vicious circle with difficult barriers to break. Physical barriers are hard to overcome, which makes it more difficult to get an income to be able to pay for treatment. Half of the people with disabilities cannot afford healthcare<sup>7</sup>

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<sup>4</sup> Information available at <https://www.alimed.com/diagnostics/>.

<sup>5</sup> Information available at [https://en.wikipedia.org/wiki/Medical\\_device](https://en.wikipedia.org/wiki/Medical_device).

<sup>6</sup> Information available at <https://en.wikipedia.org/wiki/Disability>.

<sup>7</sup> Information available at <https://en.wikipedia.org/wiki/Disability>.

### 1.3 INVESTIGATION, REPLACEMENT OR MODIFICATION OF ANATOMY OR A PHYSIOLOGICAL PROCESS

For this category, the people who have been in an accident comes to mind. Not only those people but women who fought against breast cancer and won are also a part of this target group. The term plastic surgery fits well with this group of medical equipment. You have all sorts of implants ranging from breast implants to buttock augmentation, but also hip replacement can count in the same category. All the equipment used by plastic surgery can be seen as a modification of anatomy.

With broken bones and fractures, you need equipment to help the body to heal properly. This is where the medical equipment comes in place: stitches, metal screws, new hips, metal plates for the brain. This is what is needed for the body to heal properly.

### 1.4 CONTROL OF CONCEPTION

Control of conception can mean preventing the conception from happening or can mean instruments that can help with the birth of the baby.

### 1.5 MEDICAL EQUIPMENT MARKET

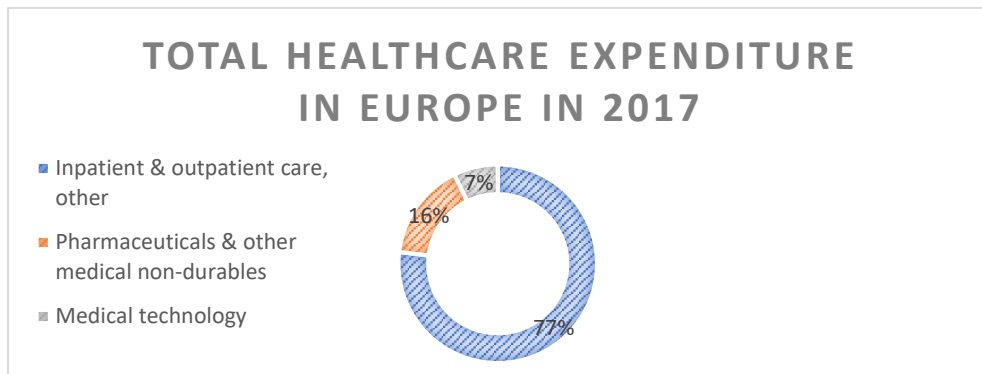
#### 1.5.1 EUROPE

The medical equipment market in Europe is roughly estimated at €115 billion in 2017. This represents 27% of the world market share and is the 2<sup>nd</sup> largest market after the United States of America. America has about 43% of the world's market share.

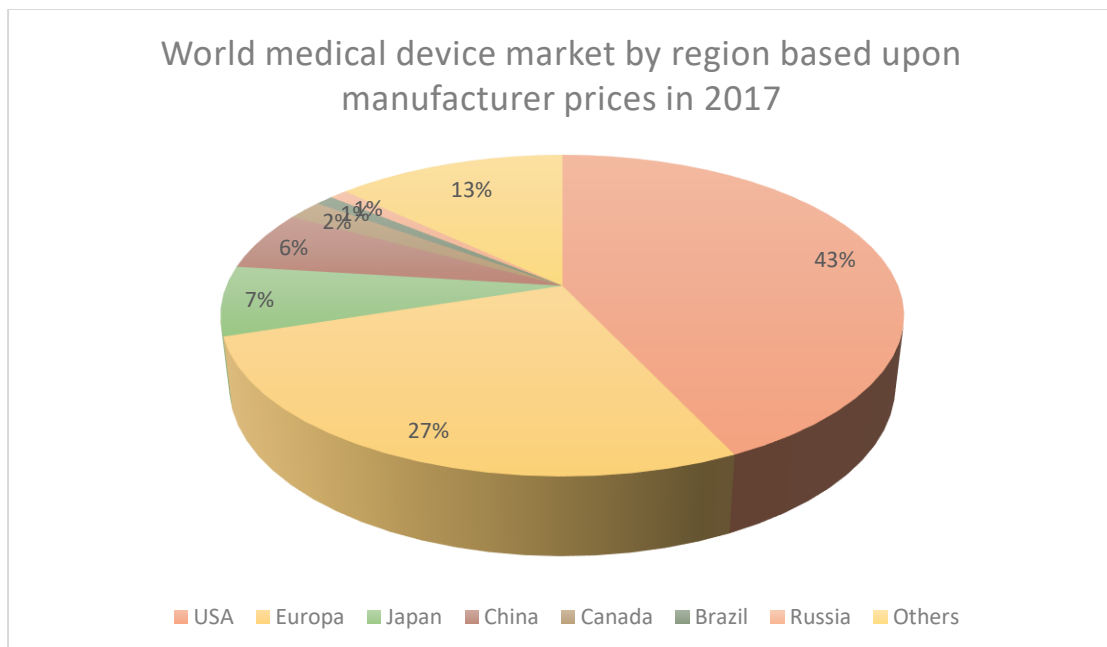
It is estimated that there are 27 000 European companies active in this sector. The top 7 countries in Europe that have the highest direct employment in this sector are Germany (200 000), United Kingdom (100 000), France (85 000), Italy (76 000), Switzerland (58 500), Ireland (38 000) and Spain (24 000).

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In the graph below, there is a breakdown of the total healthcare expenditure in Europe. The biggest category, with 77% is inpatient & outpatient care & others. The following category with 16% is pharmaceuticals & other medical non-durables. Medical equipment can be divided into two subcategories. The first subcategory is medical devices which represent 6.5% of the 7% and the other subcategory, In-vitro diagnostics represents 0.7% of the 7% <sup>8</sup>



As the graph shows, the United States of America is the market leader in this sector, followed by Europe. Europe owns about 27% of the market share, while Brazil only has 1% of the market share. Zoomed in Europe, Germany is leading the market with 27,4% followed by France with 15%. Belgium owns about 2.7% of the European market share <sup>9</sup>



<sup>8</sup> Information available at <https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf>.

<sup>9</sup> Information available at <https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085>.





### 1.5.3 LEADING BRAZILIAN MEDICAL DIAGNOSTIC COMPANIES

**Diagnosticos da America S.A.**, one of the leading Brazilian companies is specialized in making medical diagnosis equipment. They are one of the largest diagnostic medicine companies in Brazil and Latin America. They operate in more than 12 Brazilian states and as well in the Federal District. They offer more than 3 000 types of clinical analysis and diagnostic imaging services<sup>14</sup>.

Their mission is to transform the health sector by developing more personalized medicine, focusing on people's well-being, and also the quality of life. They operate with clinical analysis, imaging, and molecular diagnostics, and genomic medicine through a network of great capillarity. One of their brands is Alta, Delboni, GeneOne, etc<sup>15</sup>.

**Fleury SA** is a Brazilian health company founded in 1926, whose main activity is the provision of medical services and diagnostic medicine. With around 60 million exams performed in 2016, Fleury is the second largest company in the Brazilian field behind DASA. Among the main brands of the group are Fleury Medicina e Saúde, Labs D'or, Campana, etc<sup>16</sup>.

Through these brands, they present in the markets of São Paulo, Rio de Janeiro, Rio Grande do Sul, Paraná, Bahia, Pernambuco, Rio Grande do Norte, Distrito Federal, and Maranhão. They are partners of several hospitals, to perform diagnosis, both clinical and image analysis, and other specialities. They provide high value-added diagnostic information to conduct the work of doctors in these institutions<sup>17</sup>.

### 1.5.4 TRENDS

One of the trends in 2019 was the breakthrough in heart surgery. Open heart surgeries are risky and are also invasive. The progress that is made in the medical field allows the surgeons to experiment with new medical devices and new surgical techniques such as replacing mitral and tricuspid valves. These provide better access to the heart when using a catheter. A study showed that this technique has been proven to save lives and also reduces the recovery time of the patients.

The use of medical devices to help defeat drug addiction is rising. Drugs can save lives but can also just as easily destroy them too. They overburden the public services and disrupt communities, and because of this reason, the companies try to come up with innovative use of medical device technology.

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<sup>14</sup> Information available at <https://advantage.marketline.com/Analysis/ViewasPDF/Brazil-healthcare-providers-98153>.

<sup>15</sup> Information available at <https://dasa.com.br/>.

<sup>16</sup> Information available at <https://advantage.marketline.com/Analysis/ViewasPDF/Brazil-healthcare-providers-98153>.

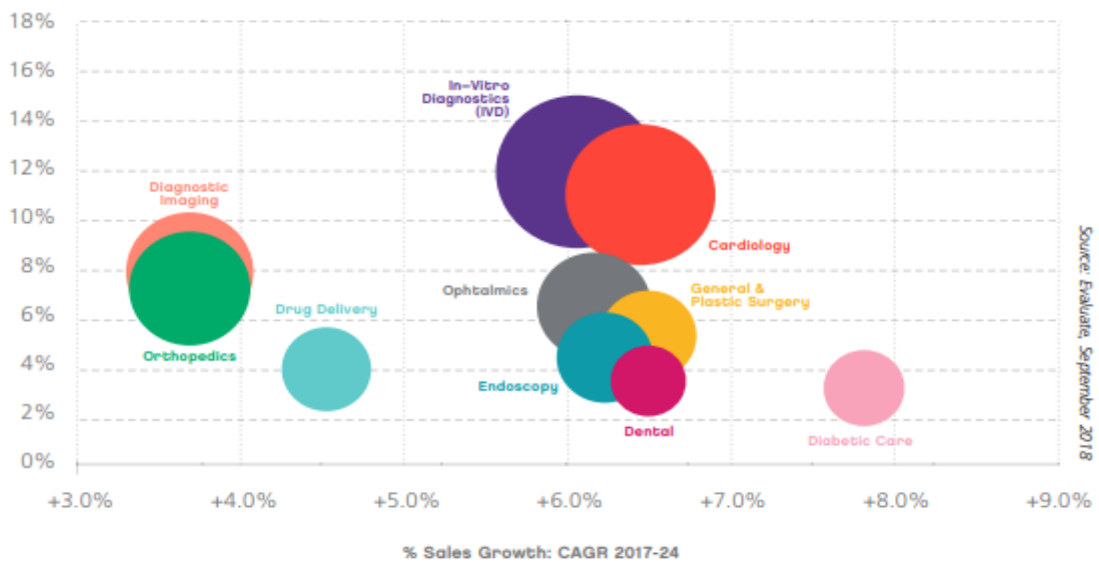
<sup>17</sup> Information available at <http://www.grupofleury.com.br/SitePages/nossos-negocios.aspx>.

Wearable technology is on the rise as well. This field is gaining popularity. **Gartner** is a world's leading research and advisory company and estimates that this field will grow 26% and up to 225 million shipments. The wearables are becoming more and more common and bigger. Non-medical companies are also paying attention to this trend. **Apple** and **Samsung** already have devices like this. You can measure your heartbeat, steps you take, and blood pressure.

Consumer good companies are also entering the sector. Non-medical device companies are engaging in medical technology. **Bose**, for instance, is working on a technology to improve hearing aids, but they aren't a company in the medical field<sup>18</sup>.

Companies will be producing more protecting gear, masks, alcohol gel to prevent a second pandemic from happening. The pandemic might inspire companies to come up with new preventing devices or technology.

Innovation is very important in this industry. It renews the growth but can also lead to great unanticipated problems. Manufacturers now have more modern technology than before; which leads to more production but also leads to a smarter and more capable way of producing complex items. The potential threat here is that many manufacturers are using the internet to improve their manufacturing chain, and this can lead to vulnerability of attacks<sup>19</sup>



<sup>18</sup> Information available at [https://www.mpo-mag.com/contents/view\\_online-exclusives/2019-09-18/top-10-trends-in-the-medical-device-and-equipment-industry/](https://www.mpo-mag.com/contents/view_online-exclusives/2019-09-18/top-10-trends-in-the-medical-device-and-equipment-industry/).

<sup>19</sup> Information available at <https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-1.pdf>.

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## 2 BRAZIL

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### 2.1 BRAZIL GENERAL MARKET INFORMATION

Brazil is the biggest country in South America with the capital being Brasília. Brazil is also the only country in South America that has Portuguese as an official language. The current president being Jair Bolsonaro. Brazil has Brazilian real as currency, exchange rate 1 euro = 6.03 reais (May 2020)<sup>20</sup>

The total area of Brazil is 8515 767 km<sup>2</sup> and the estimated population is 210 million inhabitants, which makes Brazil the 6<sup>th</sup> largest populated country in the entire world. The country is a member of various international organizations like the UN, World Bank, WTO, Mercosur, BRICS, and G-20. On the political side, the country faced a lot of corruption scandals with Petrobras being the centre of it. In the Corruption Perceptions Index of Transparency International, was Brazil ranked as 105<sup>th</sup> country out of 180 countries, meaning that there is still a lot of corruption going on in the country. On risks, the country scores 4 out of 7 on political risk, 1 being not a threat and 7 being a big threat<sup>21</sup>

Economically wise, Brazil is considered to be an advanced emerging economy. It has the 9<sup>th</sup> largest GDP in the world (Nominal) and 8<sup>th</sup> in PPP measurement. Of that GDP is the service sector the largest component and the industrial sector being the second-biggest sector. It is the biggest producer of coffee, orange juice, beef, poultry, and mid-size aircraft (Embraer) and is the world leader in the mining sector (iron, aluminum, manganese and niobium). The financial heart of the country is São Paulo<sup>22</sup>.

Their main export partners are China, the European Union, United States, Argentina, and Japan. Brazil was between the time-period 2002 to 2012 known to be the fastest-growing major economies in the world. At the end of 2013, the economic growth started to decrease and at the start of 2014 the country went into recession. The industrial sector counts for 28.5% of the GDP. This industry ranges from automobiles, computers, aircraft, and petrochemicals<sup>23</sup>.

When it comes to social factors, Brazil is one of the most diverse countries in the world. Life expectancy is of 79 years for women and 72 for the men. Most people are Christians – 66% Catholics and 22% Protestants, 8% declare having no religion<sup>24</sup>.

Throughout the last 15 years, Brazil got millions of people out of poverty but still, around 10% of the population lives in poverty. The country still did not manage to close the gap between the poor and the rich<sup>25</sup>.

The country also faces some serious crime violence. The high rates represent the murders and robberies. The homicide rate in Brazil is between 30-35 per 100 000 inhabitants. This places Brazil in the top 20 most dangerous countries by intentional homicide rate. This

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<sup>20</sup> Information available at <https://www.x-rates.com/calculator/?from=EUR&to=BRL&amount=1>.

<sup>21</sup> Information available at <https://www.transparency.org/cpi2019>.

<sup>22</sup> Information available at [https://en.wikipedia.org/wiki/Brazil?wprov=srpw1\\_0](https://en.wikipedia.org/wiki/Brazil?wprov=srpw1_0).

<sup>23</sup> Information available at [https://en.wikipedia.org/wiki/Economy\\_of\\_Brazil](https://en.wikipedia.org/wiki/Economy_of_Brazil).

<sup>24</sup> Information available at [https://www.suapesquisa.com/religiao/religiao\\_brasil.htm](https://www.suapesquisa.com/religiao/religiao_brasil.htm).

<sup>25</sup> Information available at <https://www.macrotrends.net/countries/BRA/Brazil/poverty-rate>.

country also has the most murders a year by a total number of 62 318 murders every year. Another problem that the country has is the lack of healthcare and child labor<sup>26</sup>.

Even though Brazil is an emerging country, the big cities are still very modern and up to date with developed countries. Since the 90s, the Brazilian middle class is growing rapidly which means that the population starts to buy expensive and luxurious products.

São Paulo is the heart of the financial world in Brazil. The city is the home where technology booms. In recent years technology has been booming and more specifically the software area. Brazilians are one of the most enthusiastic users of social media and almost 50% of the population is engaged in online activities which leads Brazil to be the 5<sup>th</sup> largest country on having mobile phones in the world.

When it comes to the ICT market in Latin America, Brazil is the place to be. Brazil has one of the largest markets when it comes to ICT. Brazilians tend to communicate with family and friends using the internet and mobile phones and this results of Brazilian homes without a fixed line. The ICT market is expected to account for 11% of the GDP in 2020. The government of Brazil also noticed this, and therefore they heavily invest in innovation for digital transformation projects. It is believed that the total investments were around US\$105 Billion US dollars in 2017<sup>27</sup>.

Brazilian environment is extraordinary, and this contributes to the rising tourism sector; however, this also brings its challenges along with them. Deforestation, illegal poaching, illegal wildlife trade, and all kinds of pollution have their effect on the country itself and can cause discussion throughout the world especially when it comes to the Amazon rainforest<sup>28</sup>.

The Amazon rainforest has huge biodiversity, which means that the largest collection of plants and animals. Experts suggest that there at least 40 000 plant species in the tropical forest, most of them still unknown. They might hold the key to the future of medicine<sup>29</sup>.

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<sup>26</sup> Information available at [https://en.wikipedia.org/wiki/Crime\\_in\\_Brazil](https://en.wikipedia.org/wiki/Crime_in_Brazil).

<sup>27</sup> Information available at [https://www.flandersinvestmentandtrade.com/export/sites/trade/files/market\\_studies/THE%20ICT%20SECTOR%20IN%20BRAZIL-2019.pdf](https://www.flandersinvestmentandtrade.com/export/sites/trade/files/market_studies/THE%20ICT%20SECTOR%20IN%20BRAZIL-2019.pdf).

<sup>28</sup> Information available at [https://en.wikipedia.org/wiki/Amazon\\_rainforest](https://en.wikipedia.org/wiki/Amazon_rainforest).

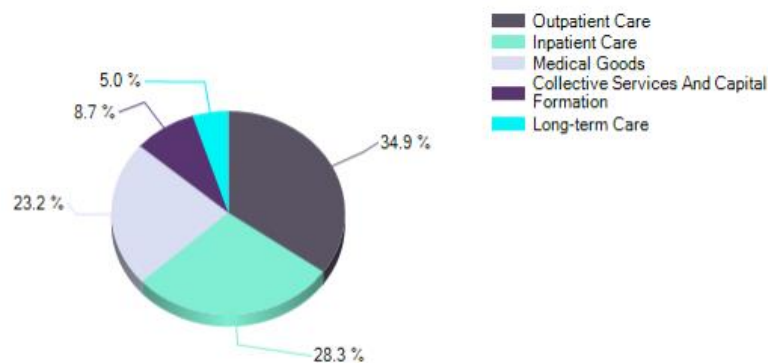
<sup>29</sup> Information available at <https://www.howandwhat.net/pestel-analysis-Brazil-Brazil-pestel-analysis/>.

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## 2.2 HEALTHCARE PROVIDERS BRAZIL

The healthcare providers sector of Brazil is valued at a total of \$224.9 billion US dollars, and it grew by 5.1%. This includes final consumption spending on healthcare goods and services. The goods and services in this sector include long-term care, medical goods, inpatient, and outpatient<sup>30</sup>.

The largest segment of the healthcare providers sector in Brazil is outpatient care which accounts for 34.9% of the total value. The third place being medical goods which account for 23.2% of the total value of the sector. Looking geographically Brazil has the second-largest market in the Americas, accounting for 5.3% of the total market share<sup>31</sup>



SOURCE: MARKETLINE

MARKETLINE

When making the comparison between Belgium and Brazil, there is an interesting detail which varies from each other. Looking at the Belgium distribution channel, the government has a 78.8% share of the distribution channel, and only 21.2% belong to private. When looking at the distribution channel of Brazil, the private channel has a share of 66.6% while the government only holds 33.4% of the total market share<sup>32</sup>.

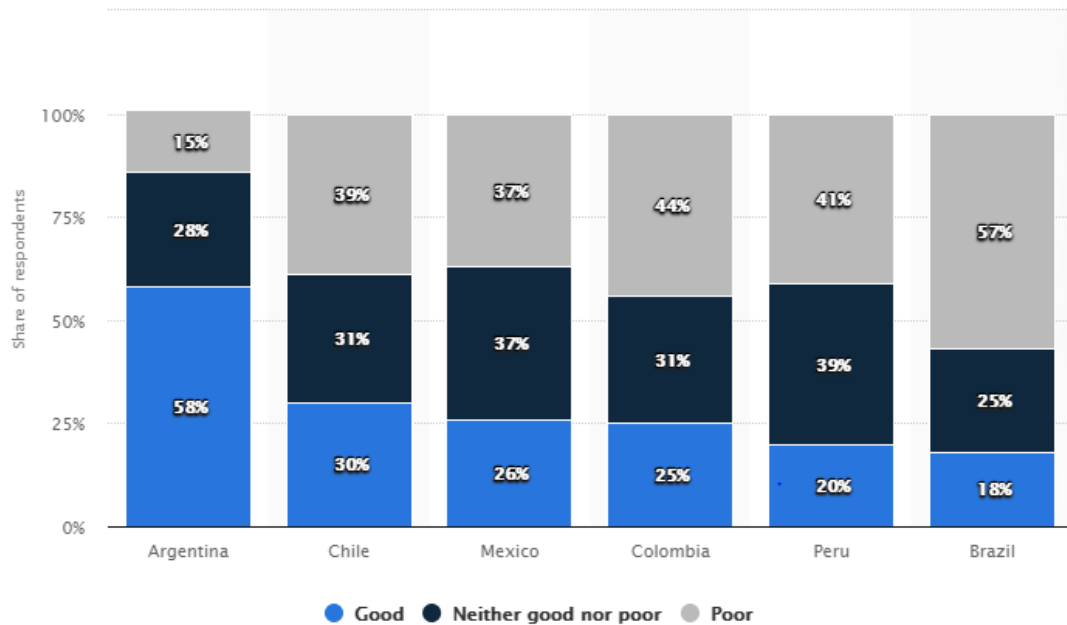
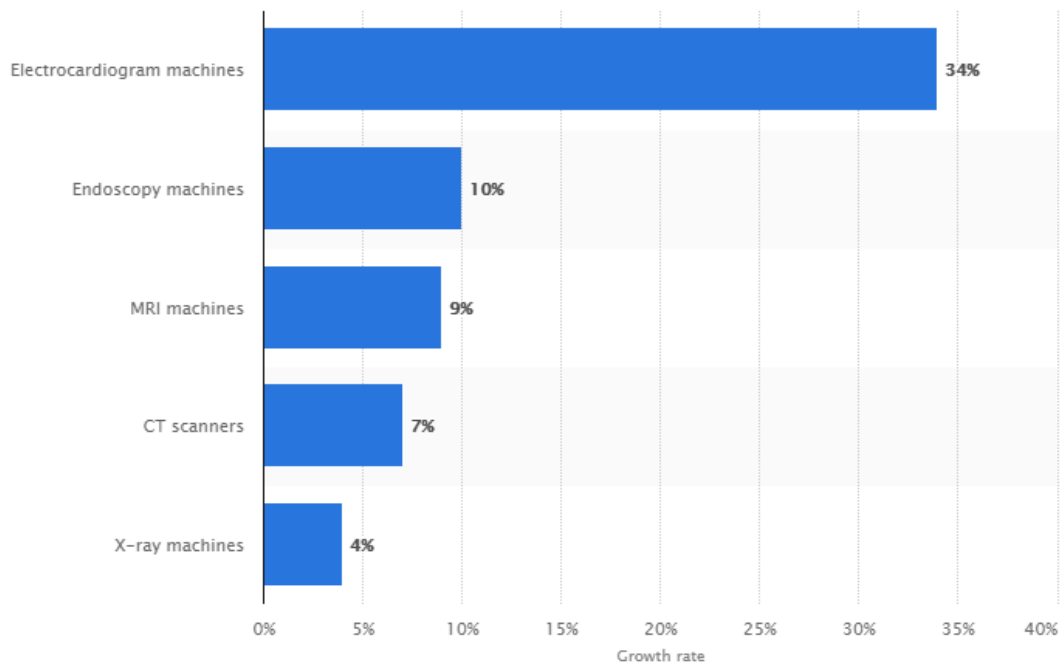
<sup>30</sup> Information available at <https://advantage.marketline.com/Analysis/ViewasPDF/Brazil-healthcare-providers-98153>.

<sup>31</sup> Information available at <https://advantage.marketline.com/Analysis/ViewasPDF/Brazil-healthcare-providers-98153>.

<sup>32</sup> Information available at <https://advantage.marketline.com/Analysis/ViewasPDF/belgium-healthcare-providers-98152>.



This graph shows the growth rate of medical equipment at hospitals in Brazil in 2017. Electrocardiogram machines and endoscopy machines are on the rise, whereas x-rays not, mainly because all hospitals are long time ago equipped with them<sup>33</sup>.



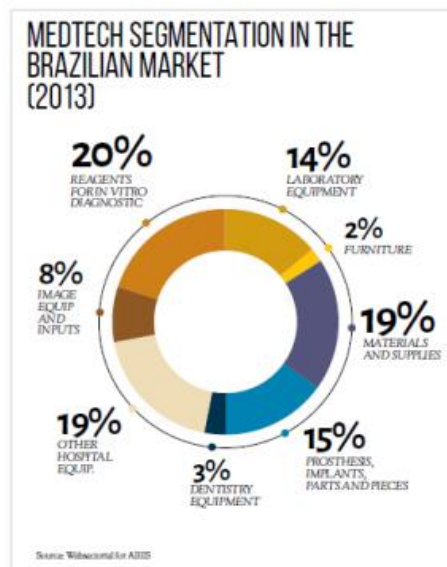
In the graph above, there is a comparison between several countries based on the quality of healthcare received in those countries as of 2018. Argentina is the only country where the quality is considered good above 50% rate.

<sup>33</sup> Information available at <https://www.statista.com/statistics/883206/Brazil-medical-equipment-growth/>.

Brazil is doing the worst compared to many other Latin American countries. This means there is a lot of room for improvement, especially when taking into account that for Brazilians health is one of their top three demands, other being better education services and lower corruption rates<sup>34</sup>.

Brazil is the largest medical equipment market in Latin America and is predicted to expand through the next years but with COVID-19 we cannot be sure of this prediction anymore. The country before the virus was a major in producing medical equipment and importing.

Medtech largest segmentation in Brazil consists mostly of reagents for in vitro diagnostic, materials and supplies, and hospital equipment. Together these three categories make up for almost 60% of the Brazilian market.



<sup>34</sup> Information available at <https://www.statista.com/statistics/911442/accessible-healthcare-quality-latin-america-country/>.

### 2.3 HEALTHCARE IN BRAZIL

Healthcare in Brazil is a constitutional right. This right is provided by private and government institutions. The Brazilian Federal Government (Union of 27 State members) runs primary healthcare while the operation of hospitals is a responsibility of each State. The most serious health problems in Brazil are childhood mortality, motherhood mortality, mortality by non-transmissible illness, and mortality caused by external causes.

Another problem that Brazil is facing is obesity. The consequences of obesity are diabetes, sleep apnea, and breathing problems, osteoarthritis, and many more. Because of these consequences, they need more in vitro diagnostic equipment to cope with the consequences. They need equipment to measure their blood pressure and sugar level as well as wheelchairs and crutches.<sup>35</sup>

The target market of medical equipment is very diverse. It can be needed by anyone and everyone. The country is big, and this means that one disease can be very common in the south but not in the north part of the country. The most common disease in Brazil is malaria but mostly in Amazon region, where the smallest part of the population lives. Yellow fever is nowadays the most common disease throughout the whole country, even in more developed areas like São Paulo and Rio de Janeiro.

The health system in Brazil is very expensive. It is the most expensive country in Latin America to seek private health care. It can cost up to 20-30% more than the neighbouring countries. It is important to explain that the health system in Brazil is a mix of public and private operations, but around 70% of the population has to rely only on the public system.

### 2.4 COVID-19 IN BRAZIL

The world now, is facing a very hard challenge. Covid-19 is conquering the world, and every country is doing its very best to get the pandemic under control. Brazil has 615.870 (June 5, 2020) confirmed cases and counts 34.039 (June 5, 2020) death, and there are 274.997 (June 5, 2020) who are recovered. Many people believe that the actual number of cases is much higher due to the fact they do not test as much as they should. Brazil is the second country with most cases around the world only behind the USA Russia and is expected to be the next world epicentre of the disease<sup>36</sup>.

The virus is causing a lot of political issues in Brazil. President Jair Bolsonaro urges that this virus is no less dangerous as mild flu and that the media made up this virus. More concerned about the economy of Brazil than the health he fired, Luiz Henrique Mandetta, federal minister of health and less than a month afterwards new appointed minister Teich. Mandetta and Teich supported local (State and City) government's social distancing measures, this against the wishes of Bolsonaro<sup>37</sup>.

While president Jair Bolsonaro has been pushing against the restrictions and urges people to go to work, local governments have been taking drastic measures ensuring social

<sup>35</sup>women are overweighted in Brazil. Information available at [https://en.wikipedia.org/wiki/Healthcare\\_in\\_Brazil](https://en.wikipedia.org/wiki/Healthcare_in_Brazil).

<sup>36</sup> Information available at <https://www.worldometers.info/coronavirus/>.

<sup>37</sup> Information available at <https://valor.globo.com/politica/noticia/2020/04/18/em-despedida-privada-mandetta-falou-em-ingratido-e-risco-de-colapso.ghtml>.



distancing and promoting staying indoors. Fearing a collapse of the health system Brazil decided to clear imported products from import duties to fight the pandemic faster. These goods are treated as a priority by the Brazilian federal custom's<sup>38</sup>.

The new political crisis raises instability in Brazil. Even though it is too early to make economic forecasts, the strong political instability generated by the now ex-minister Sergio Moro's bombastic resignation is yet another blow to the Brazilian economy and adds volatility to an already fragile picture.

An official source already cites new market projections pointing to a 6% to 8% drop in GDP. Another interlocutor points out that this moment right now, demands actions to generate a climate of stability and this movement of the now ex-ministers goes exactly in the opposite direction<sup>39</sup>.

Brazil expands the production of ventilators. There have been exceptional actions made to expand the production capacity of equipment that are essential to light the current pandemic. Even though the expansion is approved by Anvisa (The Brazilian Health Regulatory Agency) the facilities aren't licensed yet.

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### 3 OPPORTUNITIES

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The medical device industry in Brazil is the largest market in South America, the value was estimated at US\$ 4.7 billion in 2015, but over the recent years, the market share has grown and is estimated to grow to US\$5.5 billion by 2020.

The market share of imported medical devices in Brazil is fairly low, most of it coming from the EU and the USA because of higher technology added to it. Domestic manufacturers mainly focus on the local demand which means that they also have fairly low exportation of medical devices.

Recently, Brazilian federal government and Anvisa made import rules more flexible and also some tax reductions were implemented<sup>40</sup>.

The most imported types of equipment in Brazil are<sup>41</sup>:

- Pacemakers
- Stents
- Lung ventilators
- Orthopedic implants
- X-Ray machines

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<sup>38</sup> Information available at <https://edition.cnn.com/2020/04/16/americas/Brazil-health-minister-fired-intl/index.html>.

<sup>39</sup> Information available at <https://valor.globo.com/politica/noticia/2020/04/27/nova-crise-politica-eleva-instabilidade.ghtml>.

<sup>40</sup> Information available at [http://portal.anvisa.gov.br/noticias/-/asset\\_publisher/FXrpx9qY7FbU/content/dispositivo-medico-publicadas-regras-de-classificacao/219201?p\\_auth=vzGZqTQs&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp\\_auth%3DvzGZqTQs%26](http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/dispositivo-medico-publicadas-regras-de-classificacao/219201?p_auth=vzGZqTQs&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp_auth%3DvzGZqTQs%26).

<sup>41</sup> Information available at <https://globalhealthintelligence.com/pt-br/analise-de-ghi-pt-br/situacao-do-mercado-de-dispositivos-medicos-no-brasil-em-2017/>

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## 4 CHALLENGES

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### 4.1 REGULATION

#### 4.1.1 EUROPE

Regulations on medical devices and technologies are very strict and do not always match the regulation guides from Brazil. When making medical devices in Europe, you must have the CE marking. This is a certification mark that indicates that the product passed all the health, safety, and environmental rules so that they can be distributed in the European Economic Area. CE stands for Conformité Européenne<sup>42</sup>.

#### 4.1.2 BRAZIL

There are many difficulties faced by those who want to export to Brazil or Brazilian companies that want to import. Anvisa stated in 2010 that only their technicians could validate and approve the use of each product. Another part of the regulation is that the inspection must be done in the country of origin. So, when a Belgian company wants to export to Brazil, the inspection must take place in Belgium. The problem here is that the agency has only a limited number of technicians which can cause delays when the importation orders are higher than the technicians. This rule can actually be perceived as a non-tariff barrier.

The products that enter Brazil are regulated by Anvisa; they are also subject of approval at the borders when entering. These products can be subjected to physical inspection, and in some cases, you may require authorizations before their embarkation in the exporting country<sup>43</sup>.

They made exceptions to this rule, sometimes they can use the information sent by the foreign entities which end up with not sending Brazilian technicians to inspect it. Simple products, like scissors and syringes, do not need a pre-shipment inspection<sup>44</sup>.

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<sup>42</sup> Information available at <https://nl.wikipedia.org/wiki/CE-markering>.

<sup>43</sup> Information available at <http://portal.anvisa.gov.br/exporting-to-Brazil>.

<sup>44</sup> Information available at [http://portal.anvisa.gov.br/noticias/-/asset\\_publisher/FXrpx9qY7FbU/content/dispositivo-medico-publicadas-regras-de-classificacao/219201?p\\_p\\_auth=vzGZqTQs&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp\\_p\\_auth%3DvzGZqTQs%26](http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/dispositivo-medico-publicadas-regras-de-classificacao/219201?p_p_auth=vzGZqTQs&inheritRedirect=false&redirect=http%3A%2F%2Fportal.anvisa.gov.br%2Fnoticias%3Fp_p_auth%3DvzGZqTQs%26).

When importing medical devices into Brazil, certain documents are required. For example, one of the documents you need is the operating permit issued by Anvisa and to obtain this document the company and the technical manager need to be registered, pay fees, and need to be approved by Anvisa<sup>45</sup>

Another document that is needed is the registration of the equipment by the entity. Now, this process involves several procedures and requiring several documents. Following documents are required:

- Statement of company size
- Form of the importer of medical products
- Proof of payment of the health surveillance fee
- Model of the label
- Model of the operating instructions
- Technical report
- Product's certificate of free trade abroad
- Authorization of the foreign exporter or manufacturer for the commercialization of the product in Brazil
- Proof of compliance with specific technical regulation

It can be that other types of equipment may need more paperwork to get the product to Brazil.

## **4.2 IMPORT TAXES<sup>46</sup>**

There are three ways to import goods into Brazil: the first option is to directly import the goods into Brazil. The second option is to import the goods by order, and the third one is to import it on behalf of third parties.

Importers look for suppliers, import goods, and distribute throughout the country. The importers are responsible for all the logistics procedures. During this transaction, the importer is the legal owner of the goods and is responsible for all the transaction costs.

Importing by the order is similar to the first model, so during the transaction, the goods belong to the buyer. Using this model requires a local buyer for whom the goods are purchased. The last model, import on behalf of third parties, is a model where a purchaser is looking for a trading partner. The bill of lading is consigned to the importer. This person holds the ported production possession, and the ownership belongs to the third party, and he also funds the operation.

Import duty in Brazil is a federal tax upon customs clearance of foreign goods. At the moment of the import declaration, the federal government registers the customs values of the goods and they are classified according to the General Agreement on Tariffs and Trade (GATT). The importer is the one responsible for paying all the taxes prior to distribution, except for IVA.

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<sup>45</sup> Information available at <https://theBrazilbusiness.com/article/how-to-import-medical-equipment-to-Brazil>.

<sup>46</sup> Information available at <https://www.amcham.com.br/howto/howto-publications/sectorial-information/logistics-facilities/how-to-import-into-Brazil>.





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## 6 TRADE FAIRS

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### 6.1 MEDICAL FAIR BRAZIL

International exhibition on Hospital, Diagnostic, Pharmaceutical, Medical & Rehabilitation on Equipment & Supplies in São Paulo. The event takes place in September. The fair is a unique opportunity to connect with 12 000 professionals.

ABIMO – Brazilian Medical, Dental, and laboratories Device Manufacturer Association is supporting and carrying out this event while Messe Düsseldorf is responsible for the organization of this event.

A few of the product categories, which are showcased during this event are Diagnostic equipment, hospital medical equipment, diagnostic tests, and much more. During this event, there are 77 foreign representatives and 12 subsidiaries, they also provide marketing in over 130 countries with their expertise in organizing health fairs.

The visitor target groups are Hospital administrator and manager, Medical assistants, Biomedic, Biochemical, Nurse, Clinical Engineer, Pharmaceutical, Physiotherapist, Laboratory manager, Hospital manager, Doctor, Hospital operator, Rescuers<sup>51</sup>.

### 6.2 HOSPITALAR

This event is a professional trade show which is devoted to the introduction of products in the healthcare sector. The event hosts 1 200 exhibitions brands and over 70 countries are participating in this event. During this event, there are as well seminars given by more than 670 speakers on various subjects. Over 90 000 professional visitors attended last year's edition.

2020 will be the year of the 27<sup>th</sup> edition and it will strengthen the position as a source to create business opportunities and will improve the segment's technological development. Hospitalar is a part of the Informa group, which is a worldwide leader in businesses; trade shows have digital platforms that bring healthcare professionals together.

Due to Covid-19 the event is postponed to the second half of 2020. This is an annual event that takes place in May in São Paulo Expo<sup>52</sup>.

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<sup>51</sup> Information available at <https://www.medicalfair-Brazil.com.br/en/>.

<sup>52</sup> Information available at <https://www.hospitalar.com/en/home..html>.

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## 7 CONCLUSION

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Brazil in general is known as a difficult export market, with a lot of bureaucracy, lots of paperwork (especially for the importer) and high final prices, but opportunities are there.

Main reason is that most of the high technology medical devices are not locally produced and thus the same problems that apply to the Flemish exporter will apply for other European and American competitors.

The Brazilian middle-class, high middle class and richer part of the population have access to state-of-the-art hospitals, doctors and technology. That is more than 25% of the population, a market of around 50 million people<sup>53</sup>.

They prefer to be treated at home instead of travelling abroad, surrounded by family, friends and doctors that will take care of them in their own language and in their own country.

*The information in this publication is provided for background information that should enable you to get a picture of the subject treated in this document. It is collected with the greatest care based on all data and documentation available at the moment of publication. Thus this publication was never intended to be the perfect and correct answer to your specific situation. Consequently it can never be considered a legal, financial or other specialized advice. Flanders Investment & Trade (FIT) accepts no liability for any errors, omissions or incompleteness, and no warranty is given or responsibility accepted as to the standing of any individual, firm, company or other organization mentioned.*

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<sup>53</sup> Information available at <https://www.logisticadescomplicada.com/o-brasil-suas-classes-sociais-e-a-implicacao-na-economia-2/> .