How To Get Your Medical Equipment Certified and Ready for Brazil

The 8th Largest Medical Equipment Market in the World
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Introduction

Its famous beaches brand Brazil as an attractive tourist destination, but did you also know that Brazil is the largest medical equipment market in South America, and the eighth largest in the world? Brazilian medical equipment revenues in 2009 reached an estimated US$4.9 billion - an increase of 16% from the previous year! As an exporter of medical equipment, you just can’t afford to leave this money on the table.

Brazilian Medical Equipment Revenues (in US$ billions):

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<th>2007</th>
<th>2008</th>
<th>2009</th>
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<tbody>
<tr>
<td>Market Size</td>
<td>3.41</td>
<td>4.25</td>
<td>4.94</td>
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<tr>
<td>Local Production</td>
<td>1.98</td>
<td>2.14</td>
<td>2.33</td>
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<tr>
<td>Exports (FOB)</td>
<td>0.57</td>
<td>0.57</td>
<td>0.59</td>
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<tr>
<td>Imports (Global – FOB)</td>
<td>2.03</td>
<td>2.18</td>
<td>2.21</td>
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<td>Imports from U.S.</td>
<td>0.79</td>
<td>0.85</td>
<td>0.81</td>
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Source: Abimed, MDIC and US International Trade Commission (converted to US$)

Of the approximately US$2.2 billion in medical equipment Brazil imported in 2009, the United States accounted for US$0.81 billion - a little less than 40%. Currently, US sales are primarily distributed via local agents, distributors and importers, who in turn sell the equipment to hospitals and clinics. This includes medical and dental equipment and devices, radiological and diagnostic imaging equipment, and laboratory equipment.

Projected Market Growth

Abimed (Brazilian Association of Medical Equipment Importers) estimated that the Brazilian medical equipment market reached approximately US$5.5 billion by the end of 2010. It is projected to grow by 15-25% annually for the next 10 years, in part due to the increased need for home health care as Brazil’s population ages. Public health institutions and private health insurers are already seeking to reduce costs by moving more patients to home care. With the expansion of home care services and increasing consumer demand for the latest technology, this market is projected to experience rapid and steady growth with a likely 16% increase in 2010, thus representing perhaps the greatest opportunity for US exporters.
Particularly in demand are medical equipment and devices that are capable of offering around-the-clock in-home services, including in-home ICUs, laboratory exam devices, business management software, and sophisticated databases to control patient treatment. This expansion and increased focus will in turn drive the standardization of procedures for home health treatment. New opportunities for US exporters abound, particularly for:

- More advanced medical equipment
- Disposables
- Diagnostic devices
- Implants and components

In addition, the public sector is modernizing and upgrading obsolete equipment, representing a further opportunity.  
(Source: Massachusetts Office of International Trade & Investment (MOITI), Market Brief: Brazil Medical Device Industry).

**Opportunity Is Knocking – Will You Answer?**

Over the last eight years, Brazilian medical industry revenues have increased by almost 50%. Its health care industry is projected to grow at a CAGR (Compound Annual Growth Rate) of around 14.5% during 2010-2013. Although the market is growing rapidly, few foreign medical equipment exporters have thus far taken advantage of this market’s potential and there are few high-quality local Brazilian manufacturers of advanced medical products. This scarcity of local resources should ensure Brazil’s reliance on imports for some time. The perception of local buyers is that products made in the US, Canada, and Europe is of comparable quality and reliability to those manufactured in Brazil (Source: Market Brief: Brazil Medical Device Industry).

**Your Brazilian Foothold Automatically Gains Entry into Three Other Countries**

In addition to the current size and projected growth of the Brazilian medical market, there are also opportunities offered by the union between Brazil and Argentina, Uruguay, and Paraguay, referred to as Mercosul (from the Portuguese Mercado Comum do Sul or Southern Common Market), which greatly simplifies exporters’ expansion into foreign markets. To put it simply, getting your product certified to export to Brazil will give you the proverbial “foot in the door” to springboard your expansion into these other three countries. While these markets are obviously smaller, they will expand your company’s foothold and increase your brand recognition. Argentina is the fourth most populated country in Latin
America (behind Brazil, Mexico, and Columbia) and as of 2005, it imported US$115 million in medical equipment and devices, a figure which jumps to over US $300 million when medical instruments, implants, disposables, and supplies are included. The US currently leads this market with a 46% market share in 2005 (Source: Market Brief: Brazil Medical Device Industry).

**Seven Smart Steps to Begin Exporting to Brazil**

All medical equipment and devices intended for sale in Brazil must be registered with the Brazilian national health administration agency, the Agencia Nacional Vigilancia de Sanitaria (ANVISA). This agency has enforcement powers similar to the FDA, including cancellation of operation permits for drugs, food, medical and cosmetic products and licensing of manufacturers and distributors.

If your medical device is electrically powered, you will likely need to obtain INMETRO certification from an authorized Certification Body in Brazil. Also, as of May 2010, ANVISA requires most medical device manufacturers to comply with Brazil’s Good Manufacturing Practice (GMP). Intertek’s in-country partners can assist you with coordinating INMETRO testing, modifying your existing FDA GMP, or ensuring an ISO 13485-compliant system, and can also act as your Brazilian Registration Holder.

Expanding to a foreign market can be difficult if you aren’t familiar with the procedures, governing bodies and standards. Intertek can remove these obstacles by managing your medical device registration process, in seven steps:

1) Recommendation of consultants for the submission of technical documents to ANVISA.

2) Helping with certifying electro-medical devices falling under the scope of IEC 60601-1, performed by an INMETRO (National Institute of Metrology, Standardization and Industrial Quality) Certified Body, enabling your product to obtain the INMETRO Mark of Safety.

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3) Conducting testing and providing you with the Certification Body (CB) test reports so that your product can obtain the INMETRO mark plus the mark of the certifying organization.

4) Merging your existing Intertek testing and regulatory surveillance audit assessments with INMETRO processes. Once your product is certified, it will bear the INMETRO mark. If you already have a Certification Body (CB) Report, Intertek can test any differences between Brazilian national standards that are applicable to your electrical and electronic product.

5) Providing accredited, third-party quality management system auditing and certification to ISO 13485:2003 and/or many other international standards.

6) Helping with the annual surveillance assessment of your product required by all manufacturers outside of Brazil to maintain their certification. Intertek’s partnerships in Brazil will be invaluable in helping you maintain your product’s certification. This annual assessment focuses on certain aspects of ISO 9001 and routine production tests of the medical device assessment, and must be performed by a certification agency regardless of any other management system registration held by the manufacturer.

7) Recommending a partner that can help with the registration process for your medical device, with the ANVISA medical database. All medical devices shipped to Brazil are checked by Brazilian Customs against the ANVISA medical database for registration requirements and are allowed to enter Brazil only if properly registered.
# Brazil, In a Snapshot:

| Mandatory certification - Safety | • Mandatory certification is required for insulated wires & cables to 750V, electro-medical equipment, hazardous location equipment, equipment for gas system, electrical cord and cable, protection device (circuit breaker, fuse, etc.) switches, voltage stabilizers, plug and socket and household equipment will be mandatory as of July 2011.  
• On Jan. 1, 2005, plugs must comply with standard NBR 14136 (based on IEC 60906-1). NEMA configurations are no longer accepted. |
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<tr>
<td>Certification body</td>
<td>Certification bodies must be accredited by INMETRO (National Institute of Metrology, Standardization and Industrial Quality).</td>
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| Safety standards                | • Brazil National Standards (NBR). are primarily IEC-based standards.  
• AC supply voltage is 110-127 V, 60 Hz and 220V, 60 HZ, depending on location.  
• Power supply cords must meet specific requirements for conformity assessment. |
| Mandatory certification mark    | INMETRO Mark plus the mark of the certifying organization. |
| EMC requirement                 | Yes for specific products i.e. electrical equipment. |
| Intertek test report acceptability | Intertek CB test report is acceptable if testing is performed in an Intertek ISO 17025 accredited lab under the ILAC agreement. Testing must be performed by lab personnel, no witness or off-site testing is acceptable. |
| User manual in local language   | • Portuguese is required for mandatory certification  
• Portuguese, Spanish or English is acceptable for voluntary certification  
• Portuguese rating and label required |
| Sample requirement              | • Minimum of one sample (or more) for mandatory certification  
• Not required for voluntary certification |
| Factory inspection requirement / Intertek inspection report acceptability | Initial and follow-up factory inspections are required for mandatory certification. Initial factory inspection is performed by two Brazilian auditors and one Intertek auditor. Follow-up inspection can be performed by Intertek. |
| Delivery time at the certification body | INMETRO: Varies between 6 to 8 weeks  
ANVISA: Varies between 6 to 12 months for product and certification requirements |
Summary

Intertek’s product testing and certification specialists will provide the knowledge and guidance you need to certify your electrical and electronic medical equipment for use in the Brazilian market. No other test lab has strategic partners in Brazil that can perform your radio and wireless testing simultaneously.

Intertek’s partnerships in Brazil allow us to accelerate not only the testing reports, but the whole certification process, saving you both time and money. For example, with Intertek’s local auditors, you won’t need to fly an auditor from Brazil (and spend the time and money to get his visa!) just because you manufacture your product in another country!

Intertek has been in business, worldwide, for over 100 years, and can act as a consultant to help manufacturers know what they will need to be in compliance with Brazilian standards.

Establishing yourself in Brazil will provide you a foothold into the South American market - and Intertek can help you get there!

About Intertek Group

Intertek is a leading provider of quality and safety solutions serving a wide range of industries around the world. From auditing and inspection, to testing, quality assurance and certification, Intertek people are dedicated to adding value to customers’ products and processes, supporting their success in the global marketplace.

Intertek has the expertise, resources and global reach to support its customers through its network of more than 1,000 laboratories and offices and over 24,000 people in more than 100 countries around the world. Intertek Group plc (ITRK) is listed on the London Stock Exchange in the FTSE 100 index.