

## Medical Device Regulatory Requirements for

# Brazil

**Updated: September, 2008**

**Disclaimer:** The information contained on this website is derived from public sources and is current to the best of our knowledge. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted.

For general information on Brazil, please visit the CIA World Factbook entry on that country at <https://www.cia.gov/library/publications/the-world-factbook/geos/br.html>.

### Overview

Brazil has a series of regulations on imports of medical equipment. Firms must go through a lengthy registration process with Brazil's regulatory agency ANVISA in addition to obtaining licenses to sell their products within that country. The length of time between filing an application for registration and final approval by the government is variable, but this process often takes six months to two years to complete. The process for registration of medical products has been harmonized across the MERCOSUR<sup>1</sup> countries in the past few years. Manufacturers must also prove compliance with Good Manufacturing Practices (GMP).

### Regulatory Agency

The Brazilian National Health Surveillance Agency (ANVISA) is an autonomous agency linked with the Ministry of Health under a management contract. ANVISA is the regulatory authority responsible for regulation of medical products and pharmaceuticals. All products must be registered with ANVISA before being introduced to the Brazilian market (see contact information below).

### Regulations

Law No. 6360 of 1976, Decree 74.094/97 regulates medical devices in Brazil. Passed in 2001, RDC-185 is the main resolution pertaining to medical devices. It outlines the specific documents necessary in order to register medical devices and equipment with ANVISA.

All medical devices are classified into four classes: Class I, Class II, Class III, or Class IV, based upon their risk to the human body. Class I devices represent the lowest amount

---

<sup>1</sup> MERCOSUR countries include Argentina, Brazil, Paraguay, and Uruguay

of risk and Class IV devices pose the highest. The classification rules can be found in Annex II of RDC-185, and are very similar to those of the U.S. FDA and the European Union's Medical Device Directive (MDD).

Resolution No. 56 from RDC/ANVISA passed in April of 2001 stipulates that all medical devices must meet essential principles.

### **Documents Required**

For medical devices Class II, III or IV, the importer or distributor must provide the following documentation for registration:

1. A copy of payment bank receipt provided by ANVISA.
2. Identification of the manufacturer or importer and its medical device according to Annex III A, III B, and III C in RDC 185/01 declaring the technical and legal responsible;
3. A copy of authorization of the manufacturer to import and commercialize its medical device in the country;
4. A copy of registration or certificate of free trade or equivalent document issued by the competent authority where the product is manufacture and/or commercialized;
5. A copy of the certificate of accomplishment of legal requirements determined by technical regulations, in the format of Anvisa's legislation -for medical products.

For Class I products, it is only required to provide the documentation on the items 1, 2 and 5 above.

Other documentation that must be provided for registration of medical devices:

1. A Medical Products Manufacturer or Importer Form;
2. A copy of the facility operation license, issued by local sanitary authority;
3. A copy of the company working allowance, issued by ANVISA;
4. A copy of technical certification responsibility;
5. Two label samples used in the product packages;
6. Two copies of instructions;

7. Product technical report;
8. Copy of Conformity Certification issued by accredited certification organism;
9. Term of information truthfulness responsibility;
10. A declaration of conformity.

In addition to the documents necessary for registration, these two documents are necessary:

1. An import license, either Automatic or Non-Automatic;
2. A certificate of Brazilian GMP.

### **Labeling Requirements**

Act n. 8078, known as the Consumer Protection Code (CDC), was passed on September 11, 1990 and requires that product labeling provide the consumer with correct, clear, precise, and easily readable information regarding product contents, importer's name, address and telephone number.

All of the above mentioned documents and labels must be translated into Portuguese.

### **Used/Refurbished Equipment**

On February 15, 2001, ANVISA published resolution RDC number 25, which regulates imports of used medical equipment. The resolution imposes strict requirements that used equipment must meet before it can be imported into the country. Some of the requirements include:

1. The equipment must be thoroughly cleaned and refurbished;
2. All parts and pieces subject to wear and tear must be replaced;
3. The equipment must be professionally calibrated to meet original specifications and must be certified by the original manufacturer;
4. New labels must be affixed and an instruction manual must be provided;
5. Submit the year the equipment was refurbished;

6. The equipment must pass thorough quality control tests; and
7. Make spare parts and components available in Brazil during the useful life of the equipment.

There are severe penalties for companies that do not follow the requirements listed above, including assessment of stiff fines and even confiscation of the equipment. Therefore, it is critical that U.S. exporters of used medical equipment coordinate closely the transaction with the Brazilian importer. We also strongly advise that U.S. companies obtain the services of a reputable Brazilian customs brokerage firm with significant experience related to imports of medical equipment.

### **Import Duties and Taxes**

Imports are subject to a number of duties and taxes when entering Brazil. The three main duties and taxes are the Common External Tariff (CET), the Industrial Products Tax (IPI), and the Merchandise and Service Circulation Tax (ICMS). The CET is a tariff agreed on by the MERCOSUR countries for imports from non-MERCOSUR countries. The average CET is 14 percent with a low of 0 percent and a high of 20 percent, depending on the type of merchandise. The IPI is a Brazilian tax on both foreign and domestic manufactured goods. The IPI rate fluctuates between 0 percent and 15 percent depending on how essential the Brazilian government believes a good is to the Brazilian people. A general rule of thumb is the higher the CET rate, the higher the corresponding IPI rate will be. The ICMS is a state government value-added tax (VAT) applicable to both imports and domestic products and payable at all stages of sale from manufacturer to consumer. The ICMS varies for each state, with a low of 7 percent and a high of 25 percent.

### **Contact Information**

#### **I. Government Agencies**

##### **United States Embassy, Commercial Service, Brasilia, Brazil**

Ligia Pimental  
Commercial Assistant  
SES - Av. das Nações, Quadra 801, Lote 03  
Brasilia - DF 70403-900  
Tel: 55-61-3312-7450  
Fax: 55-61-3312-7656  
E-mail: Ligia.Pimental@mail.doc.gov

##### **United States Department of Commerce – São Paulo Office**

Jefferson Oliveira

Healthcare Industry Specialist  
Tel: 55-11-5186-7136  
Fax: 55-11-5186-7123  
E-mail: Jefferson.Oliveira@mail.doc.gov

**National Health Surveillance Agency (ANVISA)**

Dirceu Raposo De Mello  
Director- Chairman  
Anvisa Unidade 1 / SEPN Q. 515, Bloco B, Ed. Ômega, 5º andar  
Brasília-DF - CEP 70770-502  
Tel: 55-11-3448-3176  
E-mail: presidencia@anvisa.gov.br

**Brazilian Association for Technical Standards (ABNT) – São Paulo Office**

Pedro Buzatto Costa  
President  
Rua Minas Gerais, 190 - Higienópolis  
01244-010 - São Paulo - SP - Brasil  
Tel: 55-11-3017-3600  
E-mail: atendimento.sp@abnt.org.br

**II. Trade Associations**

**Brazilian-American Chamber of Commerce**

Sueli Bonaparte  
Executive Director  
509 Madison Avenue  
New York, NY 10022  
Tel: 212-751-4691  
Fax: 212-751-7692  
E-mail: info@brazilcham.com

**Brazilian Medical Devices Manufacturers Association**

Marcio Bosio  
Institutional Director  
Avenida Paulista, 1313 – 8 andar conj 806  
CEP 01311-923 São Paulo - SP  
Tel: 55-11-3285-0155  
E-mail: marciobosio@abimo.org.br