Medical Device Regulatory Requirements for Brazil

Updated: ***DATE***

Disclaimer: The information contained in this profile is derived from public sources, is intended to assist U.S. exporters in performing market research, and does not constitute legal advice. While this and other documents on this website are updated periodically as time and resources permit, regulatory systems are subject to change. For definitive information about a country's laws and policies, local counsel or the government of the country concerned should be consulted. Please click ***here*** {jane.earley@trade.gov} if you believe information contained herein should be updated.

For general information on Brazil, please refer to the U.S. and Foreign Commercial Service's country commercial guide, ***"Doing Business in: Brazil 2011 Country Commercial Guide for U.S. Companies,"*** {http://www.buyusainfo.net/docs/x_3004529.pdf} or visit the CIA World Factbook entry ***here.*** **{**https://www.cia.gov/library/publications/the-world-factbook/geos/br.html}.

Web links are current as of March 2011.

Overview

Brazil maintains a series of regulations that govern the importation of medical equipment into Brazil. In order to import and distribute a medical device in Brazil, the medical device must be registered with the Brazilian National Health Surveillance Agency (Anvisa), the government agency in Brazil responsible for regulating the importation of medical devices (among other medical products). The length of time between filing an application for registration and final approval by the government varies, but this process often takes three months to two years to complete, depending on the complexity of the device and the quality and sufficiency of the information accompanying the submission. The process for registration of medical products has been harmonized to a certain extent across the MERCOSUL[1] countries in the past few years. Manufacturers must also obtain a Good Manufacturing Practice (GMP) certificate from Anvisa in order to register their products.

Regulatory Agency

Under the structure of the Federal Public Administration, Anvisa is an independently administered and financially-autonomous agency associated with the Ministry of Health. Anvisa is the regulatory authority responsible for, among other activities, regulation of the importation of medical devices into Brazil. As mentioned above, all products must be registered with Anvisa prior to importation into Brazil (*see* contact information below).

Regulations

In Brazil, regulation of medical devices is governed by Law No. 6.360 of 1976, Decree 79.094/77, and a series of other regulations. Resolution RDC No. 185 of 22 October 2001 is the main regulation pertaining to medical devices (with the exclusion of *in vitro* diagnostic

[1] MERCOSUL countries include Argentina, Brazil, Paraguay, and Uruguay

products). It outlines the specific documents necessary in order to register medical devices with Anvisa.

All medical devices are classified into four groups: Class I, Class II, Class III, or Class IV, based upon their risk to the human body. Class I devices represent the lowest amount 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 Council Directive concerning medical devices (93/42/EEC). All medical devices in Brazil must meet certain principles of safety and effectiveness, as outlined in Resolution No. 56 (2001).

Documents Required
Most of the medical devices in Class I and Class II require a simplified submission of information applicable to products presenting low to moderate risk. This process is regulated by Resolution RDC- No. 24 of 21 May 2009. For medical devices classified as Class I or II, the importer or distributor must:

1. Pay an inspection fee to Anvisa and

2. Complete a registration form available from Anvisa, as required by RDC-24/2009.

For Class III and IV devices (and some Class I and II devices not covered by RDC-24/2009, the importer or distributor must provide the following documentation:

1. A copy of payment bank receipt provided by Anvisa;

2. Identification of the manufacturer or importer of medical device;

3. A copy of authorization of the manufacturer to import and market 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 manufactured and/or marketed;

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.

6. Documentation indicating that the device complies with the essential principles of safety and effectiveness established by RDC No.56 of2001.

For all registrations, a Brazilian GMP certificate must be provided, issued by Anvisa under requirements established under RDC No. 59 of 2000.

Anvisa announced that as of May 2010, it would require plant inspections of all medical device manufacturers marketing Class III and IV products in Brazil, and would no longer accept GMP certificates issued by the U.S. Food and Drug Administration or ISO 13485 certification (the latter necessary for CE Marking). RDC No. 25 of 21 May 2009, which came into effect in May

2010, sets forth an inspection scheme for these manufacturers. As of this writing, the details of this requirement have not been finalized.

Labeling Requirements
Law no. 8.078, known as the Consumer Protection Code (CDC), was passed in 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.

Penalties
There are severe penalties for companies that do not comply with the requirements listed above, including assessment of stiff fines and even confiscation of medical devices and equipment. Therefore, it is critical that U.S. exporters of medical devices and equipment coordinate the transaction closely 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 MERCOSUL's Common External Tariff (CET), the Industrial Products Tax (IPI), and the Merchandise and Service Circulation Tax (ICMS). The MERCOSUL CET, which is agreed upon by the MERCOSUL countries for imports from non-MERCOSUL 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, U.S. & Foreign Commercial Service, Brasilia, Brazil
Ligia Pimental, Commercial Assistant
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

U.S. & Foreign Commercial Service – 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