

Medical Device Regulatory Requirements for Argentina

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Overview

As of May 1, 2006, Argentina completed a long-awaited transition period which unified the process with other Mercosur¹ countries for registration of medical products and importers of the same in an attempt to streamline market entry. Previously, medical product applications and importer registrations were regulated by a patchwork of legislation. Companies are also asked to comply with Good Manufacturing Processes.

Regulatory Agency

The National Administration of Drugs, Foodstuffs and Medical Technology (ANMAT) under the Ministry of Health is the regulatory authority responsible for the regulation of medical products and pharmaceuticals. Importers of medical products must also register with ANMAT (*see* contact information below).

Regulations

Resolution 3802/2004 stipulates that the domestic manufacture or importation of medical products entered in to the Argentine market must be registered with ANMAT, in conformity with Mercosur Technical Regulations for Registration of Medical Products. These limited harmonized technical regulations are issued and enforced by ANMAT. Additional technical regulations are only voluntary and are issued by IRAM (the Standards Institute of Argentina).

This all-encompassing resolution unifies numerous previous resolutions, including the definition of medical devices, establishes ANMAT as the competent authority, describes labeling requirements, regulates dental devices, and recognizes the approval of a Mercosur-wide Technical Regulation for Registration of Manufacturers and Importers of Medical Devices. The resolution also authorizes ANMAT to regulate the manufacture and importation of medical devices in Argentina, adopts Emergency Care Research Institute (ECRI) nomenclature to identify medical products, recognizes established risk assessment categories (I – IV), refers to sanctions for violations, and establishes a “grandfathering” period for products already on the market to transition to new Mercosur-wide regulations.

¹ Mercosur countries include Argentina, Brazil, Chile, Paraguay, and Uruguay.

Documents Required

Required documents vary according to product but may include:

1. Certificate of Free Sale (CFS). The CFS is issued by the U.S. authority (FDA or the State Department of Health) stating that the equipment is freely sold and marketed in the U.S. according to federal rules and regulations. This document must include the name of the U.S. manufacturer providing the specifications of the equipment and its accessories. If the accessories or models were not included in the CFS, the interested company must attach a letter from the manufacturer giving the codes, models and accessories.
2. Protocol Analysis or Certificate of Analysis. This document is authored by the manufacturer's quality control division or technical staff, which may be a physician, engineer, biochemist, or other designer, depending on the nature of the product. This document must include results from applicable tests, including microbiological and chemical tests, skin sensitivity and /or human biocompatibility (according to the product) as well as the ethylene oxide waste control, or any other sterilization method used. The importer is responsible for registration of products and must submit documentation notarized by the Argentine consulate or embassy.²
3. Operation Manual. Instructions for use must be specific for each model.
4. Catalogs. Catalogs must provide technical specifications, and accessories lists, wherever applicable.

Labeling Requirements

Resolution 2318/02 provides instructions for labeling of medical products. Labeling must include a product description, as well as information on packaging material, storage conditions, lot number, expiration date, importer's data, and address

All the above-mentioned documents and labels must be translated into Spanish.

Used/Refurbished Equipment:

Until 1994, Argentina prohibited the importation of used or refurbished medical equipment. Restrictions on imports of used medical equipment are established by Resolution 909/94, Annex II and III of Resolution 748/95, and by Resolution 235/99. This legislation stipulates the following:

² For contact information on Argentine consulates in the United States, click on <http://www.embassyofargentina.us/espanol/consuladosargentinoseneeu/consuladosargentinoseneeu.htm>

- 1) Refurbished goods must be accompanied by a certificate issued by the original manufacturer, or by a technical assessment certificate, authenticated by the Commercial Section of the Argentine Embassy or local Consulate.
- 2) Refurbishment may be done in Argentina by the importer, provided he is the end user. These goods may not be resold.
- 3) The foreign vendor must ensure the availability of after-sales service and spare parts, provide user's manuals, and have an agent based in Argentina to implement servicing required.
- 4) Used equipment may not be older than ten years.

For more information on used and refurbished equipment, please visit http://www.ita.doc.gov/td/health/PreOwnedMedEquip_FINAL_060506.pdf.

Import Duties and Taxes

New medical equipment imports are subject to the Mercosur Common External Tariff (AEC) ranging from 0 to 16 percent. Imports of used or refurbished medical equipment are subject to a tariff of up to 24 percent. Under the Capital Goods Act, purchases of new equipment incur payment of a 10.5 percent value-added tax (VAT), while purchases of used or refurbished equipment cause payment of a 21 percent VAT, both of which are assessed on the CIF value.

Government Purchases

Government institutions and some private organizations follow procurement practices calling for public bids when securing goods and services. Invitations to bid are sent to potential suppliers listed with purchasing departments at hospitals and in the Suppliers' Registry (Padrón de Proveedores) at the appropriate level of government (state or city government of Buenos Aires: *see* contact information below). Nearly all hospitals require registration with a government agency, even though each public hospital makes its own purchasing decisions.

Contact Information:

I. Government Agencies

United States Embassy, Commercial Service, Buenos Aires, Argentina

Liliana Paz
Medical Industry Sector Specialist
Commercial Service
U.S. Embassy, Buenos Aires, Argentina
Tel: 54-11-5777-4519
Fax: 54-11-5777-4203
liliana.paz@mail.doc.gov

National Administration for Medicine, Food, and Medical Technology

Administración Nacional de Medicamentos, Alimentos, y Tecnología Médica (ANMAT)
Ministerio de Salud
Av. de Mayo 869
(1084) Buenos Aires
Argentina
Tel: (5411) 4-340-0800
Fax: (5411) 4-340-0800 ext. 1510
www.anmat.gov.ar

Standards Institute

Instituto Argentino de Normalización
Peru 522/56
1068 Buenos Aires, Argentina
Tel: 54-114-345-6606
Fax: 54-114-349-3755

Customs Service

Dirección General de Aduanas
Administración Federal de Ingresos Públicos
Azopardo 350
1328 Buenos Aires
Tel: 54-1-343-0661/0101/1551
Fax: 54-1-331-9881; 345-1778

Suppliers' Registry, City of Buenos Aires

Padrón de Proveedores
Gobierno de la Ciudad de Buenos Aires
Av. de May 525, PB Oficina 20
1084 Buenos Aires
Tel: 54-11-4323-9461

II. Trade Associations

Argentina-U.S. Chamber of Commerce

Cámara de Comercio Argentina-E.E.U.U.
Viamonte 1133, Piso 8
1001 Buenos Aires, Argentina
Tel: 54-114-371-4500
Fax: 54-114-371-8400

Argentine Association of Distributors and Importers of Medical Devices

Cámara Argentina de Distribuidores e Importadores de Equipos Médicos –CADIEM

Florida 15, Piso 10

1005 Buenos, Aires, Argentina

Tel: 54-114-331-6368

Fax: 54-114-331-0981