

Medical Device Regulatory Requirements for Peru

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Overview

Both the public and the private sector provide health care in Peru. The public sector health services providers are the Ministry of Health (MOH), the Social Security Service (ESSALUD) and the Armed Forces hospitals. Private sector providers include profit and non-profit clinics. Public institutions care for about 75 percent of existing patients.

Public health, social security and armed forces hospitals are only allowed to purchase new medical equipment and devices while private sector clinics may purchase new or refurbished medical equipment and devices. (*See below for more information on refurbished medical equipment*).

Regulatory Agency

The Directorate General of Pharmaceuticals, Inputs and Drugs (Dirección General de Medicamentos, Insumos, y Drogas or DIGEMID) of the Ministry of Health is the regulatory agency for the health care sector. The legal framework regulating the registration requirements for medical equipment and devices are established in Law No. 26842 dated July 20, 1997.

Regulations

It is mandatory to obtain a sanitary registry or "Registro Sanitario" to market medical equipment in Peru or to participate in a bidding process. This registration must be submitted to Peruvian customs each time the same equipment is imported.

To request the Registro Sanitario, the following steps should be considered:

- (a). The importer or dealer must be legally registered and obtain a tax identification number known as the "Registro Único del Contribuyente" or "RUC."
- (b) The interested company must fill out a form called a registration request called the "Solicitud de Inscripción," providing the following information:
 - Subject of the request
 - Name of the medical equipment, device or material

- Presentation format
- Type of material used in the primary and secondary packing/packaging
- Country of origin
- Name, address, and RUC of local company or authorized representative (Use of local agents is of great importance in Peru, as tenders are only issued to locally-based distributors. *See below* for more information on the use of local distributors).

Required Documentation

The following documents must be attached to this request:

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. 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.
Following are additional documents required for medical devices:
 - For surgical and dental instruments: chemical composition
 - For dental materials: qualitative components
 - For stainless steel instruments: number of the steel, the hardness, and any other relevant tests. The DIN or ISO codification must be indicated.
3. Operation Manual. Instructions for use must be specific for each model.
4. Catalogs. Catalogs must provide technical specifications, and accessories lists, wherever applicable.
5. Labeling Requirements. Labeling must include a product description, as well as information on packaging material, storage conditions, lot number, expiration date, importer's data, address and RUC.

Additional information:

- All the above-mentioned documents must be translated into Spanish language (a notarization is not required.)
- The certificate of free sale, the protocol analysis/analysis certificate and other documents should not be older than two years.
- The registration fee per piece of equipment, device and material is approximately US\$100 and is valid for a 5-year period.

According to law 26842, DIGEMID must issue the approval of the registration within approximately seven working days. Nevertheless, approvals have been reported to take thirty to sixty days.

Refurbished/Used Equipment:

There is no explicit restriction on the import of refurbished medical equipment in Peru. However, as a matter of practice over recent years, DIGEMID is not issuing the “sanitary registry” for refurbished medical equipment imported by local companies. Physicians requiring equipment for their own use have been allowed to import one type of refurbished equipment every year.

Import Duties and Taxes

Tariffs on medical equipment include an *ad-valorem* custom duty of 7 percent and a 19 percent value added tax (VAT).

Follows is an example of the landed cost of \$1,000 worth of medical device merchandise into Peru.

CIF Value of Merchandise	1,000.00
Ad-valorem tariff duty (4%)	40.00
Sales tax base	1,040.00
Value added tax (19%)	197.60
Custom broker charges (1-2% FOB value)	100.00
Port charges (approx 3%)	30.00
Handling charges (\$20-\$40)	20.00
Bank charges-letter of credit (3% of FOB, min fee\$277)	277.00
Landed cost (US\$)	1,664.60

Distribution

The most common method of distribution is the appointment of a qualified representative. Appointing an agent or distributor is advisable if the company is serious about developing the market on a sustained basis. At, present, U.S. companies are successfully locating qualified local agents.

Government Purchases¹

Public tenders are usually published in the main Peruvian newspapers (*El Peruano* and *El Comercio*.) Government hospitals of the Ministry of Health, in an effort to ensure transparency for government tenders, is currently using the United Nations Office for Project Service

¹ Public tenders are only issued if the value of the purchase exceeds 450,000 soles (\$136,000). Otherwise, purchases are made directly by the government.

(UNOPS) to notify potential suppliers. The social security agency, ESSALUD, mostly buys centrally through its procurement office.

Public sector purchases must be carried out in accordance with Government Procurement Regulations (Ley de Contrataciones y Adquisiciones del Estado) and the budget of each agency. According to the procurement regulations, which entered in force in March 2001 a preference exists for domestic suppliers.

Other documents required when responding to government tenders include:

Representation Agreement, issued by the manufacturer indicating the name of their representative in Peru. The agreement must be legalized by a Peruvian Consulate in the United States and registered by the Peruvian Ministry of Foreign Affairs.

Certificate of Good Manufacturing Practices, issued by the foreign government authority (FDA or State Department of Health)

Proof of conformity with ISO 9001 and ISO 13485.

Proof of conformity with electrical standards IEC-601-DINVDE0750-1 or its international equivalent as applicable.

Update

In December, 2005, the United States and Peru completed negotiations a Trade Promotion Agreement (Peru-TPA) that provides for equitable and reciprocal trade liberalization between the two countries. For medical equipment, 98 percent of U.S. industrial exports will receive duty-free treatment immediately upon implementation of the agreement. The only products not subject to immediate tariff elimination are orthopedic and fracture appliances. Duties on these products will be eliminated over five years. The agreement also allows for free importation of remanufactured goods with tariffs on these goods eliminated over ten years. For more information and updates on the U.S.-Peru Trade Promotion Agreement, please visit http://www.ita.doc.gov/td/tradepolicy/fta_peru.html

Contact Information

Government Agencies

Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)

Ministerio de Salud

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Jesus Maria, Lima 11, Peru

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Contact: Dra. Amelia Villar, General Director

Contact: Dr. Anibal Diaz, Executive Director of Sanitary Authorizations

Web: www.minsa.gob.pe/infodigemid/

Trade Associations

Asociación de Clínicas Particulares
(Association of Private Clinics)
Av. Dos de Mayo 1502, Of. 202
San Isidro
Lima 27, Peru
Phone: (511) 422-4024
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