

Medical Device Regulatory Requirements for Colombia

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Regulatory Agency

The regulatory agency is the National Institute of Surveillance of Medicine and Foods in the Ministry of Health. The Colombian Ministry of Foreign Trade controls imports and exports and enforces regulations.

Registration

The Colombian Government registers imports and exports through the Colombian Ministry of Foreign Trade (previously registered by INCOMEX). Under the Decrees 1292 and 1298, Resolutions 2092 and 5039, the following is required, but not enforced:

- a. Certificate to Foreign Government
- b. Letter of Authorization
- c. Final Product Drawings
- d. List of Components/Materials
- e. Manufacturing Method
- f. Labels/Directions for Use
- g. Sterilization Parameters
- h. Packaging Materials
- i. Quality Control Test Methods
- j. Product Brochure

Import License

Medical equipment is classified on the free import list, which means that they do not require an approved import license. However, the importer has to register the transaction with the Ministry by completing a form provided by the Ministry at a cost of approximately US \$15. The form must be completed in Spanish, except for trade names, book titles, or other terminology

that cannot be translated. It must include the following information:

- a. Import value - FOB price in U.S. dollars
- b. Customs schedule classification. Only those products classified under the same four initial digits of the Harmonized Tariff Schedule can be included in the same registration form.
- c. Units - Quantity - Unit Price - Total Value
- d. Product description. Transcription of the product description, as it appears in the Harmonized Code, and a complete description of the product to facilitate its easy and unmistakable identification, specifying characteristics such as commercial, technical or scientific name, trade mark, model, size, final use, etc.
- e. Name and address of foreign supplier
- f. Shipping company name and address
- g. Colombian port of entry
- h. Country of origin
- i. Shipping port

Although the categories of goods may be on the free import list, an import license is still required when: (1) the importer is a government entity; (2) the importer requests exemption from payment of import duties; (3) the goods are classified as non-reimbursable. The latter is the case when the payment does not require use of the country's international reserves, which is very often true for oil, gas and mining equipment.

Standards

The Colombian Institute of Technical Standards (ICONTEC) is a national governmental organization in charge of setting standards for products and equipment manufactured or imported into Colombia. Standards established by ICONTEC are generally in agreement with international standards and practices.

Pre-shipment Certification

Through Decree 861, adopted in May of 1995 and enforced February 1, 1996, the Colombian Government officially established a list of sensitive products that must undergo inspection and clearance for imports into Colombia. This new customs system calls for pre-shipment

certification by authorized international certification companies (ICCs) and the intervention of Customs intermediation companies (CICs) as sole authorized private customs agents. Two ICCs and 25 CICs have been authorized to operate under the new system.

Import Duties and Taxes

Since August of 1991 all duties were consolidated into four tariff levels: (a) zero per cent for primary goods, inputs and capital goods not produced within the country; (b) 5 and 10 percent for the same categories produced in country; (c) 15 and 20 percent for final consumer goods. The average duty is currently 11.9 percent. For medical equipment duties range between 5 and 15 percent.

Since January 1996, most imports and sales transacted in Colombia (including medical equipment) are subject to a 16 percent value added tax (IVA). This tax applies to domestically-produced goods as well as imports and, in the case of imports, is assessed on the CIF value (in Colombian pesos) plus any applicable import tariff.

Importers may deduct the paid Value Added Tax (IVA) from their monthly IVA tax report when retail sales are made to third parties either as the final product, or as a part of a manufacturing or any other process that adds value to the imported product. This deduction is not allowed for imports performed by importers who are final users.

As a member of the Andean Community Market (ANCOM) and the Latin American Integration Association (LAIA), which replaced the Latin American Free Trade Association (LAFTA), Colombia maintains a system of preferential tariff rates for eligible imports from member countries. In December of 1991, the presidents of the Andean Common Market (ANCOM) countries (Bolivia, Colombia, Ecuador, Peru, and Venezuela) met in Cartagena and decided to accelerate the regional free trade market with common external tariff schedules of 5, 10, 15, and 20 percent. The Agreement became effective in January of 1995.

Distribution

A key element for success in marketing is to appoint a reliable and well-informed representative. Colombian representatives of medical equipment are willing to take new and additional U.S. brands (new to market). If supplying to the public sector, the U.S. firm should have a representative available and duly registered with prospective end-users to respond quickly to international and/or private bids.

Introducing new technology based equipment into the Colombian market usually requires promotion including the following: market exposure at national and international congresses of the different medical specialties; publication in medical scientific magazines; accurate and complete information provided to the medical specialty association(s); seminars for medical doctors organized by the local representative of the U.S. manufacturer.

Contacts

Government Agencies

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