

Medical Device Regulatory Requirements for Venezuela

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

Web links were current as of April 2007.

Overview

Regulatory Agency

The Office of Registration and Control for Medical and Paramedical Equipment and Supplies (OICEMP), a department of the Ministry of Popular Power for the Health (MPPS) is charged with regulating medical and dental device registration in Venezuela.

Regulations

All medical equipment, apparatus, systems, etc., whether imported or locally manufactured, must be registered with OICEMP. For imported goods, MPPS coordinates with the Venezuelan Customs to verify the equipment's origin and specifications before it can actually be sold in the local market. All imported medical equipment and supplies, including disposable items, undergo scrutiny in customs before it be registered by MPPS.

Documents Required

All documentation must be in Spanish. U.S. Food and Drug Administration clearances are accepted, so products already on the U.S. market should experience little difficulty entering the Venezuelan market.

The registration of medical devices from the United States requires all the following documentation:

- a) application form (*Registro Sanitario de Materiales o Equipos para la Salud*), with fees
- b) proof of current registration of Venezuelan solicitor with OICEMP

- c) copy of original registration (for registration renewals)
- d) FDA certificate of free sale for the product, translated into Spanish
- e) FDA issued certificate of compliance with Good Manufacturing Practice, translated into Spanish
- f) letter of authorization to sell the product in Venezuela, issued by the manufacturer
- g) final product drawings
- h) list of components' materials
- i) labels and directions for use
- j) packaging materials
- k) quality control test methods and records
- l) stability studies certificate
- m) clinical publications
- n) product brochure (in Spanish)

Labeling

Labeling requirements for Venezuela, as well as for most Latin American countries, are as follows, all of which must be in Spanish:

- Name of the device
- Country of origin
- Name of the manufacturer
- Importer or distributor's address
- Date of manufacture, series, and model
- Expiration date
- If appropriate, indication of the product's sterility
- Any special storage conditions
- Intended use of the product
- Definition of any symbols and warnings
- User instructions
- Indication if device is refurbished

Taxes and Duties

HTS code 3005: bandages and similar articles, impregnated or coated with pharmaceuticals or put up for retail sale for medical, surgical, dental or veterinary uses -- 10, or 15%.

HTS code 3306: preparations for oral or dental hygiene, including denture fixative pastes and powders -- dental floss yarn: 20%.

HTS code 3407: modeling pastes, including those for children; dental impression compounds; preparations for use in dentistry, with a basis of plaster -- pastes: 20%, wax & impression components: 15%, other preparations: 10%.

HTS code 9018: instruments and appliances used in medical, surgical, dental or veterinary sciences (including electro-medical and sight-testing); parts etc. thereof -- 5, 10, or 15%.

HTS code 9402: medical, surgical, dental or veterinary furniture; barbers' and similar chairs having rotating, reclining and elevating movements; parts thereof -- furniture: 20%, parts: 15%.

Contact Information

Government Agencies

Ministerio del Poder Popular para la Salud (MPPS)
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Trade Associations

Asociación Venezolana de Distribuidores de Equipos Médicos, Odontológicos, de Laboratorios y Afines (AVEDEM)
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