

Medical Device Regulatory Requirements for Mexico

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For general information on Mexico, please refer to the U.S. and Foreign Commercial Service's country commercial guide, "*Doing Business in Mexico: 2010 Country Commercial Guide for U.S. Companies*," or visit the CIA World Factbook entry at <https://www.cia.gov/library/publications/the-world-factbook/geos/mx.html>.

Web links are current as of June 2011.

Introduction to the Mexican Regulatory System

The Secretariat of Health in Mexico regulates health products including medical devices. The *Ley General de Salud*, or General Health Law, available at <http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm> mandates the Health Secretary to register medical products in Mexico and issue regulations for the importation and exportation of health products (medical devices, pharmaceuticals, drugs, biological products for human use) and food. The Federal Committee for Protection from Sanitary Risks (COFEPRIS) is the unit within the Health Secretariat that has received this charge, and within its mandate also collects information regarding manufacturers, importers, and distributors, and also issues advertising permits for these products.

COFEPRIS issues Sanitary Registrations and Sanitary Authorizations for importation of medical devices and supplies. The Sanitary Authorization is an import permit, for which the applicant must provide specific information about the shipment to be imported. The Sanitary Registration is the marketing authorization for medical devices. COFEPRIS usually takes several months to process registrations.

The Mexican General Health law covers all health products including medical devices, which have been defined in the Official Mexican Standard on labeling of medical devices (NOM-1237-SSA1-2008) as the following: medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental equipment and supplies, surgical and healing equipment, and hygienic products.

Article 83 of the *Reglamento de Insumos Para la Salud*, or Health Products

Regulation, classifies medical devices according to a three-tier risk-based classification system similar to that of the U.S. FDA and the European Union Medical Device Directives. The classification is as follows:

- Class I devices: Defined as those that “are very well known in the medical field, with proven effectiveness and safety, and that generally are not introduced into the human body.”
- Class II devices: Defined as “well known in the medical field, but may have a variation in the raw materials of which they are made, or different component composition or concentration, and that are introduced into and kept in the human body for less than thirty days.”
- Class III devices: Defined as “new products or products recently approved in the medical field, or products that are introduced and kept in the human body for more than thirty days.”

Market Entry and Registering a Medical Device

The first step for medical devices to enter the Mexican market is for manufacturers to appoint a local representative. A good local representative must be familiar with the import documentation and must be capable to apply for the necessary import permits. In some cases, the importer may also act as distributor, especially in the case of equipment and instruments that tend to have more complex regulatory requirements. In the case of materials and supplies, importers generally act more as wholesalers and leave the retail sales to others.

As in any export market, U.S. exporters of medical equipment must do the appropriate due diligence before appointing a representative and, moreover, before signing any type of agreement or contract. This is particularly important in the case of government procurement. It has been reported in Mexico that individuals approach new-to-market companies with the false promise of knowing high-ranking officials in the Mexican government that will help them secure a purchase with public health care institutions. The United States Department of Commerce, through its U.S. Commercial Service in Mexico City, offers a service called the International Company Profile, through which potential business partners can be further screened for their financial status. For information on how to use this service, please see the listing for the American Embassy in Mexico in the “Contacts” section below, or click http://www.export.gov/salesandmarketing/eg_main_018198.asp

Registering a Medical Device

To be imported into Mexico, all medical devices must be registered through the Sanitary Registration process with the Mexican Secretariat of Health. To start the registration process, an application is required (original and one copy) along with the proper fees according to the risk assessment classification and according to the Federal Law on Fee Payment. The following documents are required:

- The scientific and technical information describing the characteristics of the device and demonstration of its safety and efficacy
- A copy of the label, in Spanish, with information as required by Official Mexican Norms

- Instructions for the device's use or operation manual, in Spanish
- Description of manufacturing process
- For medical equipment, a description of the product's structure, materials, parts, and functions
- Certificate of Good Manufacturing Practices (GMP)
- Laboratory test results verifying the product's specifications
- Bibliographic references
- In the case of medical devices that use radiation sources, a copy of the license issued by the Mexican Energy Secretariat (National Nuclear Safety Commission)

User instructions are required for those medical devices needing explicit instructions for proper use or operation and which do not require a more detailed operating manual. User instructions are to be submitted in duplicate at the time of registration and contain the following information:

- product description
- list of components or parts of the product, as appropriate
- statement of intended use
- storage conditions, if applicable
- warnings and contraindications, if applicable
- adverse events, when applicable
- for contrast media, the listing of the route of administration, dosage form and the content of active ingredient per unit dose

Operation manuals are necessary for equipment or instruments that require more in-depth instructions for proper use or operation. Operation manuals must be submitted in duplicate containing the following information:

- product description
- intended use
- components or parts of the medical device
- instructions for: assembly and disassembly, operation, cleaning, maintenance, and calibration, when applicable
- warnings

Medical equipment, prosthetics, orthotics, functional aids and dental supplies, hygiene products, surgical and healing materials must be accompanied by a diagram of the functional components, parts and structure.

Class II and class III implantable devices must be accompanied by a list of materials used in the medical device listing the names and composition of materials used and their role.

There are special instructions for raw materials, active ingredients, and additives for implants, contrast media and certain diagnostic agents. For these products, the registrant must provide the following information.

- Information related to the active ingredients in the manufacture of the medical device described above should include the chemical name, generic name or description and the name of the commercial active ingredient when appropriate.

- In the case of new molecules, the registrant must indicate the structural formula, including the relative and absolute stereochemistry, molecular formula and molecular mass
- Physical and chemical characteristics
- Manufacturing information for the active ingredient, including full description of the manufacturing process

For medical devices that require an expiration date, the registrant must present a stability study. This stability study must be reviewed and signed by the manufacturer's quality control officer. The manufacturer shall establish the methodology and test conditions to ensure that original features are retained during the product life cycle.

Registrants must present available information on adverse events that have arisen during marketing or use wherever the product is used. Sterility reports where applicable are also required.

For diagnostic agents for determination of hepatitis C, hepatitis B, HIV-AIDS, and allergens, evaluation results for effectiveness issued by a laboratory approved by the Health Secretariat are required. In the absence of an approved laboratory with the necessary testing facilities, the testing may be performed abroad.

For imported products COFEPRIS requires these documents as well:

- Certificate of Free Sale (or Certificate for Foreign Government) issued by the authority of the country of origin, translated into Spanish. In the case of U.S.-made devices, these certificates are issued by the Food and Drug Administration (FDA), and assures the authorities of the importing country that the product complies with U.S. law. For more information on FDA certificates, please click <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>
- Certificate of Good Manufacturing Practice in force issued by the health authority country of origin or equivalent document issued by the body authorized by the country of origin, translated into Spanish.
- Original or certified copy of the original letter of representation issued by the manufacturer, if the product is not manufactured by the parent company, subsidiary or affiliate of the registrant in Mexico, authenticated that the legal procedure that exists in the country of origin, translated into Spanish

Where the manufacturer of the product is different from the registrant the following must be presented in addition to the above:

- Agreement or contract duly signed by both parties, which should note that the product is manufactured in accordance with the approved specifications.

Registrations last five years and may be renewed.

COFEPRIS is required to respond to registration applications within the following time frames:

- Class I devices: (including sterile) within thirty days.

- Class II devices: within thirty-five days working days.
- Class III devices: within sixty working days.

The registration, when approved, belongs to the manufacturer, who retains the option of changing its distributor/representative in Mexico. Manufacturers are obliged to inform the Health Secretariat of any new appointment for distributor(s) in Mexico for imported registered products.

In January 2008, the Health Secretariat announced that it would review the registration of all medical devices, and registration holders would need to update relevant information. As a result of this burden, response times by COFEPRIS for registrations have taken much longer than anticipated. In an effort to meet its regulatory requirements, on August 17, 2010, the Mexican Official Gazette announced that the Health Secretariat could develop regulations to find conformity assessment procedures required by foreign countries for the use, sale and distribution of medical devices in their countries to be equivalent to Mexico's requirements. COFEPRIS stated that as of November 25, 2010, it would initiate a pilot program consisting of expedited reviews for certain medical devices that have been cleared by the U.S. Food and Drug Administration and Health Canada. As of this writing, details of how this program would work have not been defined.

Labeling

The Mexican Official Standard on labeling of medical devices, NOM-137-SSA1-2008 (Labeling Standard) was published in the Mexican Official Gazette on December 12, 2008. This standard specifies the information that must be contained on labels of domestic and foreign manufactured medical devices offered to Mexican consumers. The Labeling Standard is available at <http://dof.gob.mx/normasOficiales.php?codp=3570&view=sj>.

According to the Labeling Standard, the label must be in Spanish, and may include another language. When information on the label is in a language other than Spanish, it may be up to the same size and typeface proportionality, and not contradict the Spanish-language text. The minimum information required is as follows:

- Generic product name
- Trade product name
- Domestically-manufactured products must be indicated as such
- Imported products must state the country where the device was made or manufactured, as well as the corporate name and address of the importer or distributor in Mexico
- Country of origin
- Registration Number issued by the Ministry of Health.
- Product expiration date as appropriate
- Lot number or serial number
- Contents
- Instructions for use
- In the case of culture media powder, the method of preparation
- Warnings of incidents that may result from use of the product, if applicable

- Warning legends as appropriate.
- In the case of equipment and diagnostic agents involving radiation sources a warning stating: "Danger, radioactive material for medical use only" containing the internationally recognized logo to indicate radioactive material
- Sterile products require the legend or symbol "sterile product"
- Words "non-toxic," or "pyrogen free" where appropriate
- The word "disposable" where appropriate
- Symbols for units of measurement in conformity with the General System of Units when appropriate.
- When the product features require special storage temperatures, they must be stated and expressed in ° C and humidity conditions required for the product special or any other specific condition when applicable, as protecting the light, same to be indicated on the label or back accordingly
- Medical devices are marketed as a kit, system or package should declare their components
- Products which by their nature or size of units that are sold or supplied may not contain label, back label by its size or may not contain all the information listed in the preceding paragraphs, must contain at least following:
 - Generic name
 - Trade name.
 - Lot number
 - The expiration date, if applicable
 - Content, except when it is obvious.
- *In Vitro* Diagnostic agents must contain the following:
 - The words: "For use in clinical laboratories" when the diagnostic agents are used in medical devices or equipment located in clinical or laboratory units in hospitals
- Bulk medical devices only require labeling on the multi-pack, contain at least the following information:
 - Generic name
 - Trade name.
 - Lot number
- The expiration date, if applicable.
- When the medical device requires specific software for its operation, this program must declare the appropriate version.

The label may be attached after the product is imported but before sold to consumers. The attached label should not cover the original label.

The labeling requirements *do not* apply to:

- Highly specialized medical equipment
- Medical equipment used in commercial, industrial or by service providers and not sold to consumers
- Medical equipment imported by persons or institutions for their own use
- Medical equipment imported by educational or scientific institutions

- Samples of health care products or diagnostic agents imported to be used exclusively for the certification process to comply with Mexican standards
- Other medical equipment, when a label cannot be adhered because of specific reasons or size. In this situation, the Health Secretariat will decide the course of action
- Other medical equipment, health care products or diagnostic agents determined by the Health Secretariat.

This information must be on products for retail sale. Listing this information on the container in which a product is packed for shipment will not satisfy the labeling requirement.

Import Documentation

Follows is a list of documents that must be presented in order for [products to receive a Sanitary Authorization and for] the imported product to be released from Mexican Customs.

- Import Declaration. Called the *pedimento de importación*
- Commercial invoice (in Spanish). Must include issue date and price, name and address of the consignee, detailed listing of goods, and name and address of supplier
- Bill of lading or airway bill
- Sanitary import notice. Required for all products intended for human consumption, including food and beverages (to be submitted on company letterhead, and which should contain the name of the product, quantity, name and address of the producer, name and address of the importer, the port of entry and the applicable import tariff numbers)
- NAFTA certificate of origin. As applicable in order to obtain North American Free Trade Agreement (NAFTA) tariff benefits. Under NAFTA, certain products, including most medical devices, that originate in Canada, Mexico, or the United States enjoy low or zero tariff rates when traded between these three countries. In order to receive this preferential treatment, products that qualify must have a NAFTA certificate of origin. For information on NAFTA Rules of Origin and the Certificate of Origin, please visit http://www.export.gov/logistics/eg_main_018131.asp.
- Certificate of Free Sale or Certificate to Foreign Government (see above)

Clearance through customs is done electronically. It is strongly recommended that U.S. exporters send the required export documentation to their customs broker for review in advance of preparing their goods for shipment. After checking all the documents, the customs broker will customarily send the documentation package back to the exporter for any necessary corrections. The exporter then returns these documents to the customs broker with the product ready for export.

Once the included Import Declaration is validated, the customs broker pays all applicable duties and taxes on behalf of the importer. The Mexican customs service may conduct a random document and shipment inspection before granting final clearance.

Contacts

*Embassy of the United States of America
U.S. & Foreign Commercial Service
Paseo de la Reforma No. 305
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06500 Mexico, D.F.*

Tel: (011-52-5) 211-0042

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<http://www.buyusa.gov/mexico/en>

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U.S. Commercial Service, Mexico City

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The Commercial Service helps American companies and business people export their products to Mexico.

American Chamber of Commerce of Mexico, A.C.

Calle Blas Pascal 205, 3.er piso

11510 Mexico, D.F.

Tel.: (52-55) 5141-3800

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<http://www.amcham.com.mx/CWT/External/WCPages/index.aspx>

Contact: International Trade Director

Non-profit organization which helps American companies do business in Mexico.

Comisión Federal Para la Protección Contra Riesgos Sanitarios (COFEPRIS)

(Federal Commission for Protection from Sanitary Risks)

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www.cofepris.gob.mx

Administración General de Aduanas

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