

Medical Device Regulatory Requirements for Israel

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Israel Regulatory System

Ministry of Health (MOH) in Israel is the government agency charged with meeting Israel's health care needs and regulations. The MOH recognizes Food and Drug Administration (FDA) certification and the European Union CE Mark, and approves products carrying such certifications without further requirements. Furthermore, MOH implements FDA's recommended indications for the device. MOH approval stipulates marketing authorization in the USA, and therefore accepts 510K, PMA and export certificates such as the Certificate to Foreign Government.

Registration

Medical devices, including biologics, must be registered with Israel's Ministry of Health (IMOH) before they can be sold in the country. Companies wishing to export medical equipment or devices to Israel must have a local Israel agent or distributor who should request a pre-marketing approval from the IMOH. The request should be accompanied by one of the following documents: the U.S. Food and Drug Administration (FDA) 510(k) marketing authorization, or Pre-Market Approval (PMA). Biological devices fall under medical device classification and require FDA's Center of Biologics Certificate. In most cases CE Mark (European Union) and Canadian documentation are also accepted by IMOH.

For any imported medical device the Israeli importer/agent must submit a registration application to MOH Department of Medical Devices. The application should include (if available) a certificate issued by a competent authority of one of the following countries: Australia, Canada, European Community (CE) Member States, Japan, or United States of America. If such a certificate is not available, the registration process is still available but will take a longer time, and MOH will determine what type of testing is needed. Product registration supported by an existing FDA documentation usually takes approximately eight to twelve weeks.

The application for regulation of a medical device shall be submitted to the

Department of Medical Devices at the MOH. The application should be submitted on the special form designated for this purpose and shall include the following:

Name and address of the manufacturer, and of the importer as applicable,

Description of the intended use of the medical device and of its medical indications,

Technical details of the medical device and of its components, and in the event that the device or the components are not new, information should be provided regarding renovation and the date,

Certificate attesting to the safety of the device, issued by a competent authority of one of the following countries: Australia, Canada, European Community (EC), Member States, Israel, Japan, and the United States of America,

Information on any risk which may be associated with the use of the device (including precautionary measures to be taken),

Instruction for use of the device in Hebrew. The MOH may allow the instructions to be in English for certain devices,

Details of the standards to which the device complies,

Description of the technical and maintenance services, including periodic checks and inspections, and

Declaration, as appropriate of local manufacture/importer, and of the foreign manufacturer.

Note: A license (marketing authorization) for a medical device, granted by the MOH, is valid for five years from the date of registration of the device, except for implants with a life –supporting function, for which the validity is for two years from the date of registration.

In addition to the usual requirements for the registration of medical devices, as applicable to the particular device, specific requirements exist for the products detailed hereunder, which should be included in the application:

- Tissues, including corneas, for transplantation into human beings
- Medical devices containing components derived from animal origin
- Kits for diagnosis of HIV infection
- Coronary stents

Registration costs \$222 per single item, and \$1,112 per catalog registration.

Catalog registration is, for example, on an EKG device with different channels and accessories. Registration fees are updated by the IMOH twice a year.

Standards

The Standards Institution of Israel (SII) is the agency responsible for developing most product standards, compliance testing, and certification of products and industry quality assurance system. SII requires testing the compliance of electric medical devices with Israel's electric standard of 220 V, 50 Hz. The importers must cover the costs for SII testing. Some standards may apply to home care products that are categorized as furniture, with or without a mechanical control system.

Customs Duties

Under the U.S. – Israel Free Trade Agreement (FTA), U.S. goods, including medical equipment, face no import duties upon entering Israel. In order to benefit from the FTA, products must have a U.S. Certificate of Origin for Exporting to Israel. Value Added Tax (VAT) of 18% is levied on the CIF landed cost. Some orthopedic devices are subject to customs duty of up to 6% of their CIF value, if imported from third countries.

U.S. Certificate of Origin for Exporting to Israel

In order to benefit from the provisions of the free Trade Area Agreement (FTAA), a special “U.S. Certificate of Origin for Exporting to Israel” (CO) must be presented to the Israeli customs. The CO does not need to be notarized or stamped by the Chamber of Commerce if the exporter is also the manufacturer. Instead, the exporter should make the following declaration in Box 11 of the certificate: “The undersigned hereby comply with the original requirements specified by those goods in the U.S.-Israel Free Trade Area Agreement for goods exported to Israel.” The actual forms are printed by a number of commercial printing houses in the United States. For assistance please contact the Trade information Center at 1-800-USA-TRADE or fax: 202-482-4473. The Trade Information Center also maintains documentation requirements on the Internet at www.export.gov/tic. It is possible for exporters to apply for a blanket CO, or “Approved Exporter” status. An “Approved Exporter” is only required to present an invoice that substitutes for the CO, and contains an “Approved Exporter” number and a declaration that the goods comply with the original requirements. Certification and notarization are not necessary.

Other Documentation

The Israel Customs prefer that exporters use their own commercial invoice forms. These forms should contain all required information including name and address of supplier, general nature of the goods, country of origin of the goods,

name and address of the customers in Israel, name of the agent in Israel, terms, rate of exchange (if applicable), Israel import license number (if applicable), shipping information, and a full description of all goods in the shipment. This description should include shipping marks, quantity of measure, composition of goods, tariff heading number, gross weight of each package, net weight of each package, total weight of shipment, price per unit as sold, and total value of shipment. The total value of shipments includes packing, shipping, dock and agency fees, and insurance charges incurred in the exportation of the goods to Israel. The commercial invoice must be signed by the manufacturer, consignor, owner, or authorized agent. U.S. exporters should also double check with the freight forwarder, shipping company or importer to find out if any other documentation, including bill of landing and packing list, is required. It is imperative to have these issues clear before the goods arrive at the Israeli port to avoid any possible delays and storage fees. Goods, which have been transshipped through third countries, require a Certification or Non-Manipulation from the Customs Authority or the third country.

Use of Agents and Distributors: Finding a Partner

Local clinics prefer to purchase medical supplies through an agent who registers the devices with the Ministry of Health, and who will be able to provide after-sales service. One of the first issues a potential agent will raise with the U.S. manufacturer is the possibility of exclusivity, and the vast majority of agencies have exclusive representation rights. Some exporters use a commission agent who conducts limited promotional campaigns and calls on potential buyers. Exporters of more expensive, heavy industrial equipment most commonly use this approach. Partnering up with a good local representative that has good contacts in the industry, proven reliability, loyalty, technical suitability and after-sales service capability is a key factor to success in selling and maintaining a continued presence in the Israeli marketplace. In general, it is recommended to appoint a local representative/distributor or agent who has an in-depth knowledge of the market, is reliable, and is well connected with the different key players.

The most common approach used by exporters of light industrial equipment and consumer goods is to obtain a local importer/distributor. Distributors will import on their own account, carry sufficient stock to satisfy ongoing demand or to use for demonstration, maintain their own sales organization, supply spare parts and maintain a service division, if applicable. The local representative often provides legal support for ongoing operations. While concluding a representation agreement, U.S. companies should be sure to include the following elements:

1. Contract duration
2. Exclusivity (if applicable)
3. Compensatory amount as a function of contract duration, in case of termination of exclusivity

4. Promotional input by agent and volume of sales, and
5. Dispute settlement mechanism, either by arbitration, or by assigning a tribunal (preferably U.S.).

Labeling

Medical devices must have Hebrew labeling that states country of origin, name and address of the manufacturer, and name and address of the Israeli importer. U. S. exporters should consult with their local representatives and the Israeli authorities about labeling requirements and standards, since these may differ from other countries. Biological materials should be labeled indicating their content, weight, and volume in metric units. It is important to note that the metric system is the measurement used in Israel.

Implantable medical devices require mandatory labeling in the patient's file. The labels must contain the following information:

Name and address of the manufacturer, name and address of the importer, type of implant, size, serial number, batch number, reused implant, medication element needed, and U.S. Israel Free Trade Agreement & Customs Evaluation.

Key Contacts in Israel:

For further information and assistance with agent/distributor search in Israel please contact:

Ms. Yael Torres

Commercial Specialist

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U.S. Embassy in Tel Aviv

Tel: 972-3-519-7611

Fax: 972-3-510-7215

www.BuyUSA.gov/israel

For general inquiries please contact:

Ministry of Health

www.health.gov.il

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