

Medical Equipment/Devices Registration and Documentation Requirements for Import

Summary

This report presents the registration requirement and the standard procedure to import medical devices into India. It provides an overview of the Indian Government's plan to regulate this industry. The report also contains information on the documentation requirements for importing into India.

Background

For the purchase of medical equipment/devices the government authorizes the government owned and private hospitals to issue global tenders. These tenders are permitted even if a product is manufactured domestically. Most of the government tenders follow two parts: technical bid and commercial bid. All the government tenders are time consuming as public hospitals often have extensive bureaucratic structures and decisions are sometimes hard to reach. Generally the government decides on the lowest bidder. The private hospitals evaluate the products on the basis of the technology, cost and price. Decision-making is faster in the private hospitals.

For U.S. companies maintaining one or more technically trained Indian distributor/agent is the best way to enter the large Indian market. Agents must offer service support for all medical equipment, including for public relations. Indian end users consider service support as an important factor in their equipment purchase decisions. Agents maintain close contact with the government officials, decision makers and the purchase department of the private hospitals. They obtain advance information regarding potential business, and handle the trade promotion activities. The agents keep the foreign supplier informed of the local market opportunities, conditions and competition, and finally negotiate sales opportunities.

Customs duty is levied on the imported medical devices. The duty levied depends on the product classification and the end user. The products that are classified by the Ministry of Health as "life saving medical equipment" have reduced duty applicable on them. Also, the government hospitals/institutions are permitted to import equipment/devices at a reduced duty. The government hospitals can import at a lower duty rate only if the product is imported directly from the manufacturer. Hence, though the distributor facilitates the sale and follows-ups with the government hospitals the invoicing and payment is made directly to the foreign company. This is applicable only for the government institutions and not the private institutions.

Regulation

Presently, the Indian market for medical devices is largely unregulated. Medical devices are freely imported into India. The purchaser (whether it is a government hospital, a private hospital or a doctor) evaluates the quality of the product being purchased.

Normally, the FDA and CE approved products are preferred because of their better quality and performance. But, India being a price sensitive market, low priced medical devices find a big market.

To ensure the quality of healthcare service, the Government of India is in the process of developing regulations for medical devices. According to industry contacts and the Ministry of Health officials, a notification is expected that would bring a select group of medical devices under the regulatory framework.

The authority regulating medical devices will be the Central Drug Standard Control Organization (CDSCO) in the Ministry of Health. The website (<http://www.cdscsco.nic.in>) The CDSCO is the authority, which lays down rules, standards and approves import and manufacturing of drugs, diagnostics, devices, and cosmetics. Currently, CDSCO's functions are to establish the standards and regulations for drugs, blood and blood products, intravenous fluids, and vaccines. With added responsibility of regulating the medical devices industry, CDSCO will be the approving authority for import, manufacture and sale of medical devices in India.

The regulatory procedure will be clear only after the government notifies the regulations and the CDSCO provides the import guidelines. But as we understand it, subsequent to the government's notification, foreign and India companies will have to apply for permission to import, and sell medical devices in India. Both the manufacturer and the importer will have to register with CDSCO. The Indian importer will have to obtain a "no objection" certificate to import and sell in India. However, it is expected that for products that are approved by the FDA and/or CE, the registration process to obtain an approval to sell will be a trouble-free. To register a new medical device or non FDA/CE approved devices in India, an application will have to be submitted to the regulatory authority along with documents such as details of the regulatory status in other countries; restrictions of use in approved countries; a free sale certificate from the country of origin. The current CDSCO application forms for approval are available on the web link <http://cdscsco.nic.in/html/importdrugs.htm>.

Import procedure

The standard operating procedure for importing medical equipment/devices into India consists of the following steps.

The U.S. exporter provides the proforma invoice stating the offer price, which is inclusive of the insurance and freight cost. On reaching an agreement on the mode of payment, which can be a letter of credit or wire transfer of funds; the Indian importer places the order for the product.

The exporter either ships the consignment or uses the airfreight. At the port of entry the importer or its customs clearing agent is responsible to clear the goods for home consumption after the payment of duties.

The “bill of entry” has to be submitted in four copies (original and duplicate are meant for customs, third copy for the importer and the fourth copy is meant for the bank for making remittances). On the bill of entry, the purpose for which the device will be used is generally mentioned. The following documents are required along with the bill of entry.

- Signed invoice
- Packing list
- Bill of Lading or Delivery Order/Airway Bill
- GATT declaration form duly filled in
- Importers/Clearing House (agents) declaration
- License wherever necessary
- Letter of Credit/Bank Draft/wherever necessary
- Insurance document
- Import license
- Industrial License, if required
- Test report in case of chemicals
- Catalogue, Technical write up, Literature in case of machineries, spares or chemicals as may be applicable
- Separately split up value of spares, components machineries
- Certificate of Origin, if preferential rate of duty is claimed

According to industry contacts the “certificate of origin” is not an essential document for all imports (earlier it was mandatory) but it is still a preferred document in order to expedite clearances. However, if the product is being imported under a preference duty rate, the certificate of origin is essential.

The consignment is then sent to the appraising section of the Customs House for assessment and payment of duty. Assessment of the duty essentially involves proper classification of the product imported. The assessing officer takes note of the invoice and other declarations submitted along with the bill of entry to support the valuation claim, to consider whether the transaction value method and the invoice value claimed is acceptable, or whether the value needs to be re-determined.

All imported goods are required to be examined for verification of correctness of the description given in the bill of entry. However, only a part of the consignment is selected on a random basis and examined.

After the assessment of the duty liability, the importer has to deposit the duty calculated with the treasury or the nominated banks, and then seek delivery of the goods from the custodians.

Key industry contact:

Drugs Controller General (India),
Central Drugs Standard Control Organization,
Ministry of Health and Family Welfare,
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The Directorate of Foreign Trade,
Ministry of Commerce and Industry
Website: <http://dgft.delhi.nic.in/>

For more information or assistance in exploring business opportunities and establishing a presence in the Indian market, please contact:

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