

## **Medical Device Regulatory Requirements for Jordan**

**Disclaimer:** The information contained on this website is derived from public sources and is current to the best of our knowledge. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted.

### **Introduction to the Jordan Regulatory System**

Ministry of Health (MOH) in Jordan oversees the laws and regulations of the entire healthcare sector. Reporting to the Ministry of Health (MOH) are Royal Medical Services (RMS), Jordan University Hospital (JUH), and King Abdullah University and health services in other governmental entities (municipalities, school health at the Ministry of Education, and Health and Safety Department at the Ministry of Labor). Jordan medical market relies entirely on the imports of medical equipment, and U.S. manufacturers continue to be Jordan's most important suppliers of medical equipment and services, with approximately 30% of the import market share.

### **Medical Regulations**

The Ministry of Health sets technical rules and specifications applicable to all medical equipment to ensure that all products being sold to Jordanian end users meet the requirements of safety and quality.

In Jordan, public sector tenders do not require regulatory review if the product has been authorized for marketing in the US, Europe or Japan. Other specifications are stipulated in the tender terms on a case-by-case basis.

Medical equipment procured by the public sector is tested either by the beneficiary itself (i.e. Ministry of Health, Royal Medical Services, etc.) or the Royal Scientific Society. This testing is not applicable to medical equipment procured by the private sector, which is not subject to any testing procedures.

There are Standard customs clearance procedures to be applied. The documentation required includes invoices, notarized certification of origin, and packing lists. In addition, the equipment must be certified for use in the country of origin.

The Ministry of Health prohibits the importation of used and refurbished medical devices into the Kingdom for both private and public health institutions.

### **Customs Duties**

U.S. - Jordan Free Trade Agreement was signed in 2000. This agreement will progressively lower and eventually eliminate all tariffs between the two countries by 2010. The majority of medical equipment, which falls under HS code 90/18 and 90/21, and some items under HS codes 85 and 84, are exempt from customs duties. However, all medical products are subject to sales tax of 0, 4, or 16 percent if they are procured from a local distributor depending on the product.

In addition, hospital projects are granted exemption from fees and taxes once every seven years for the purchase of furniture and supplies required for modernization and renewal. The Council of Ministers may offer incentives or guarantees or other privileges for the number of years to any project established within a number of sectors, including hospitals, as it sees fit. In granting these incentives the Council of Ministers considers the nature of the project's activity, its geographic location, its contribution to increasing exports, creating jobs, exploiting national natural resources and accelerating economic development, and in special cases the national interest. Interested investors are encouraged to check the Jordan Investment Law for details ([www.jordaninvestment.com](http://www.jordaninvestment.com))

### **Agent/Distributors**

Most foreign companies appoint a local agent to handle sales and distribution. These agents must be Jordanian and registered with the Ministry of Industry and Trade. Import licenses are required and foreign currency payments cannot be made without them. The necessary amount of foreign exchange is allocated (calculated or imposed) when the import license is issued.

The terms of finance and credit between agents and the represented company are negotiable and adjustable. According to the Jordanian law, agents do not receive severance payment or compensation upon the abrogation of the agency unless these terms were included in the agency agreement. Often, supplying reliable after sale services as well as spare parts and maintenance services are very important to maintaining a competitive advantage.

Local distributors usually use Letters of Credit when dealing with foreign suppliers of medical equipment. A grace period of 30 to 90 days is granted to local distributors to settle their accounts.

### **Tenders**

Parastatal companies purchase commodities through calls for international tenders. These are announced in the daily press. The Commercial Service of the U.S. Embassy in Amman reports most of these tenders to the U.S. Department of Commerce. U.S. firms must use a Jordanian agent to purchase tender documents from the issuing public sector entity.

In many cases, a U.S. firm may not be able to provide the wide variety of products required in large tenders. However, a company can offer a bid by forming a consortium. Jordanian buyers prefer a single bid or an entire tender rather than having to piece together bids for each component. Public sector hospitals may request credit in their procurement tenders. While suppliers offering credit will certainly have a better chance of winning bids, sales without credit are sometimes made since other factors such as price, quality, and a delivery schedule may be of greater importance.

Ministry of Health tenders are issued by the General Supplies Department, while the University of Jordan, Royal Medical Services and the Ministry of Defense all release their own tenders. Tenders are published in the Jordan Times and the Middle East Economic Digest.

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The Jordanian Ministry of Health [www.moh.gov.jo](http://www.moh.gov.jo)

The Jordan Medical Council [www.jmc.gov.jo](http://www.jmc.gov.jo)

The Higher Health Council [www.hhc.gov.jo](http://www.hhc.gov.jo)

The Jordanian Association of Manufacturing of Pharmaceuticals & Medical Appliances [www.japm.org.jo](http://www.japm.org.jo)

General Supplied Department [www.gsd.gov.jo](http://www.gsd.gov.jo)

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