

Medical Device Regulatory Requirements for Turkey

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Introduction to Turkey Regulatory System

In Turkey, there is no legislation or practice, which restricts access to the market by foreign exporters, or which mandates preference for locally manufactured products. Medical devices on open sale in the United States may normally be imported for similar sale in Turkey. However, all medical equipment imports are subject to the approval of the Turkish Standards Institution (TSE). All medical devices, imported or locally produced, must be CE marked in order to be sold into the Turkish market. Custom made medical devices intended for clinical investigations and made available to specialist doctors, and the medical devices that will be displayed during fairs and exhibitions do not have this requirement of needing the CE mark.

Equipment meeting the directive definition of products needing to conform to EU technical regulations must have evidence of meeting the requirements either through verified laboratory testing conducted by an EU approved notified body or by a manufacturer's self-declaration if the directive dictates. Companies selling to the Turkish market must submit evidence of conformity compliance

(CE Mark) either by providing a notified/consularized conformity certificate from a notified body or a manufacturer's issued certificate of conformity, which declares compliance of all relevant standards and directive annexes.

The Ministry of Health (MOH) in Turkey bans the importation of used/refurbished medical devices.

Foreign suppliers of medical equipment have to comply with ISO 9000 or equivalent standards. The U.S. Standard ANSI/ASOQ Q90 and the EN 29000 series in the European Community are both equivalent to ISO 9000.

Medical Regulations

Turkey is in a transitional phase and has adopted the New Approach Directives of the European Union. According to the New Approach Directives medical devices fall under one of the three directives.

90/385/EEC Medical Devices: Active Implantable,

93/42/EEC Medical Devices: General,

98/19/EC Medical Devices: In Vitro Diagnostic

All medical devices, imported or locally produced, should be marked, in order to be sold in the Turkish Market.

Custom made medical devices - intended for clinical investigations and made available to specialist doctors and the medical devices that will be displayed during fairs and exhibitions shall not bear the CE mark.

Analytical and clinical laboratory products, which are connected to computer

systems, fall under the following directives as well:

73/336/EEC Low Voltage Equipment

89/336/EEC Electromagnetic Compatibility

Depending on the nature of the medical device, third-party review or assessment may be required. For those medical devices, associated with higher risk levels, a notified body should be involved in the CE marking process.

For Class 1 medical devices, the manufacturer or the authorized representative in the EU, can self-certify the product and issue a declaration of conformity.

The declaration of conformity must contain the following: product identification; the EU Directives compiled with; the standards used to verify compliance with the directives; names of the notified body if required; the place and date issue; manufacturer's name and address; be signed on behalf of the manufacturer or the authorized representative and identify that signatory. The declaration of conformity is submitted together with the technical file.

There is no registration requirement for the medical devices at the moment.

However, Turkish Health Industry Employers' Association and the MOH are working cooperatively to establish a registration mechanism in Turkey in order to conduct post market surveillance.

Duties

Turkey, being a member of the Customs Union, does not impose any duties on the CU member countries. Most of the analytical and clinical laboratory devices imported from the developed countries (including the United States of America)

are also duty free.

Procurement Practices

All public procurements are subject to the Public Procurement Law No: 4734-4735 and the related directives, which establish the principles and procedures to be applied in procurements held by all public entities and institutions governed by public law or under public control or using public funds. For detailed information please visit <http://www.kik.gov.tr/index2.htm>

Contact Lists:

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Useful Websites

www.saglik.gov.tr

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

SEIS (Turkish Health Industry Employer's Association)

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Fax: 90 312 430-6183

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SADER (Healthcare Products Manufacturers and Representatives Association)

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