Legal

Legal framework: Yes

Authorizing legislation: Decree Law No. 663 www.saglik.gov.tr\%2FTR\%2FAna-sayfa\%2F1-0\%2F20150619.html&edit-text=&act=txt - Provides the Ministry of Health the power to protect the public health by overseeing the market of medical devices.


Notes: Turkey has several national directives and guidelines for each step of medical device life cycle.

National Regulatory Authority

National Regulatory Authority present: Yes


Responsibilities of the NRA: Decree Law No. 663, Article 27, Registration, Regulation of clinical investigation, Market surveillance and audit, Vigilance actions (FSQA etc), Licencing of establishments, Responsible with medical device safety. Others.

Medical device definition

Medical device defined: Yes

Notes: The medical device definition of 93/42/EEC is translated into Turkish and can be found on the national medical device directive.

Text: ‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.


In vitro diagnostic medical device (IVD) defined: Yes

Text: Defined separately.

Medical device classification

Classification: Yes

Categories: For medical devices, classes I, IIa, IIb, and III. For IVD , ListA, ListB, self-testing and other

Classification rules: Yes

Classification rules details: MEDDEV Guideline Documents

Essential principles

Essential principles: Yes


Conformity assessment

Conformity assessment bodies: Yes

Details: A notified body is authorized to process information and documentation for conformity assessment. Medical Devices Directive, Art. 9 & 14.


For Class I (only non-steril and non-functional measurement) devices, the manufacturer or its authorized representative can self-certify the product and issue a declaration of conformity. The basic requirements for conformity in Annex I of the Medical Devices Directive should preferably be published in English, French or German. See Art. 5.

Reliance

Reliance: Yes

Details: Pursuant to Art. 4 of the Ordinance on Medical Devices, Turkey relies on one of three EC directives, depending on the class of device:
b. IVDs - Annex I of Directive 98/79/EC
c. active implantable medical devices - Annex I of 90/385/EEC

Jurisdictions: EU

Article 25 of the Medical Devices Directive specifically sets out compliance with
- 93/42/EEC - Medical Devices Directive
- 98/79/EEC - Medical Devices Directive on diagnostics
- 2000/70/EEC - human blood
Also, under Active Medical Devices Directive, the Ministry of Health accepts active medical devices that meet the harmonized EU requirements. See Art. 7. It lists conforming EU directives, including 90/385/EEC on active implantable medical devices, as it amends directives 93/42/EEC, etc. See Art. 23. An EC Declaration of Conformity fulfill the obligations

Clinical investigation
Clinical investigation controls: Yes
Details: Medical Devices Directive, Art. 13, authorization for clinical trials, in most cases, is necessary. Pursuant to Art. 12 of the Active Medical Devices Directive, a manufacturer must provide information on an Ethics Committee and the justification for the research to the Ministry.

Registration and listing
Registration of establishment: Yes
Details: The directive distinguishes 3 types of licencing.
1- responsible manager of establishment
2- clinical support personnel (to physician during surgical operation)
3- sale and promotion personnel
Licencing of (2) and (3) is depending on educational background of applicant. There is a list of bachelor branches for this. If any applicant does not have educational requirements, a training program is applied based on special rules.
All establishments are registered by NRA.

Listing of medical devices: Yes
Details: The Ministry must keep a record of all devices that are imported or offered for sale on the market. Medical Devices Directive, Art. 16. The Ministry must keep track of all active implantable medical placed on the market. Active Medical Devices Directive, Art. 13. All medical devices are registered in the Turkish system.

Import controls
Import controls: N/A
Details: There is a free-circulation of medical devices bearing a CE marking. The CE marking is mandatory for medical devices. All medical devices must be recorded in the registry system.

Post market controls
Post Market Surveillance: Yes
Details: The national directive about medical device market surveillance and audit ensures managing of the market surveillance processes. (http://saglik.gov.tr/TR/belge/1-530/urunlerin-piyasa-gozetimi-ve-denetimine-dair-yonetmelik.html)

Inspection (QMS): No
Details: For medical devices there is an audit and vigilance system.

Enforcement: Yes

Adverse event reporting: Yes
Details: Medical device directives (All three) and MEDDEV Guidance document. The audit process of the manufacturer/importer/distributor will be initiated after complaints of the user. There is a national notification to market.

Field safety corrective action monitoring: Yes
Details: MEDDEV Guidance Documents
Mandatory for manufacturers if necessary. Initiated after adverse event reporting.

Advertising: Yes
Details: According to the national directive A medical device; if 1- is included to reimbursement, and/or 2- is generally used by health professionals in hospitals, cannot be advertised.

Labelling: Yes
Details: According to the EU medical device directives (93/42/EEC 98/79/EC 90/385/EEC), we have a announcement to manufacturers and importers. Labelling must include: product name, content, using constraints, manufacture name and adress, CE marking
If including below properties, all of them must add to label as inscription:
- sterile, single use and custom made
- for use of clinical investigation
- special user manual
- special keeping and usage conditions
- phthalate
- sterilization method
- warnings and/ or actions to be taken
- radioactive property
- inscription of “For Personal Use” for IVD products
Labels must be Turkish except international harmonized standard names.