Legal
Legal framework: Yes
Authorizing legislation: Medical Cure and Medical Education Act
Regulations of equipment and medical supplies http://www.fda.gov.ir/item/2641
Medical Device Directive http://www.fda.gov.ir/item/2641
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Food and Drug Administration of Iran - http://www.fda.gov.ir/
Responsibilities of the NRA: http://www.fda.gov.ir/item/2641 - Supervision of activities in the field equipment and medical supplies, organization and administration of the notified guidelines, including guidelines processes governing the production, importation, clearance, export, transport and storage, distribution, supply, purchase, installation, operation and maintenance of medical equipment procedures. Implementation of the guidelines communicated by all natural or legal persons active in the field of medical equipment and medical institutions and centers.

Medical device definition
Medical device defined: Yes
Notes: Medical devices are defined as medical supplies and equipment.
Text: equipment and medical supplies is any product, devices, equipment, tools and accessories, machinery, implant, material, reactive, laboratory calibrator, software, intended by the manufacturer to be used (alone or in combination with other items for humans for the following purposes:
- Diagnosis, monitoring, prevention, or treatment of disease reduction.
- Continue life support or support.
- Control and contraception.
- Create a process sterilization or disinfection and cleaning equipment, environment and medical wastes to Desirable carrying out medical, therapeutic and health.
- Providing information for medical purposes by laboratory methods on Human samples.
- Diagnosis, monitoring, treatment, relief, compensation or correction of injury or disability replacement or modification of physiological or anatomical processes. - Study, evaluation and replacement or correction of physiology or anatomic process Regulations of equipment and medical supplies, Art. 1.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: Yes
Categories: Medical devices are classified according to the GHTF guidelines into four classes A, B, C and D, where class A is the lowest and D is the highest level of risk.
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: Medical equipment and supplies must prove safety and performance. Regulations of equipment and medical supplies, Art. 14

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: N/A

Reliance
Reliance: N/A
Details: N/A
Jurisdictions: N/A
Clinical investigation
Clinical investigation controls: N/A
Details: N/A

Registration and listing
Registration of establishment: Yes
Details: Manufacturers need to be registered and receive a licence before they can enter the market. Regulations of equipment and medical supplies Art. 3
Listing of medical devices: N/A
Details: N/A

Import controls
Import controls: Yes
Details: See Regulations of equipment and medical supplies, e.g. Section 4, Art. 47- Art. 61

Post market controls
Post Market Surveillance: N/A
Details: Batch release for high risk medical equipment is required. Regulations of equipment and medical supplies. Art. 36
Inspection (QMS): N/A
Details: N/A
Enforcement: N/A
Details: N/A
Adverse event reporting: N/A
Details: N/A
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Medical equipment must be labelled. Regulations of equipment and medical supplies. Art. 27.4.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.