Legal
Legal framework: Yes
Authorizing legislation: Medical Devices Importation Directives Including Sterilizers and Detergents http://www.jfda.jo/Download/Laws/32_188.doc - This directive defines medical devices and classifies those devices by risk. The Medical Device Committee evaluates importation requests for higher risk (Items B and C) devices.
Drug and Pharmacy Law No. 80 (2001); Amendment law No. 30 (2003) http://www.jfda.jo/Download/Laws/32_129.doc
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Medical Devices & Supplies Directorate, Jordan Food and Drug Administration http://www.jfda.jo/Default.aspx
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: Every device / tool / material / or item used separately or engaged with other including all programs needed for operating same which are prepared by the manufacturer for human use for the purpose of achieving any of following:
1. Diagnosis, prevention, supervision, treatment or reduction of diseases.
2. Diagnosis , supervision, reduction of / usage instead of any damage.
3. Diagnosis, replacement / or amendment to the physiological situation.
Medical Devices Importation Regulations, Art. 2.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: Yes
Categories: Class I, 2A, 2B, 3, and Active Implants
Classification rules: Yes
Classification rules details: Jordan relies on the EU directives to classify its devices, namely the Medical Devices Directives 93/42/EEC and the Active Implantable MDD 90/385/EEC. Medical Devices Importation Directives, Art. 2.

Essential principles
Essential principles: N/A
Details: N/A

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

Reliance
Reliance: Yes
Details: N/A
Jurisdictions: USA, EU
See Medical Devices Importation Directives, Appendix No. 1, 2.1-2.2.

Clinical investigation
Clinical investigation controls: N/A
Details: N/A
Registration and listing

Registration of establishment: Yes
Details: An applicant to receive an importation certificate must have a certificate of registration from the Ministry of Industry & Trade. Medical Devices Importation Directives, Appendix No. 1.
Listing of medical devices: N/A
Details: N/A

Import controls

Import controls: Yes
Details: The Medical Device Committee evaluates importation requests. Medical Devices Importation Directives, Art. 4.

Post market controls

Post Market Surveillance: N/A
Details: N/A
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: Yes
Details: One may not advertise any medical device unless approved by the Director General, except for advertisements published in special medical magazines. Medical Devices Importation Directives, Art. 10.
Labelling: Yes
Details: Single use medical devices outer packaging must show the lot number, expiry date, the name of the manufacturer or the holder of the authorization, the country of origin, and storage conditions. If the device is CE marked, the CE marking should be part of the label. Medical Devices Importation Directives, Appendix No. 3.

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.