Bahrain

World Bank income group: High income

Legal
Legal framework: No
Authorizing legislation: N/A
Guidelines: N/A
Notes: Officially, Bahrain has no medical device regulations. However, in practice, there may be some control over medical device importation by referring to the Saudi Food and Drug Administration decisions.

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Pharmaceutical Product Regulatory Office, National Health Regulatory Authority
http:/ /www.nhra.bh/SitePages/View.aspx?PageId=14
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: No
Text: N/A
In vitro diagnostic medical device (IVD) defined: No
Text: N/A

Medical device classification
Classification: No
Categories: N/A
Classification rules: No
Classification rules details: N/A

Essential principles
Essential principles: No
Details: N/A

Conformity assessment
Conformity assessment bodies: No
Details: N/A
Pre-marketing / procedure: N/A

Reliance
Reliance: Yes
Details: The NHRA accepts both the FDA and CE classification models.
http:/ /www.arazygroup.com/services/licensale/regions/bahrain#sthash.gexp5mTj.dpuf
Jurisdictions: EU

Clinical investigation
Clinical investigation controls: No
Details: N/A

Registration and listing
Registration of establishment: No
Details: N/A
Listing of medical devices: No
Details: N/A

Import controls
Import controls: No
Details: N/A
Post market controls
Post Market Surveillance: No
Details: N/A
Inspection (QMS): No
Details: N/A
Enforcement: No
Details: N/A
Adverse event reporting: No
Details: N/A
Field safety corrective action monitoring: No
Details: N/A
Advertising: No
Details: N/A
Labelling: No
Details: N/A

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.