Legal

Legal framework: Yes
Authorizing legislation: N/A
Notes: The manufacture, import and sale of medical devices, which are regulated under the Drugs Act 1940 and Drug (Control) Ordinance 1982 & Rules

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Directorate General of Drug Administration http://dgda.gov.bd/
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, material or other similar or related article [. . .] and are:
  a. intended by the manufacturer to be used alone or in combination for human beings for one or more specific purpose(s) of;
  i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
  ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  iii. investigation, replacement, modification or support of the anatomy or of a physiological process,
  iv. supporting or sustaining life,
  v. control of conception,
  vi. disinfection of medical devices,
  vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body. AND
  b. which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means[.]
Guideline for Registration of Medical Devices, 1.1.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately
In vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donation from the human body, solely or principally for the purpose of providing information:
  a. concerning a physiological or pathological state, or
  b. concerning a congenital abnormality, or
  c. to determine the safety and compatibility with potential recipients, or
  d. to monitor therapeutic measures.
Products for general laboratory use are not in vitro diagnostic medical devices.
Guidelines on Registration of Medical Devices, 2.

Medical device classification

Classification: Yes
Categories: Class A, B, C, and D
Classification rules: Yes
Classification rules details: Annexure 1: Medical Device Classification procedure

Essential principles

Essential principles: Yes
Details: N/A

Conformity assessment

Conformity assessment bodies: Yes
Details: Yes
Pre-marketing / procedure: Conformity assessment procedures are the responsibility of the manufacturers and notified bodies. Guidelines on Medical Device Registration, 4.3.
Class A devices - carried out by the manufacturers; no requirement to obtain a manufacturing license from DGDA; manufacturer informs DGDA of compliance through a Declaration of Conformity
Classes B, C, and D - certification by a notified body is required as to the design and manufacture of the service; manufacturers and importers must apply for permission along with supportive documents as to safety and performance. Guidelines on Medical Device Registration, 4.6-4.7.

Reliance
Reliance: Yes
Details: For manufacturers that have undergone QMS and product certification through an NRA outside of Bangladesh, they must provide documents for registration of their product. Guidelines on Medical Device Registration, 4.8

Jurisdictions: European Economic Area (CE marked devices) - Guidelines on the Registration of Medical Devices, S. USA - Guidelines on the Registration of Medical Devices, 7.1

Clinical investigation
Clinical investigation controls: Yes
Details: In the case of Class B, C and D devices which are intended for clinical investigations in Bangladesh, the manufacturer or the authorized representative of the manufacturer or importer shall notify the DGDA before starting that investigation and follow the prevailing international accepted standard, i.e. ISO 14155 or equivalent standard. Registration Guidelines for Medical Devices 2015, 13.1

Registration and listing
Registration of establishment: Yes
Details: All medical devices of Class B, C and D, as per the below mentioned classification shall be registered before they are imported or manufactured into the country. Annexure 2: Procedure for registration of Medical Devices for manufacture and import into Bangladesh, Registration Guidelines for Medical Devices 2015

Listing of medical devices: Yes
Details: All medical devices of Class B, C and D, as per the below mentioned classification shall be registered before they are imported or manufactured into the country. Annexure 2: Procedure for registration of medical devices for manufacture and import into Bangladesh, Registration Guidelines for Medical Devices 2015

Import controls
Import controls: Yes
Details: All medical devices of Class B, C and D, as per the below mentioned classification shall be registered before they are imported into the country. Annexure 2: Procedure for registration of Medical Devices for manufacture and import into Bangladesh, Registration Guidelines for Medical Devices 2015

Post market controls
Post Market Surveillance: Yes
Details: Once a class B, C, or D medical device is placed on the market, the manufacturer or importer must maintain post-marketing surveillance program and monitor the performance of the device. Guidelines on Registration of Medical Devices, 5.

Inspection (QMS): Yes
Details: For device(s) falling under Classes B, C and Class D which constitute a medium to high risk potential, certification by a notified body with regard to QMS and in case of Class D certification for the design of the device(s) is required. The manufacturers and/or importers are required to apply for registration along with documents specified by DGDA. Based on these documents and inspection carried out, if required, the registration will be issued by DGDA. Guidelines on the Registration of Medical Devices, 4.6

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: Adverse incidents must be reported to the designated authority in the DGDA. Appropriate corrective actions may be applied to prevent recurrence of said events. Guidelines on Medical Device Registration, 5.

Field safety corrective action monitoring: N/A
Details: N/A

Advertising: N/A
Details: N/A

Labelling: Yes

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.