Legal

Legal framework: Yes

National Regulatory Authority

National Regulatory Authority present: Yes
Name: National Agency for Food and Drug Administration and Control (NAFDAC) - http://www.nafdac.gov.ng/products/medicalsmenu
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A medical device means any instrument, apparatus or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal. CAP N1 Laws, Art. 31.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification

Classification: N/A
Categories: N/A
Classification rules: N/A
Classification rules details: N/A

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: N/A
Details: N/A
Jurisdictions: N/A

Clinical investigation

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

Registration and listing

Registration of establishment: N/A
Details: N/A
Listing of medical devices: Yes
Details: All medical devices must be registered to be manufactured, imported, exported, advertised, sold or distributed in Nigeria. Guidelines for Registration of Imported Medical Devices in Nigeria, Art. B.1.
An application for registration must be made either by the Nigerian manufacturer or through an authorized representative for a manufacturer outside of Nigeria. Guidelines for Registration of Imported Medical Devices in Nigeria, Art. B.1.
Import controls
Import controls: Yes

Post market controls
Post Market Surveillance: Yes
Details: The Pharmacovigilance/Post Marketing Survey (PV-PMS) Directorate provides post marketing surveillance of NAFDAC regulated products, which include medical devices. http://www.nafdac.gov.ng/about-nafdac/directorates/pharmacovigilance-post-marketing-surveillance
Inspection (QMS): N/A
Details: N/A
Enforcement: N/A
Details: N/A
Adverse event reporting: Yes
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Labelling: Yes
Details: All labels must be clear and informative and include at minimum:
- name of the product
- name and address of the manufacturer
- NAFDAC registration number
- batch number, manufacturing date, and expiry date
- net contents
- directions for safe use
Any regulated product in a foreign language will not be considered for registration unless an English translation is included.
Guidelines for Registration of Imported Medical Devices in Nigeria, D.

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.