Namibia

World Bank income group: Upper middle income

Legal
Legal framework: N/A
Authorizing legislation: N/A
Guidelines: N/A
Medical devices are included in this Act, but the regulatory controls listed do not apply to medical devices.

National Regulatory Authority
National Regulatory Authority present: N/A
Responsibilities of the NRA: The Namibia Medicines Regulatory Council has no specific responsibilities assigned in regulation of medical devices

Medical device definition
Medical device defined: N/A
Text: A medical device means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent used or purported to be suitable for use for medical or veterinary purposes, and includes a part or an accessory of a medical device. Medicines Act, Art. 1.
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: No
Details: N/A
Jurisdictions: No

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: The Namibia Medicines Regulatory Council purports to register medical devices, but there does not appear to be any legislative mandate or form to apply to register. http://www.nmrc.com.na/productreg

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

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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.