Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Zambia Medicines Regulatory Authority (ZAMRA)
http://www.zamra.co.zm/
Responsibilities of the NRA: The functions of the Authority are stipulated by the Medicines and Allied substances Act (No. 3) of 2013 Part II. See also http://www.zamra.co/#/services/cipy

Medical device definition
Medical device defined: Yes
Text: A medical device "includes an instrument, apparatus, component, part of accessory manufactured or sold for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms of the disease, or abnormal physical state in human beings or animals[.]." Medicines and Allied Substances Act, Art. 2.
Note: Medical devices are included in the definition of “allied substances.” Medicines and Allied Substances Act, Art. 2.
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: One must obtain marketing authorization from the ZAMRA prior to a medical device’s placement on the market, advertisement, manufacture, sell, import, supply, administration, or dealing. Marketing Authorization procedure described in Art. 39 of the Medicines and Allied Substances Act.

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

Clinical investigation
Clinical investigation controls: Yes
Details: No person may conduct a clinical trial involving an allied substance (which includes medical devices) without a clinical trial certificate. Medicines and Allied Substances Act, Art. 49.

Registration and listing
Registration of establishment: Yes
Details: A person may not manufacture, distribute, or deal in any allied substance without a license. Medicines and Allied Substances Act, Art. 33.
Listing of medical devices: Yes
Details: The Authority shall keep and maintain a Register of Marketing Authorisations issued under the Medicines and Allied Substances Act. See Art. 48.
Import controls
Import controls: Yes
Details: A person may not import any allied substance (the definition includes medical devices) without an import permit. Medicines and Allied Substances Act, Art. 35.

Post market controls
Post Market Surveillance: Yes
Details: The ZAMRA may require any manufacturer, shop, wholesale dealer, distributor, importer, exporter, or other person to submit information so that the ZAMRA may monitor performance. Medicines and Allied Substances Act, Art. 6.

Inspection (QMS): Yes
Details: Any premises may be subject to inspection.
A person may not sell a harmful medical device. And, a person may not manufacture, sell or supply any medical device that does not meet prescribed quality standards. Medicines and Allied Substances Act, Art. 65.

Enforcement: Yes
Details: One who sells a harmful medical device or manufactures, imports, sells or supplies a device that does not meet the prescribed standards on quality is liable for a fine and/or imprisonment. Medicines and Allied Substances, Art. 66.
One who manufactures, distributes, deals or imports an allied substance may be liable for a fine and/or imprisonment for not obtaining the appropriate license/import permit. Medicines and Allied Substances Act, Arts. 33, 35.
Note: There are penal provisions in each Part of the Medicines and Allied Substances Act for violations of certain articles.

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 an allied substance (which includes a medical device) without a marketing authorization issued by the ZAMRA. Medicines and Allied Substances Act, Art. 39. Fraudulent, misleading, and deceptive advertisement of allied substances (which definitionally include medical devices) is prohibited. Medicines and Allied Substances Act, Art. 61.

Labelling: Yes
Details: Fraudulent, misleading, and deceptive labelling of allied substances (which definitionally include medical devices) is prohibited. Medicines and Allied Substances Act, Art. 61.

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.