Legal
Legal framework: Yes
Authorizing legislation: Law on Registration of Medical supplies 2010
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Text: Medical Supplies are the supplied products to be used in medical environments. Law on Registration of Medical supplies 2010, Art. 2.
In vitro diagnostic medical device (IVD) defined: N/A
Text: N/A

Medical device classification
Classification: Yes
Categories: according to GHTF and FDA principles. Law on Registration of Medical supplies 2010, Art. 10
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: Medical supplies should show that they are safe, of good quality and effective. Law on Registration of Medical supplies 2010, Art. 3

Conformity assessment
Conformity assessment bodies: Yes
Details: Law on Registration of Medical supplies 2010, Art. 8
Pre-marketing / procedure: Outside Sudan, the medical supply should be registered in the producing country. Law on Registration of Medical supplies 2010, Art. 5

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: Yes
Details: Manufacturer must be registered. Law on Registration of Medical supplies 2010, Art. 4
Listing of medical devices: Yes
Details: Law on Registration of Medical supplies 2010, Art. 5

Import controls
Import controls: N/A
Details: N/A
Post market controls

Post Market Surveillance: N/A
Details: N/A

Inspection (QMS): Yes
Details: Regional Health Authorities are responsible for inspection and controls. Law on Registration of Medical supplies 2010, Art 16

Enforcement: Yes
Details: Law on Registration of Medical supplies 2010, Art. 19

Adverse event reporting: N/A
Details: N/A

Field safety corrective action monitoring: Yes
Details: When products should be recalled, users and patients should be informed. Law on Registration of Medical supplies 2010, Art 16.

Advertising: N/A
Details: N/A

Labelling: N/A
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.