Legal

Legal framework: Yes

National Regulatory Authority

National Regulatory Authority present: Yes
Name: Food, Medicine and Health Care Administration and Control Authority of Ethiopia http://www.fmhaca.gov.et/
Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes
Text: A medical device refers to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, that is:
a) recognized in a pharmacopoeia or any supplement to it;
b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or;
c) intended to affect the structure or any function of the body of a human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or other animals and is not dependents upon being metabolized for the achievement of any of its principal intended purposes. Guideline (Sept. 2014), p. 6.
In vitro diagnostic medical device (IVD) defined: Yes

Medical device classification

Classification: Yes
Classification rules: Yes

Essential principles

Essential principles: Yes
Details: Guideline (Sept. 2014) Section I, Art. 6 for Medical device essential safety and performance requirements.
Essential principles of IVD medical devices are listed in Art. 7, pg. 16 of the Guideline (Sept. 2014).

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: Yes
Details: An agency agreement should be made between the manufacturer of the medical device for registration and the agent responsible for the import, distribution, and sale of the product in Ethiopia. Guideline (Sept. 2014), Section I, Art. 2
Listing of medical devices: Yes
Details: All medical devices should be registered with FMHACA. Guideline (Sept. 2014)

Import controls
Import controls: N/A
Details: N/A

Post market controls
Post Market Surveillance: Yes
Details: Prior to and after placing the product on the market, the manufacturer should put a process in place, as part of its quality management system, to assess the continued conformity of the device to the essential principles of safety and performance through the post-marketing phase. Guideline (Sept. 2014), Section II, Art. 2.2

Inspection (QMS): Yes
Details: The manufacturer should always provide certification of conformity against internationally recognized standards for all class devices. The adequacy of the standards in relation to safety and performance of the device should be discussed with relevant supporting data for Class II and higher devices. In case the provided certification is found to be unsatisfactory, the Authority may conduct an onsite audit and inspection of the facilities of Class III and IV device manufacturers. Unless it is deemed to be necessary, the QMS of Class I medical device manufacturers’ facilities are normally not subjected to onsite inspection. Guideline (Sept. 2014), p. 40, 50.

Enforcement: N/A
Details: N/A

Adverse event reporting: Yes
Details: Both the manufacturer and the NRA must sign an agreement that they are both responsible for post-marketing reporting of the device. Guideline (Sept. 2014), p. 26.

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

Advertising: N/A
Details: N/A

Labelling: Yes
Details: Labels may appear on the device, on packaging, or as instructions for use. They must:
- be in English and/or Amharic
- not be presented in a false, misleading, or deceptive way
- be appropriately formatted etc.

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.