Legal

Legal framework: Yes


General Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices [hereafter General Regulations]


Hazardous Substances Act No. 15 of 1973 (regulations regarding electromedical devices)


National Regulatory Authority

National Regulatory Authority present: Yes

Name: Medicines Control Council (MCC) http://www.mccza.com/

Responsibilities of the NRA: N/A

Medical device definition

Medical device defined: Yes

Text: A medical device means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent-

a) used or purporting to be suitable for use or manufactured or sold for use in-

i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or

ii) restoring, correcting or modifying any somatic or psychic or organic function; or

iii) the diagnosis or prevention of pregnancy,

and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or

b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device.

Medicines and Related Substances Control Act, Art. 1.

In vitro diagnostic medical device (IVD) defined: Diagnostic reagent is included in the definition of a medical device (see above).

Text: N/A

Medical device classification

Classification: Yes

Categories: Class A, B, C, and D

General Regulations, Art. 12.

Classification rules: Yes


Essential principles

Essential principles: Yes

Details: See Guideline: Medical Devices and IVDs Essential Principles.

Conformity assessment

Conformity assessment bodies: Yes

Details: Notified bodies must be approved by South Africa. General Regulations, Art. 1, 9.

Pre-marketing / procedure: N/A

Reliance

Reliance: N/A

Details: N/A

Jurisdictions: N/A
Clinical investigation

Clinical investigation controls: Yes
Details: One must apply to the Council to conduct a clinical investigation on an unregistered medical device or on a new intended purpose of medical device or IVD. General Regulations, Art. 17.

Registration and listing

Registration of establishment: Yes
Details: Manufacturers must obtain a license, import and/or export a medical device and/or IVD in South Africa. Registration of Medical Devices and IVDs, p. 9; Medicines and Related Substances Control Act, 1965, Art. 22C; see also General Regulations, Art. 8.
Listing of medical devices: Yes
Details: All medical devices, except custom made devices, and all IVDs shall be registered with the Council. See General Regulations, Art. 9-12.

Import controls

Import controls: Yes
Details: An importer must be licensed by the Council to import medical devices. General Regulations, Arts. 4, 6.

Post market controls

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

Inspection (QMS): Yes
Details: As part of an application to register a medical device, the manufacturer must certify a QMS is in place. See General Regulations. Premises are subject to inspection. General Regulations, Art. 6.

Enforcement: Yes
Details: Medical devices or IVDs may be seized if they are unregistered and sold in contravention of the Act, suspected counterfeit, expired, etc. General Regulations, Art. 16. One who fails to comply with the Act may face a fine and/or imprisonment. General Regulations, Art. 20.

Adverse event reporting: Yes
Details: The applicant or holder of a registration certificate for a medical device or an IVD must inform the Council of suspected adverse events that result from that device. General Regulations, Art. 18.

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

Advertising: Yes
Details: Permitted advertisements to certain audience (i.e. public vs. health professionals) vary according to the classification of the medical device or IVD. Nonetheless, no advertisement may be false or misleading. General Regulations, Art. 22.

Labelling: Yes
Details: The label of a medical device should be in English. General Regulations, Art. 23 for the list of label requirements.

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.