**Legal**

**Legal framework:** Yes

**Authorizing legislation:** Tanzania Food, Drug, and Cosmetics Act (FDCA) (2003)  
http://www.tic.co.tz/media/TFDA%20ACT.pdf

**Guidelines:** Guidelines on the Submission of Documentation for Registration of Medical Devices (Oct. 2009)  

**Notes:** Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015 - http://www.tfda.or.tz/index/sites/default/files/THE%20TANZANIA%20FOOD%2C%20DRUGS%20AND%20COSMETICS.pdf

**National Regulatory Authority**

**National Regulatory Authority present:** Yes

**Name:** Tanzania Food and Drugs Authority  
http://www.tfda.or.tz/

**Responsibilities of the NRA:** As related to medical devices, the TFDA:
- regulates all matters relating to the quality and safety of medical devices
- regulates the manufacture, importation, labelling, marking or identification, storage, and sales of medical devices
- ensures evidence of existing and new adverse events are monitored, analyzed, and acted upon
- ensure that clinical trials on medical devices are conducted in accordance with prescribed standards
- foster cooperation between stakeholders
- approve and register products, manufactured or imported into, and intended for use in Tanzania
- examine, grant, issue, suspend, cancel, and revoke licenses or permits issued
- provide the public with unbiased information on products
- prescribe standards on quality
- maintain registers
- take legal measures on complaints made by consumers made against manufacturers

FDCA, Art. 5.

**Medical device definition**

**Medical device defined:** Yes

**Text:** Medical device or devices means, an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:
- (a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
- (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 man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolised for the achievement of any of its principle intended purposes

FDCA, Art. 3.

**In vitro diagnostic medical device (IVD) defined:** Yes

**Text:** Defined, Included in Medical Device definition See FDCA, Art. 3.

**Medical device classification**

**Classification:** Yes

**Categories:** Class A, B, C, and D

**Guidelines:** p. 11

**Classification rules:** Yes

**Classification rules details:** Classification is done based on the GHTF document “Principle of Medical Device Classification.” Guidelines, p. 12.

**Essential principles**

**Essential principles:** N/A

**Conformity assessment**

**Conformity assessment bodies:** N/A

**Details:** N/A

**Pre-marketing / procedure:** A person must have an appropriate license to manufacture for sale, sell, offer, supply, or import a medical device. FDCA, Art. 22. Exceptions are made for custom-made devices. Id. Art. 23.

One must provide a declaration of conformity that contains an attestation that a device complies with applicable international standards. Guidelines, p. 20.

**Reliance**

**Reliance:** Yes

**Details:** N/A

**Jurisdictions:**
Clinical investigation
Clinical investigation controls: Yes
Details: To conduct a clinical trial, one must be (1) the holder of a product registration that authorizes a clinical trial and (2) also the recipient of a "Clinical Trial Certificate." FDCA, Art. 61. Further, one may only conduct a trial of a medical device with the authorization of the Director General. FDCA, Art. 62. To apply to conduct a clinical trial, a person must submit an application that includes an Ethical Clearance Certificate. FDCA, Art. 63. Once the TFDA receives the application, it will conduct an investigation to authenticate the safety, efficacy, and quality of the medical device and then register the product for purposes of clinical trials. FDCA, Art. 64. The TFDA monitors all stages of the clinical trial to ensure protection from adverse events. FDCA, Art. 69.

Registration and listing
Registration of establishment: Yes
Details: A person may not sell, supply or store a medical device except in registered premises. FDCA, Art 18.
Listing of medical devices: Yes
Details: The TFDA will approve registration of medical devices that it considers
- in the public interest
- safe, efficacious, and of acceptable quality
- to comply with GMP
FDCA, Art. 51.
If the TFDA approves registration, then it will enter in data on the medical device into the register, assign a registration number, and issue a certificate of registration. FDCA, Art. 53, 54; see also Guidelines p. 15.
Note: The TFDA registers all medical devices it approves for use in clinical trials. See FDCA, Art. 64. Some low risk medical devices (i.e. class A) need not be registered. Guidelines, p. 12. Exemption from registration does not also discharge legal obligations of medical device dealers to keep records, report adverse events, and recall devices. See id.

Import controls
Import controls: Yes
Details: A person must have a license to import a medical devices. See FDCA, Art. 22; 73.

Post market controls
Post Market Surveillance: Yes
Details: Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015. Art. 42; form No. 03
Inspection (QMS): Yes
Details: FDCA, Art. 105, Art. 106
Enforcement: Yes
Details: There are various provisions that impose financial penalties on violations of the FDCA. See, e.g., FDCA Art. 22 (4) fine on those who do not obtain an appropriate license); Art. 76 (fine and/or imprisonment for the importation of counterfeit medical devices)
The Minister, after consulting with the Director General, may make regulations to prohibit, control, or restrict manufacture, dispensing, possession, sale or use of a medical device. FDCA, Art. 58. Further, if the Minister finds that a medical device lacks claimed therapeutic value, he or she may prohibit the manufacture, sale, or distribution of the device. FCDA, 60.
An inspector, upon finding a product is unfit or does not meet requirements, may
- affix a mark to the device
- destroy the product
FDCA, Art. 99.
An inspector may take any sample for analysis. FDCA, Art. 101. He or she may also enter the premises entered on the register or on the license and examine any certificate, license, or other information. The inspector may also close premises found to contravene the law. FDCA, Art. 106.
Adverse event reporting: N/A
Details: N/A
Field safety corrective action monitoring: N/A
Details: N/A
Advertising: Yes
Details: False advertising is prohibited by the FDCA, Art. 96, 98.
One must obtain written approval for promotional activities. FDCA, Art. 98.
Labelling: Yes
Details: No person may sell any registered medical device unless it is labelled with the registered name, number, and directions for use in English and/or Kiswahili. FDCA, Art. 56; see also Guidelines, p. 24.
No person may sell or supply a medical device that is marked or labelled in such a way that it falsely describes the product or is likely to mislead. FDCA, Art. 92.