

*The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices)
Regulations, 2015*

GN. No. 315 (contd.)

GOVERNMENT NOTICE NO 315 published on 31/07/2015

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT,
(CAP.219)

REGULATIONS

Made under Section 122(1)(c)(e)

THE TANZANIA FOOD, DRUGS AND COSMETICS
(CONTROL OF MEDICAL DEVICES) REGULATIONS, 2015

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PART I
PRELIMINARY PROVISIONS

- Short title **1.** These Regulations shall be cited as the Tanzania, Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015;
- Scope of application **2.** These Regulations shall apply in all areas of Mainland Tanzania;
- Interpretation **3.** In these Regulations, unless the context otherwise require-
- Cap 219 “act” means the Tanzania, Food, Drugs and Cosmetics Act;
- “active diagnostic medical device” means an active device that, whether used alone or in combination with another medical device, is intended to be used for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity;
- “active medical device” means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity;
- “active therapeutic medical device” means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury;
- “adverse event” in relation to a medical device, means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such device is used by or administered to humans;

“advertisement” means the publication, dissemination or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of that medical device by any means or in any form;

“applicant” means a person who owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications, the product is manufactured and who shall be the marketing authorisation holder and have the primary responsibility of the product on the Tanzanian market;

authority” means the Tanzania Food and Drugs Authority or its acronym “TFDA” established by section 4, subsection (1) of the Act;

“central circulatory system” means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries;

“central nervous system” means the brain, meninges and spinal cord;

“continuous use” means;

- (a) the uninterrupted use of the medical devices, not including any temporary interruption of its use during a procedure or any temporary removal of the medical device for purposes such as cleaning or disinfection; or
- (b) the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its product owner;

“consignment” a quantity of goods that are sent to a person or place to be sold;

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- Cap 191
- “directions for use” means full information as to the procedures recommended for achieving the optimum performance of the medical device, and includes cautions, warnings, contra-indications and possible adverse effects;
- “disposal” means the discharge deposit, injection, dumping, spilling, leaking, emitting, or placing of any solid wastes or hazardous wastes into or on any land or ground or surface water or into the air such that it is rendered harmless”;
- “environmental inspector” means an inspector appointed under or designated pursuant to section 182 of the Environmental Management Act;
- “immediate danger” means a situation where a patient is at risk of losing his life or an important bodily function if no immediate preventative measure is taken;
- “*In vitro* diagnostic device” or its acronym “IVDD” means a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body;
- “intended purpose” means the use for which the medical device is intended according to the specifications of its manufacturer;
- “inspector” means an inspector appointed, authorized or recognized under the Act;
- “label”, means any written, printed or graphic representation that appears on or is attached to the medical device or any part of its packaging, and includes any informational sheet or leaflet that accompanies the medical device when it is being supplied;
- “life supporting or life sustaining” means that the medical device is essential to, or yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life;
- “Local Responsible Person” means a person residing in

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- Tanzania mainland or corporate body registered in Tanzania mainland who has received a mandate from the Applicant to act on his behalf with regard to matters pertaining to registration of medical devices;
- “Long-term use” means continuous use of the medical devices for a period exceeding thirty (30) days;
- “manufacture” means to make, fabricate, produce or process a medical device and includes-
- (a) any process carried out in the course of so making, fabricating, producing or processing the medical devices; and
 - (b) the packaging and labeling of the medical devices before it is supplied;
- “manufacturer” means a person who sells medical devices under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf;
- “medical device” means a device within the meaning of the Act;
- “medical device family” means a group of medical devices that are made by the same manufacturer, that differ only in shape, color, flavor or size, that have the same design and manufacturing process and that have the same intended use;
- “medical device group” means medical devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name;
- “medical device group family” means a collection of medical device groups that are made by the same manufacturer, that have the same generic

- name specifying their intended use, and that differ only in the number and combination of products that comprise each group;
- “Minister” means the Minister for the time being responsible for health;
- “Near Patient In vitro Diagnostic Medical Devices” or “near patient IVDD” means an *in vitro* diagnostic medical devices that is intended for use outside a laboratory, or at the point of care, such as a pharmacy, a health care professional’s office or the bedside;
- “Non-invasive medical devices” means medical devices other than an invasive medical device;
- “packaging” means the container and other packaging material in which the medical device is supplied;
- “permit holder” means holder of a permit issued by the Authority under regulation 34 section (1) of this regulation;
- “permit” means manufacturers, and importing wholesaler’s permits issued by the Authority under these regulations;
- “pharmaceutical product” means any pharmaceutical substance or product as defined under the Act;
- “premises” means a location that is used for activities dealing with medical devices, including sale, storage and manufacture;
- “recall” in relation to a medical device, means any action taken by its manufacturer, importer, supplier or registrant to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device may-
- (a) be hazardous to health;
 - (b) fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance; or
 - (c) not meet the requirements under regulation 65;

- “registrant”, means the person who applied for and obtained the registration of the medical device;
- “reusable surgical instrument” means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical devices, and which is intended to be reused after appropriate procedures for cleaning or sterilization of the instrument have been carried out;
- “surgically invasive device” means an invasive medical device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids;
- “superintendent” means any biomedical engineer, laboratory technician, healthcare technologist or any person with medical background in charge of a business of medical device;
- “system” means a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the medical device’s intended functions, and that is sold under a single name;
- “self testing” testing performed by lay persons;
- “test kit” means an *in vitro* diagnostic medical devices that consists of reagents or articles, or any combination of these Regulations, and that is intended to be used to conduct a specific test;
- “transient use” means continuous use of the medical device for a period not exceeding sixty (60) minutes;
- “unfit products” means medical device that are expired, improperly sealed, damaged, improperly stored, improperly labeled, counterfeit, substandard and prohibited or unauthorized;
- “validation” means confirmation by examination and the provision of objective evidence that the

requirements for a specific intended use have been fulfilled.

PART II CLASSIFICATION OF MEDICAL DEVICES

Classes of
medical devices

5.-(1) There shall be four classes of medical devices as provided in the rules set out in First Schedule to these Regulations depending on their levels of risks as follows:

- A - Low risk class
- B - Low to moderate risk class
- C - Moderate to high risk class
- D - High risk class

(2) Where a medical device belongs into more than one class, the class representing the higher risk shall apply.

PART III REGISTRATION OF MEDICAL DEVICES

Restriction for
sale of
unregistered
medical devices

6. A person shall not sell, manufacture, import or export, distribute, provide as a grant or gift or offer for sale any medical device unless it is registered by the Authority.

Application and
requirements
for registration
of medical
devices

7.-(1) An application for registration of medical devices shall be required for each single medical device or a medical device group or medical device family or medical device system.

(2) Every application shall be accompanied by the following:

- (a) a non-refundable application fee as set out in Fees and Charges Regulations in force at the time of application; and
- (b) sample or samples of the medical device and, or artwork as the case may be at the time of lodging an application.

- (3) The application referred to in sub regulation (2) shall contain the following information:
- (a) the name of the medical devices;
 - (b) the class of the medical devices;
 - (c) the identification of the medical device, including the identification of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; and
 - (d) the name and address of the applicant or the applicant and the manufacturer in case the two are different.

Submission of
an application
form for
registration

8.-(1) An application for registration of a medical device shall be submitted to the Authority by the applicant or a local responsible person appointed on his behalf.

(2) The Authority shall issue a format of application in accordance with the guidelines in force.

(3) The applicant shall be responsible for the product, information supplied in support of the application for registration and variations thereof.

(4) An applicant who is not a resident in Tanzania shall appoint a local responsible person.

(5) An original certificate of power of attorney, certified copy of a formal agreement or any other official authorization shall be submitted by an applicant as a proof of appointment of a local responsible person.

Obligation of
the Local
Responsible
person

9. The local responsible person shall:

- (a) Monitor the medical devices on the market and inform the Authority immediately after the detection of any problem relating to a registered medical devices which may endanger public health;
- (b) Facilitate communication between the applicant and the Authority on matters relating to the Medical devices;

- (c) Handle medical device recalls; and
- (d) Provide technical support and services to users of registered medical device(s).

Application for registration of Class A non-exempted medical devices

10. An application for registration of Class A non-exempted medical device shall contain the following-

- (a) copies of the label of the medical device for both primary and secondary components of a medical device system, members of a medical device family and accessories submitted for registration;
- (b) the instructions for use;
- (c) the patient information leaflet where applicable;
- (d) for sterile medical devices: the sterilization validation report;
- (e) for medical devices with measuring function: certification on medical devices metrology or equivalent;
- (f) for active medical devices, certification to electrical safety standards;
- (g) any other information as may be required by the Authority.

Registration of Class B,C and D medical devices

11. An application for registration of Class B, C and D medical devices shall contain, in addition to the information and documents set out in regulation 7 of these Regulations, the following:

- (a) a description of the medical devices and of the materials used in its manufacture and packaging;
- (b) a description of the features of the medical devices that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented;

- (c) a list of the countries other than Tanzania where the device has been sold and a summary of any reported problems with the medical device and any recalls of the medical device in those countries;
- (d) a risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements as provided in ISO 14971;
- (e) a quality plan setting out the specific quality practices, resources and sequence of activities relevant to the medical device;
- (f) the specifications of the materials used in the manufacture and packaging of the medical devices;
- (g) the manufacturing process of the medical devices;
- (h) a list of the standards complied with in the design and manufacture of the medical devices to satisfy the safety and performance requirements;
- (i) detailed summary of information of all studies which the manufacturer relies on to ensure that the medical device meets the safety and performance requirements, including-
 - (i) pre-clinical and clinical studies,
 - (ii) process validation studies,
 - (iii) if appropriate, software validation studies, and
 - (iv) literature reviews;
- (j) in the case of a medical device other than an *in vitro* diagnostic devices, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the medical

- devices;
- (k) in the case of a near patient *in vitro* diagnostic medical devices, detailed information on investigational testing conducted on the device using human participants representative of the intended users and under conditions similar to the conditions of use;
- (l) a bibliography of all published reports dealing with the use, safety and effectiveness of the medical devices;
- (m) a copy of the medical devices label; and
- (n) a copy of the quality management system certificate as stipulate certifying that the quality management system under which the medical device is designed and manufactured satisfies the requirements stipulated in the guideline in force at the time of application.

Additional
Information and
Samples

12.-(1) Where the information and documents submitted in respect of an application for registration of a medical device or variation of a medical device registration are insufficient to enable the Authority to determine whether a medical device meets the safety and performance requirements, the Authority may request the applicant to submit, on or before a specified day, additional information necessary for making the determination.

(2) In the course of examining the application, the Authority may require the applicant to provide additional information or samples of the medical devices.

Exemption
from registration

13.-(1) An medical device in Class A, may be exempted from registration due to the low risk associated with their use as provided for in the Classification Rules for Medical devices in the First

Schedule and their specific intended purpose as prescribed in the third column of the Second Schedule to these Regulations;

(2) Where the proposed intended purpose of a medical device is different from that specified in the Second Schedule, then the medical device shall require registration.

Issuance of registration certificate

14. Where the Authority determines that a medical device in respect of which an application is submitted meets the safety and performance requirements, the Authority shall:

- (a) issue to the registrant of the medical device a medical device registration certificate, in the case of an application for registration of a medical device; or
- (b) amend the registration certificate of a medical device, in the case of an application amendment of the registration.

(2) The Authority may set out in the registration certificate of a medical device terms and conditions in respect with-

- (a) the tests to be performed on a medical devices to ensure that it continues to meet the safety and performance requirements; and
- (b) the requirement to submit the results and protocols of any tests performed.

(3) The Authority may amend the terms and conditions of the registration certificate of medical devices to take into account any new development with respect to the medical device.

Refusal of issuance of registration

15.-(1) The Authority may refuse to issue or amend a medical device registration if-

- (a) the applicant does not comply with these Regulations or any provisions of the Act relating to medical devices;

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- (b) the applicant has made a false or misleading statement in the application;
- (c) the medical device does not comply with the labeling requirements set out in these Regulations; and
- (d) the applicant has not complied with a request for additional information or samples made pursuant to these Regulations by the day specified in the request.

(2) The Authority may refuse to issue or amend a medical device registration certificate if the medical device does not meet the safety and performance requirements or if the information or samples provided pursuant to these Regulations are insufficient to enable the Authority to determine whether the medical device meets those requirements.

(3) Where the Authority refuses to issue or amend a medical device registration certificate, the Authority shall:

- (a) notify the applicant in writing of the reasons for the refusal; and
- (b) give the applicant an opportunity to be heard by the Authority.

Additional
information
after registration

16.(1) Where the Authority believes on reasonable grounds, after reviewing a report or information brought to the Authority attention, that a registered medical device may not meet the safety and performance requirements, the Authority may request the manufacturer to submit information or samples to enable the Authority to determine whether the Medical device meets the requirements.

(2) The manufacturer shall, upon receipt of the request made under sub regulation (1), and within the time specified in the request, submit to the Authority information or samples requested.

Validity of

17.(1) A certificate of full registration issued

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registration,
retention and
renewal

under regulation 14(1)(a) shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees be valid for a period of five years from the date of issuance and may thereafter be renewed.

(2) Every registrant shall, in addition to the fees related to registration of each medical device, pay annual retention fees before 31st January of each calendar year.

(3) The registrant shall be required to submit biennial post-marketing surveillance reports including any adverse events.

(4) Application for renewal of registration shall be made to the Authority at least 90 days before its expiry.

(5) A grace period for renewal shall extend to 90 days after the specified expiry date.

(6) Defaulters shall pay a penalty as stipulated in Fees and Charges Regulations in force after the expiry of grace period.

Suspension or
cancellation of
registration

18. Notwithstanding to the provision of regulation 17, the Authority may suspend or cancel the registration of a medical devices if the Authority has reasonable grounds to believe that-

- (a) the registration has contravened these Regulations or any provision of the Act relating to medical devices;
- (b) the registrant has made a false or misleading statement in the application;
- (c) the registrant has failed to comply with the terms and conditions of the registration;
- (d) the registrant has not complied with a request for information or samples made pursuant to Regulation 16 of these regulations by the day specified in the request, or the information or samples provided are insufficient to enable the

- Authority to determine whether the medical devices meets the safety and effectiveness requirements;
- (e) the medical devices no longer meets the safety and effectiveness requirements;
 - (f) on the basis of information obtained after the Medical device was registered, the Quality Management System and Good Manufacturing Practices under which the medical devices has been designed, in the case of a Class C and D medical devices, or manufactured, assembled, processed, packaged, refurbished or modified, in the case of a Class B, C or D medical devices, is inadequate to ensure that the medical device meets its specifications;
 - (g) the registrant of the medical devices fails to pay the prescribed retention fee which are in force within the prescribed time;
 - (h) the registrant has failed to submit biannual post-marketing surveillance as provided under these;
 - (i) The registrant, intentionally and without justifiable cause, fails to submit reports on adverse effects.

Voluntary
cancellation of
registration

19. The Authority may on request made to it and upon the application made by the registrant of a medical device, cancel the registration of the medical devices.

Notice of
suspension or
cancellation

20. The Authority shall not suspend or cancel the registration of a medical devices until:

- (a) the Authority has sent the registrant a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

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- (b) the time set out in the notice for corrective action, if required, has passed without the action having been taken; and
- (c) the registrant has been given an opportunity to be heard in respect of the suspension.

Suspension or cancellation of registration without notice

21.-(1) The Authority may cancel or suspend the registration of a medical devices without giving the registrant an opportunity to be heard if it is necessary to do so to prevent injury to the health or safety of patients, users or other persons, by giving the registrant a notice in writing that states the reason for the cancelation or suspension as the case may be.

(2) A registrant may ask the Authority, in writing, that the cancelation or suspension be reconsidered.

(3) The Authority shall, within sixty (60) days after the date of receiving the request, provide the registrant with an opportunity to be heard.

Establishment of expert committee

22.-(1) The Director General may establish an expert committee for the purpose of advising on specific issue related to registration of medical devices.

(2) The committee established under sub regulation (1) shall execute its functions based on the terms of reference of the Director General.

Application for variation of registered product

23.-(1) An application for any variation to a registered medicinal product shall be notified to the Authority by filling in application form as set out in Third Schedule to these regulations.

(2) Application for variation shall be submitted as per the requirements set out in the Guidelines for Variation of Registered medical device in force at the time of submission.

(3) Any payment for variation shall be made in accordance with the Fees and Charges Regulations in force.

**PART IV
MANUFACTURE OF MEDICAL DEVICES**

Manufacture, sale and supply of medical device

24. No person shall manufacture for sale, import, or supply any medical device unless-

- (a) the medical device is registered;
- (b) he holds a valid premises permit issued by the Authority; and
- (c) the manufacture, sale and supply of any medical device is carried out in accordance with the conditions of the permit issued.

Prohibition of manufacture, importation, sale and supply of certain medical device

25. No person shall manufacture, import, sale, supply or procure or arrange for the manufacture of, any medical device which is:

- (a) an adulterated medical device;
- (b) a counterfeit medical device; or
- (c) an unwholesome medical device.

Registrant's obligations

26.-(1) The registrant shall ensure that the medical device meets the safety and performance requirements.

(2) The registrant shall keep objective evidence to establish that the medical device meets the requirements.

Safety and performance requirements

27.-(1) A medical devices shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to-

- (a) identify the risks inherent in the device;
- (b) eliminate the risks;
- (c) if the risks cannot be eliminated-
 - (i) reduce the risks to the acceptable level;
 - (ii) provide for protection

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- appropriate to those risks, including the provision of alarms; and
- (ii) provide, with the medical devices, information relative to the risks that remain; and
 - (d) minimize the hazard from potential failures during the projected useful life of the medical device.

Usage of
medical devices

28.-(1) A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person.

(2) A medical device shall be used as intended by the manufacturer and shall be effective for the medical conditions and purposes for which it is manufactured, sold or represented.

(3) During the projected useful life of medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

(4) The characteristics and performance of medical devices shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.

Manufacturing, packaging and
selling of
medical devices

29.-(1) A manufacturer shall take reasonable measures to ensure that every material used in the manufacture of medical devices shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.

(2) The design, manufacture and packaging of a medical device shall minimize any risk to a patient,

user or other person from reasonably foreseeable hazards, including-

- (a) flammability or explosion;
- (b) presence of a contaminant or chemical or microbial residue;
- (c) radiation;
- (d) electrical, mechanical or thermal hazards; and
- (e) fluid leaking from or entering into the medical device.

(3) A medical device which is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.

(4) A medical device which is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.

(5) A medical device performing a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the medical device is manufactured, sold or represented.

(6) Where medical devices consist of or contain software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

PART V

PERMIT TO DEAL WITH BUSINESS OF MEDICAL DEVICES

Prohibition

30. No person shall operate a business of medical device unless the person holds a valid premises permit issued by the Authority.

Application for permit to operate the business on

31. An application to operate the business of medical devices shall be submitted to the Authority in accordance with guidelines prescribed by the

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- medical devices Authority and shall contain the following-
- (a) the name and address of the owner;
 - (b) the name and physical address of the premises;
 - (c) the name, e-mail address and telephone number of the contact person to contact for any information concerning the application;
 - (d) a statement as to whether the activity of the premises is manufacturing or importation;
 - (e) an attestation by an incharge of the premises that the premises has documented procedures in place in respect of distribution records, complaint handling, recalls and mandatory problem reporting; and
 - (f) an attestation by an incharge of the premises has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of those devices.

(2) The Authority may, if satisfied that the conditions specified in these Regulations are met, it will register the premises and issue premises registration certificate as prescribed in the Third Schedule and business permit as prescribed in the Second Schedule to these Regulations

Issuance of permit

32.-(1) The Authority shall, upon satisfaction of the application issue a permit to operate a business of medical device as provided in the Third Schedule to these Regulations.

(2) A medical device premises permit shall, subject to renewal and upon application by the registrant on conditions set forth in the application format, expire on the 30th June of each year.

Retail and wholesale business permits

33. Any person who intends to deal with a business of retail or wholesale of medical devices shall make an application to the Authority.

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Refusal to issue
a premises
permit

34.-(1) The Authority may refuse to issue a premises permit if:

- (a) the applicant has made a false or misleading statement in the application;
- (b) the Authority has reasonable grounds to believe that issuing such a permit will constitute a risk to the health or safety of patients, users or other persons.
- (c) the applicant failed to meet minimum requirements of premises registration.

(2) In any case, where the Authority refuses to issue a permit to operate a business of medical devices shall-

- (a) notify the applicant in writing of the reasons for the refusal; and
- (b) give the applicant an opportunity to be heard.

Notification of
change

35. Where, after the issuance of a premises permit, there is a change to any of the information submitted at the time of application, the holder of the permit shall submit the new information to the Authority within twenty one days of the change.

Revocation or
cancellation of a
permit

36.-(1) Subject to regulation 35, the Authority may suspend or cancel a premises permit if the Authority has reasonable grounds to believe that-

- (a) the permit holder has contravened these Regulations or any provision of the Act relating to medical devices;
- (b) the permit holder has made a false or misleading statement in the application or notification of change; or
- (c) failure to suspend the premises permit would constitute a risk to a medical devices, or health or safety of patients, users or other persons.

(2) The Authority shall, before cancelling or

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suspending a premises permit, consider the risk if keeping the permit in force would compromise the health or safety of patients, users or other persons.

(3) The Authority shall not cancel or suspend a premises permit unless-

- (a) it has sent to the permit holder a fourteen (14) days written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
- (b) the time set out in the notice for corrective action, if required, has passed without the action having been taken; and
- (c) the permit holder has been given an opportunity to be heard in respect of the suspension.

Reconsideration
of a suspended
permit

37. A permit holder may request the Authority, in writing, that the suspension be reconsidered.

Restoration of a
permit

38. The Authority may, within thirty (30) days after the date of receiving the request for reconsideration of the permit, and upon satisfaction that the situation giving rise to the suspension has been corrected or if the reason for the suspension was unfounded, reinstate the business permit.

Maintenance of
distribution
records

39.-(1) The manufacturer, importer, distributor, health care facility and a retailer of medical devices shall each maintain a distribution record in respect of each medical device.

(2) The distribution record, sales and user records shall contain sufficient information to permit traceability complete and rapid withdrawal of the medical devices from the market in case of recall or any other reason.

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Period and
maintenance of
distribution
records

40.-(1) The manufacturer, importer, distributor, health care facility and retailer shall retain the distribution record maintained in respect of a medical device as long as.

- (a) the projected useful life of the medical devices, and
- (b) two years after the medical device has been dispatched.

(2) The distribution records shall be maintained in a manner that will allow for their timely retrieval.

Restriction to
mandatory
problem
reporting

41. Every registrant, manufacturer, importer and distributor of a medical device shall each make a preliminary and a final report to the Authority concerning any incident that comes to their attention occurring inside or outside Tanzania and involving a device that is sold in Mainland Tanzania and that-

- (a) is related to a failure of the medical devices or a deterioration in its effectiveness, or any inadequacy in its labeling or in its the directions for use; and
- (b) has led to the death or a serious deterioration in the state of health of a patient, user or other person.

Preliminary
report of an
incidence

42.-(1) A preliminary report shall be submitted to the Authority-

- (a) in respect of an incident that occurs in Mainland Tanzania

- (i) within twenty four (24) hours after the occurrence of the incidence the registrant, manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person; or

- (ii) Within fourteen (14) days after the registrant, manufacturer or importer or distributor of a medical devices becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it occurs; and
- (b) in respect of an incident that occurs outside Mainland Tanzania, as soon as possible after occurrence of the incidence.
- (2) The preliminary report of an adverse event shall contain the following information-
 - (a) the name of the medical devices and its identifier, including the identifier of any medical devices that is part of a system, test kit, medical devices group, medical devices family or medical devices group family;
 - (b) if the report is made by-
 - (i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and fax numbers of a representative of the manufacturer to contact for any information concerning the incident, or
 - (ii) the importer of the medical devices, the name and address of the importer and of the manufacturer, and the name, title and telephone and fax numbers of a representative of the importer to contact for any information concerning the incident;
 - (c) the date on which the incident came to the attention of the registrant, manufacturer or importer;
 - (d) the details known in respect of the incident,

- including the date on which the incident occurred and the consequences for the patient, user or other person;
- (e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;
 - (f) the identity of any other medical devices or accessories involved in the incident, if known;
 - (g) the manufacturer's or importer's preliminary comments with respect to the incident;
 - (h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and
 - (i) a statement indicating whether a previous report has been made to the Authority with respect to the medical devices and, if so, the date of the report.

Final report of an incidence and reporting time line

44.-(1) After the preliminary report is made in accordance with regulation 43, a final report shall be submitted to the Authority in accordance with the timetable established under Regulation 43(2) (*h*).

(2) The final report shall contain the following information-

- (a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
- (b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
- (c) any actions taken as a result of the investigation, which may include:

- (i) increased post-marketing surveillance of the medical devices;
- (ii) corrective and preventive action respecting the design and manufacture of the medical devices, and
- (iii) recall of the medical devices.

PART V

IMPORTATION AND EXPORTATION OF MEDICAL DEVICE

Restriction on importation and exportation

45. No person shall import or export a medical device regulated under these Regulations unless he holds a valid permit issued by the Authority for that purpose.

Applications for Import and, or Export permits

46.-(1) An application for permit to import or export medical devices shall be made to the Authority in a form prescribed in the Third Schedule to these Regulations.

(2) The forms referred to in sub regulation (1) shall be accompanied by the original proforma invoice and two (2) copies, duly filled and signed by the incharge of the business.

(3) Subject to provision of sub regulations (1) and (2), the proforma invoice shall state, for each medical devices, the following-

- (a) number and date;
- (b) name of the supplier and/or manufacturer;
- (c) country of origin;
- (d) trade or proprietary name;
- (e) the product registration number issued by the Authority;
- (f) the quantity, pack size, unit value, total value in convertible currency;
- (g) batch or Lot number;
- (h) manufacturing and expiring date;
- (i) mode of shipment (sea, air, road);
- (j) port of entry;

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(k) signature and stamp of the supplier.

Issuance of
Import or export
permits

47.-(1) The Authority, after considering the application made to it and being satisfied that the conditions set in these Regulations are met, and upon payment of a fee as prescribed in the Fees and Charges Regulations in force, shall issue an import or export permit.

(2) The import permit shall be in the form prescribed in the Fifth Schedule to these Regulations.

(3) The validity period of import permit shall be six months and for export permit three months from the date of issue.

(4) The import or export permit shall be used for a single consignment and not transferable to any other importer or exporter.

(5) In the event where shipping of the consignment takes more than one shipment (partial consignment), only three shipments shall be allowed to be covered by one import permit.

Conditions for
importation of
medical devices
for personal use

48. The Authority may, upon application by an individual, and in such amount to be determined by it, authorize the importation of medical devices for personal use.

Points of entry
Approval of
imports

49.-(1) No person shall bring into Tanzania, medical devices through any entry other than the points of entry prescribed in the First Schedule to these Regulations.

(2) The ports of entry prescribed in sub regulation (1) may be amended, varied or added from time to time.

Conditions for
donated medical
devices

50.-(1) No person shall import any medical device unless it is registered by the Authority.

(2) Notwithstanding sub regulation (1) the

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Authority may, upon request by any person or institution and on public interest, approve the importation of unregistered medical devices.

Restriction to
Importation of
free samples

51.-(1) No person shall import donated medical devices unless he complies with these Regulations.

(2) Any person who intends to import donated medical devices shall make an application by submitting a letter in a headed paper accompanied with the Donation Certificate to the Authority.

Importation of
free of charge
medical devices

52.-(1) No person shall sell, offer for sale or has in his possession for sale free sample of medical device.

(2) Subject to other conditions set in these Regulations, importation of free samples shall meet the following criteria:

- (a) samples shall bear a label printed “Free sample – Not for sale”
- (b) the quantity of the commercial pack shall not exceed 300 unit packs per single consignment.

Application for
importation of
Investigational
medical device

53.-(1) Subject to other conditions set in these Regulations, application for importation of free of charge medical devices shall be accompanied by the profoma invoice indicating the unit price of each product.

(2) Without prejudice to other conditions set in these Regulations, all free of charge medical devices shall be charged Free on Board as per Fees and Charge Regulations in force.

Revocation,
Cancellation or
suspension of
import or export
permit

54.-(1) Applications for importation of investigational medical device shall be made by a clinical trial Sponsor or Principal Investigator for a study approved to be conducted in Tanzania.

(2) Subject to sub regulation (1), applications

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shall be accompanied by Clinical Trial Approval Letter issued by the Authority.

Inspection of
imported
consignment at
Ports of Entry

55. The Authority may revoke, cancel or suspend any import or export permit issued or any other certificates made under these Regulations, if it is satisfied that the importer, exporter or consignment contravenes any provision of these Regulations.

Sampling

56.-(1) No imported medical device shall be removed out of the ports of entry or any other place before it is inspected by the inspector and released.

(2) Subject to sub regulation 1, all consignment moved from the ports of entry by direct release administered by Customs Department to other places for storage or for distribution, such places shall be deemed to be the designated ports of entry.

(3) The removal of the consignment from the place referred in sub regulation (2) shall comply with this regulation.

(4) An importer shall avail all necessary documents as may, from time to time, be requested by the Authorised inspector.

Rejection or
detention of
consignment

57.-(1) Where the inspector suspects any medical device in the consignment contravenes the provision of these Regulations or the Act, may take sample for further investigation.

(2) Subject to provision of sub regulation (1) the inspector shall dully fill in a sample collection form as prescribed in the Third Schedule to these Regulations.

Restriction of
disposal of unfit
products

58.-(1) In case a consignment fails to meet the requirements of these Regulations, the inspector shall reject or detain the consignment and order re-exportation at owners cost.

(2) Where an inspector rejects and order re-

exportation of any consignment at the ports of entry or any other place shall fill in the rejection form prescribed in Second Schedule to these Regulations.

(3) A copy of airway bill or bill of lading shall be submitted to the Authority as an evidence of re exportation of the consignment

(4) Where it is in the opinion of the inspector that the consignment be destructed, he shall recommend the same to the Authority.

PART VI HANDLING OF UNFIT MEDICAL DEVICES

Decision to
initiate disposal
of unfit medical
devices

59. No person shall dispose of any unfit medical devices unless he has requested the Authority and secured an approval to proceed with disposal procedure.

Request for
disposal of unfit
medical devices

60. The decision to initiate disposal of unfit medical devices shall be made by the Authority, Regional, District or Hospital Pharmacist, Owner or In-charge of facility or premises, Superintendent or an Inspector.

Approval to
dispose unfit
medical devices

61.-(1) Request to dispose of unfit medical devices shall be made to the Authority in Form prescribed in the Third Schedule to these Regulations.

(2) A request shall be accompanied with a list of medical devices to be disposed which shall state clearly trade name, generic name, strength, and dosage form (where applicable), type of packaging material, pack size, quantity, manufacturer, batch or lot number and market value of each product.

(3) Subject to the provision of sub regulations (1) and (2), request to dispose of unfit medical devices from Government institutions shall be accompanied by an approval from Accountant General declaring that the products have been written off and that are subject

to disposal as required by the Public Finance Act and Regulations in force for the time being.

Handling of
unfit medical
devices

62.-(1) The Authority, upon receipt of request for disposal, shall appoint an inspector to verify and authenticate the information submitted in relation to the consignment to be disposed.

(2) Verification referred in sub regulation (1) shall be made in the form prescribed in the Third Schedule to these Regulations.

(3) The Authority after verification exercise shall inform the applicant to liaise with National Environment Management Council (NEMC) or any other institution responsible for environment management on the proposed mode of destruction and issuance of disposal permit.

(4) The applicant shall submit to the Authority disposal permit from NEMC, the Authority shall liaise with Local Government Authority for disposal site, cost and date of destruction.

(5) The cost of destruction shall be borne by the owner of the consignment.

Disposal of unfit
medical devices

63.-(1) No person shall sell or supply or offer or expose for sale or supply or have in his possession for the purpose of sale or supply unfit products.

(2) Every dealer of medical devices shall adhere to the following requirements:

(a) maintain a register for unfit medical devices as prescribed in Second Schedule;

(b) keep separately medical devices with medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicines or cosmetics;

- (c) demarcate an area for keeping unfit medical devices which shall be labeled conspicuously in red ink with words “Unfit for intended use” or “Hazifai kwa matumizi”;
- (d) maintain safe custody of unfit medical devices in registered premises until they are disposed.

Prohibition to sell products subjected to recall

64.-(1) Subject to any provision of these Regulations, an Inspector, Health Officer, Environmental Inspector, Policeman and any other authorized officer shall supervise the transport of consignment from the premises to the disposal site for destruction exercise.

(2) The destruction exercise shall be supervised by Inspector, Health Officer, Environmental Inspector, Policeman and any other authorized officer and upon completion of the exercise a disposal Form prescribed in Third Schedule shall be duly filled in and signed by the supervisors and owner or representative.

(3) The Authority shall upon receiving disposal form, issue a certificate of destruction of unfit medical devices prescribed in Second Schedule of these Regulations.

PART VII RECALL OF MEDICAL DEVICES

Product recall

65. No person shall sell, offer or expose for sale or supply medical devices subjected to recall.

66.-(1) The Authority on its own motion may, at any time when it is of the opinion that medical devices may cause injury to the health or safety of patients, users or other persons, order recall of such device from the market at the costs of the registrant.

(2) The manufacturer or the importer of a medical devices may voluntarily initiate a recall of any medical devices after receiving complaints from patient or users or upon proof after investigation that such device has caused or is about to cause injury to the health or safety of patients, users or other persons.

(3) On or before undertaking a recall referred to in sub regulation (2), the manufacturer and the importer of a medical devices shall each provide the Authority with the following:

- (a) the name of the device and its identification, including identification of any medical devices that is part of a system, test kit, medical devices group, medical devices family or medical devices group family;
- (b) the name and address of the manufacturer and importer, and the name and address of the premises where the medical devices was manufactured, if different from that of the manufacturer;
- (c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
- (d) the number of affected units of the medical devices that the manufacturer or importer;
- (e) the period during which the affected units of the medical devices were distributed in Tanzania by the manufacturer or importer;

- (f) the name of each person to whom the affected medical devices was sold by the manufacturer or importer and the number of units of the device sold to each person;
- (g) a copy of any communication issued with respect to the recall;
- (h) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Authority will be informed of the progress of the recall and the proposed date for its completion;
- (i) after completion of the recall exercise the application shall be required to do the following:
 - (a) conduct an evaluation of the risk associated with the defectiveness or possible defectiveness and submit to the Authority;
 - (b) submit a proposed corrective action to prevent recurrence of the problem.
 - (i) manufactured in Tanzania;
 - (ii) imported into Tanzania, and
 - (iii) sold in Tanzania;

Submission of reports after recall

66.-(1) The registrant, LRP or importer of a medical devices shall, as soon as possible after the completion of a recall, submit to the Authority the report indicating:

- (a) the results of the recall; and
- (b) the measures taken to prevent a recurrence of the problem.

Classification of
recall

67.-(1) There shall be three classes of recall as provided in this regulation depending on nature of the health risk or adverse events.

(a) Class I is for defective, dangerous or potentially life threatening medical devices that predictably or probably could result into serious health risk or adverse events or death;

(b) Class II is for medical devices that possibly could cause temporary or medically reversible adverse health problem or mistreatment;

(c) Class III is for medical devices that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements of the Act

(2) The maximum time for recalling class I, II and III shall be 14, 21 and 30 days respectively.

(3) Notwithstanding sub regulation (2) of this regulation, the Authority reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

PART VIII ADVERTISEMENT OF MEDICAL DEVICES

Restriction on
advertisement

68.-(1) No medical device shall be promoted unless it is registered by the Authority.

(2) No person shall advertise any product or cause any product to be advertised as a medical device if that product is not a medical device.

(3) No person shall advertise any registered medical devices or cause any registered medical

devices to be advertised in such away as to represent the registered medical devices as being usable for any purpose other than that for which it has been registered.

Criteria for a medical device to be promoted

69.-(1) No medical device shall be promoted unless it is registered by the Authority.

(2) The content of promotional materials must be unbiased, accurate, informative, up to date and consistent with information approved during registration.

(3) All packaging and labelling materials shall provide information which is consistent with that approved during the registration of the medical device.

(4) Promotional material shall not contain misleading or unverifiable statements or omissions regarding quality, safety and performance or value which likely to induce medically unjustifiable product use or to give rise to undue risks.

(5) No medical device shall be promoted in a manner that is misleading or calculated to mislead, deceptive or is likely to create erroneous impression either directly or by implication regarding its character value, quantity, composition, safety or efficacy as the case may be.

(6) Promotional material that is still in use must be re-certified at intervals of no more than 12 Months to ensure that it continue to confirm to these regulations.

Content of promotional materials

70.-(1) The content of promotional materials must be unbiased, accurate, informative, up to date and consistent with information approved during registration of the product.

(2) Promotional material shall not contain misleading or unverifiable statements or omissions regarding quality, safety, and efficacy or value which

likely to induce medically unjustifiable product use or to give rise to undue risks.

(3) No person shall conduct an advertisement of a medical device unless he/she applies and be issued with a written approval from the Authority

(4) An advertisement to the general public shall not refer to the Act, or any department or official of the Authority.

(5) Every application for a permit to use a promotional material shall be made to the Authority by submitting a dully filled in Application Form For Approval of Promotional Material as prescribed in the Third Schedule.

(6) Every application for a Trade Fair Permit shall be made to the Authority by submitting a dully filled in Application Form For Trade Fair Permit as prescribed in the Third Schedule accompanied by fees as prescribed in the Food Drugs and Cosmetics (Fees and Charges) Regulations in force.

(7) Every application for a permit to use promotional material shall be accompanied by fees as prescribed in the Food Drugs and Cosmetics (Fees and Charges) Regulations in force.

(8) The Authority shall if satisfied that the proposed promotional material complies with the requirements prescribed in these regulations, issue a Permit for Advertisement as prescribed in Third Schedule with such conditions as it may consider necessary.

(9) Companies shall preserve permits for promotional material and the relevant materials in the form certified for not less than two years after the final use of the promotional material or the date of the meeting and produce them on request from the Authority.

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False or
misleading
advertisement

71.-(1) No person shall advertise any medical device or cause any medical device to be advertised in a false or misleading way.

(2) For the purposes of sub-regulation (1), an advertisement of a medical device shall be taken to be false or misleading if –

- (a) it falsely describes the medical device or gives any false information concerning the medical devices; or
- (b) it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the medical device.

Requirements
for
advertisement

72.-(1) No person shall advertise any medical device or cause any medical devices to be advertised unless the advertisement complies with and is undertaken in accordance with such requirements as may be prescribed.

(3) The requirements that may be prescribed for the purpose of sub regulation (1) of these Regulation include the following:

- (a) that the advertisement should not make certain types of claims about the medical device;
- (b) that the advertisement should be distributed or circulated only to certain classes of persons;

Comparison of
Products

73.-(1) A comparison of medical device for competition purposes is prohibited.

(2) A comparison of medical devices should not be disparaging, but must be factual, fair, reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way.

PART IX
LABELLING

Labeling

74.-(1) No person shall import or sell a medical device unless has a label that sets out the following information-

- (a) the name of a medical device;
 - (b) the name and address of manufacturer;
 - (c) the identifier of a medical device, including the identifier of a medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
 - (d) batch or lot number;
 - (e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to a medical device, such as size, net weight, length, volume or number of units;
 - (f) the words “Sterile” if the manufacturer intends to sale a medical device in a sterile condition;
 - (g) the words “for single use only” if the medical device is intended for that purpose;
 - (h) the expiry date of the medical device expressed in month and year;
 - (i) unless self-evident to the intended user, the medical conditions, purposes and uses for which the medical device is manufactured, sold or represented, including the performance specifications of the medical devices if those specifications are necessary for proper use;
 - (j) the directions for use; and
 - (k) any special storage conditions applicable to the medical devices.
- (2) The information required pursuant to sub-

regulation (1) of this Regulation shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.

(3) Subject to sub-regulation (4), if a medical device is intended to be sold to the general public, the information required by sub-regulation (1) shall -

(a) be set out on the outside of the package that contains the medical devices; and

(b) be visible under normal conditions of sale.

(4) Where a package that contains a medical device is too small to display all the information in accordance with sub-regulation (1) of this Regulation, the directions for use shall accompany the medical device but need not be set out on the outside of the package or be visible under normal conditions of sale.

(5) Notwithstanding with provision of sub-regulation (4) the accompany information shall be provided in the package inset, manual, booklet, or any other means as the case will be.

Restriction on
language

75. The information required by regulation 74 shall be in either English or Kiswahili or both English and Kiswahili.

PART X GENERAL PROVISIONS

Offence

76. Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations.

Penalty

77. Any person found guilty of an offence under these Regulations shall be liable to the penalty prescribed by the Act.

Appeals

78. Any person aggrieved by a decision of the Authority may, within 60 days lodge an appeal in writing to the Minister.

(2) Notwithstanding the provision of sub-regulation (1) of these regulation, where a person has failed to lodge an appeal within the prescribed time may within thirty days apply to the Minister for extension of time to lodge an appeal.

(a) the Minister may for any good reason extend time for the lodging of an appeal; or

(b) if a person fails to lodge an appeal within the extended time shall be barred from appealing.

(3) In determining an appeal under this regulation the Minister may-

(a) form an expert committee to advise him on the subject matter of an appeal;

(b) allow or dismiss the appeal;

(c) quash any refusal, revocation or suspension and;

(d) order a person to make a fresh application.

Compounding
of offences

79.-(1) The Director General or an Inspector authorized to act on his behalf before accepting a fine or any other thing from the person referred under sub-regulation (1) of this Regulation shall require such a person to fill in a Compounding offence Form as provided in Third Schedule to these Regulations.

(2) Subject to the provisions of these Regulations authorizing any measures that may be taken pursuant to an order of the court, no further criminal or as the case may be civil proceedings shall be taken against a person of whom power to compound offence has been exercised.

TANZANIA FOOD AND DRUGS AUTHORITY



FIRST SCHEDULE
[Made under regulation 5 (1)]

CLASSIFICATION RULES FOR MEDICAL DEVICES

PART 1

MEDICAL DEVICES OTHER THAN *IN-VITRO* DIAGNOSTIC DEVICES

Non-Invasive Devices

Rule 1

All non-invasive devices which come into contact with injured skin:

- (a) are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;
- (b) are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.

unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.

Rule 2

All non-invasive devices intended for channeling or storing body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,

unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;

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unless they are intended for use of channeling blood, or storing or channeling other body liquids, or for storing organs, parts of organs or body tissues, in which case they are Class B.

unless they are blood bags, in which case they are Class C.

Rule 3

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids intended for infusion into the body are in Class C,

Unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.

Rule 4.

All other non-invasive devices are in Class A.

Invasive Devices

Rule 5

All invasive devices with respect to body orifices (other than those which are surgically invasive) and which are not intended for connection to an active medical device, or are intended for connection to a Class A medical device only are in Class A if they are intended for transient use; are in Class B if they are intended for short-term use;

unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A, are in Class C if they are intended for long-term use;

unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the eardrum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.

All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.

Rule 6

All surgically invasive devices intended for transient use are in Class B,

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unless they are reusable surgical instruments, in which case they are in Class A; or

unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or

unless they are intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or

unless they are intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or

unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or

unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

Rule 7

All surgically invasive devices intended for short-term use are in Class B,

unless they are intended to administer medicinal products, in which case they are in Class C; or

unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or

unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or

unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or

unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;

unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

Rule 8

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All implantable devices, and long-term surgically invasive devices, are in Class C,
Unless they are intended to be placed into the teeth, in which case they are in Class B; or
unless they are intended to be used in direct contact with the heart, the central circulatory
system or the central nervous system, in which case they are in Class D; or
unless they are intended to be life supporting or life sustaining, in which case they are in
Class D; or
unless they are intended to be active implantable medical devices, in which case they are
Class D; or
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in
which case they are in Class D; or
unless they are intended to administer medicinal products, in which case they are in Class
D; or
unless they are intended to undergo chemical change in the body (except if the devices
are placed in the teeth), in which case they are in Class D; or
unless they are breast implants, in which case they are in Class D.

Active Devices

Rule 9(i)

All active therapeutic devices intended to administer or exchange energy are in Class B,
unless their characteristics are such that they may administer or exchange energy to or
from the human body in a potentially hazardous way, including ionizing radiation, taking
account of the nature, the density and site of application of the energy, in which case they
are in Class C.

Rule 9(ii)

All active devices intended to control or monitor the performance of active therapeutic
devices in Class C, or intended directly to influence the performance of such devices, are
in
Class C.

Rule 10(i)

Active devices intended for diagnosis are in Class B:

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- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or
- if they are intended to image *in vivo* distribution of radiopharmaceuticals, or if they are intended to allow direct diagnosis or monitoring of vital physiological processes,

unless they are specifically intended for:

- a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or
- b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.

Rule 10(ii)

Active devices intended to emit ionizing radiation and intended for diagnostic and /or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance are in class C.

Rule 11

All active devices intended to administer and/or remove medicinal products; body liquids or other substances to or from the body are in Class B,

unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.

Rule 12

All other active devices are in Class A.

Additional Rules

Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.

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Rule 14

All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,

unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.

Rule 15

All devices intended specifically to be used for sterilizing or disinfecting medical devices, are in Class B.

unless they are disinfectant solutions or washer disinfectors intended specifically for invasive medical devices, as the end point of processing in which case they are in Class C; or unless they are intended to clean medical devices by means of physical action only, in which case they are in Class C.

Rule 16

All devices used for that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating, contact lenses are in Class C

PART 2

IN-VITRO DIAGNOSTIC DEVICES

Rule 1

IVD medical devices intended for the following purposes are classified as Class D:

- (a) Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
- (b) Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

Rule 2

IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3

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(E), RH4 (c), RH5 (e), Kell system [Kell (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations which are classified as Class D.

Rule 3

IVD medical devices are classified as Class C if they are intended for use:

- (a) in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.
- (b) in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitides* or *Cryptococcus neoformans*.
- (c) in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae*, Methycillin Resistant *Staphylococcus aureus*.
- (d) in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis.
- (e) in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient. Examples: Enteroviruses, CMV and HSV in transplant patients.
- (f) in screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer. Example: personalized medicine.
NOTE: those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6.
- (g) in human genetic testing. Examples: Huntington's disease, Cystic Fibrosis.
- (h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing.

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- (i) In the management of patients suffering from a life-threatening infectious disease. Examples: HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping.
- (j) In screening for congenital disorders in the fetus. Examples: Spina Bifida or Down Syndrome.

Rule 4

IVD medical devices intended for self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

Rule 5

The following IVD medical devices are classified as Class A:

- (a) Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
- (b) Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures
- (c) Specimen receptacles

Note: Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD medical devices, as defined in this document. However, in certain jurisdictions products for general laboratory use are considered to be IVD medical devices.

Rule 6

IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rule 7

IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

TANZANIA FOOD AND DRUGS AUTHORITY

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LIST OF AUTHORIZED POINTS OF ENTRIES FOR MEDICAL DEVICES AND *IN-VITRO* DIAGNOSTIC DEVICES

1. Dar-es-salaam International Airport,
2. Dar es salaam Sea Port,
3. Kilimanjaro International Airport,
4. Horohoro
5. Holili,
6. Namanga,
7. Sirari,
8. Mwanza Lake Port,
9. Mwanza Airport,
10. Tanga Sea Port,
11. Tunduma
12. Mtukula
13. Rusumo
14. Kabanga
15. Kasumulo



SECOND SCHEDULE
[Made under regulation 15]

LIST OF CLASS A - MEDICAL DEVICES EXEMPTED FROM REGISTRATION

The listing is tabulated with the following items:

| <i>Item</i> | <i>Explanation</i> |
|-------------------|---|
| Keyword | An aid to facilitate the search of product in the exempted list. |
| Device identifier | The name (presented in bold) that is selected to represent a generic device group. Synonym term: (names presented in italic) are other names that are commonly used, in place of, or to identify, the device, the device identifier. |
| Description | Provides a description of the medical device that is exempted and its intended purpose. Medical devices that do not meet the description or its intended purpose, as provided in the list, shall not be exempted from product registration. |

(Applicable only if it (i) fits the given description, and (ii) is solely for the use listed below)

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| Adhesive | Adhesive Bandage <i>Bandage/dressing, adhesive</i> <i>Bandage/tape, adhesive</i> | A piece of a fabric or plastic material (not a strip) that is applied to a part of the body with a pressure-sensitive adhesive. It may or may not include an absorbent pad. It is used to cover and protect wounds, to support an injured part of the body, or to secure objects to the skin. This is a single-use device. |
| | Adhesive strip <i>Adhesive strip, general purpose</i> <i>Closure, wound, adhesive</i> <i>Strip, adhesive, general purpose</i> <i>Adhesive strip, butterfly</i> | A small, narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive, used to cover or approximate the edges of superficial wounds or fix dressings to skin. The device may include an adhesive pad and have qualities such as hypoallergenic or waterproof. The device is usually supplied sterile in precut sizes/shapes. This is a single-use device. |
| | Adhesive tape <i>First-aid adhesive tape</i> <i>Tape, adhesive</i> <i>Tape, cotton</i> <i>Tape, gauze, self-adhesive</i> <i>Tape, adhesive, hypoallergenic</i> <i>Tape, adhesive, waterproof</i> | A very long and narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a typically pressure sensitive adhesive, used to cover a surface (e.g. small wound), fix a dressing, or bind/attach objects (e.g. a venflon to a patient's body part). The device may also be applied in several layers, one overlapping the other, to cover and exert pressure on a body part (e.g. a limb). The device may have additional properties (e.g., waterproof, hypoallergenic) and is typically supplied in rolls. This is a single-use device. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|------------------------------|--|
| Applicator | Applicator, absorbent tipped | A device used for making local applications to any accessible body surface. It is typically designed as a slender rod of wood, flexible metal, or a synthetic material, to which is attached a non sterile absorbent tip at one end. This is a single-use device. |
| Bag | Ice bag | A device designed for applying dry cold therapy to an external area of the body. Ice is placed into a container that usually has flexible walls. The device may include a holder that keeps the bag in place. |
| Bandage | Bandage, self-adherent | A flexible piece, strip, or roll of fabric or plastic material that is applied to (typically wrapped around) a part of the body to secure a dressing, maintain pressure over a compress, or immobilize a limb or other body part. This is usually a single-use device. |
| | Bandage, clavicle | A strip or roll of fabric or webbed material that is wrapped around the shoulder girdle to maintain fixation and longitudinal extension of the clavicle during a period of treatment. This is a single-use device. |
| | Bandage, elastic | An elasticized fabric (e.g., polyamide, lycra) used to provide support or local pressure to a part of the body, especially a joint, while allowing movement. It may have various configurations (e.g. long flat strip, tubular) to accommodate various body parts (e.g. ankles, knees, wrists, neck). This is a reusable device. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|---|
| | Bandage, gauze <i>Cotton gauze swabs</i> | A piece or strip of fabric made of opened weave cotton or rayon fibers and of differing degrees of fineness used to cover and protect wounds. This is a single-use device. |
| | Bandage, gauze, roller <i>Cotton gauze dressing Dressing, roller gauze</i> | A long, layered, woven-cotton gauze supplied in rolls that is used to bandage heads, limbs, and difficult to dress wounds (e.g. burns, plastic surgery, or orthopaedic wounds). |
| | Bandage, pressure <i>Compression dressing Elastic bandage Crepe Bandage</i> | A piece, strip, or roll of fabric or plastic material designed to compress a local area, e.g. to stop bleeding, prevent oedema or provide support for varicose veins or ostomy aids. This is a single-use device. |
| | Bandage, traction | A large strip of fabric or plastic material used to assist in exerting desirable tensile (pulling) forces on the body. This is a single-use device. |
| Bed | Bed, hospital <i>Bed, nursing</i> | A device upon which a patient rests or sleeps, or upon which a patient may be treated. It is used in hospitals, institutions and home care and is used in conjunction with a patient's admission and treatment, or for disabled and infirmed persons. |
| | Bed, general-purpose, manually-operated <i>Bed, hospital, manual Bed, hospital, mechanical</i> | A mechanically designed bed to be used as a patient bed for general purposes in hospital wards with manual mechanisms to adjust the height and surface contour of the bed. This device may include moveable and latch-able side rails. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | Bed, general- purpose, hydraulically- powered <i>Bed, hydraulic, adjustable hospital</i> | A bed designed to be used as a patient bed for general-purpose in hospital wards that has a hydraulic mechanism to adjust the height and surface contour of the bed. This device may include moveable and latch-able side rails. |
| | Bed, general-purpose, electrically-powered <i>Bed, AC-powered adjustable hospital</i> | A bed designed to be used as a general-purpose patient bed in, e.g. hospital wards, and which is electrically powered (motorized) providing the patient/nursing staff with touch button adjustment possibilities. |
| Bedpan | Bedpan, fracture | A device used by a bedridden patient as receptacle for urine and faeces and which is designed to be used by a patient whose hips have been plastered. This device is reusable after the appropriate cleaning procedure has been done. |
| | Bedpan, general purpose | A device used by a bedridden patient as receptacle for urine and faeces. This device is reusable after the appropriate cleansing procedure has been done. |
| Binder | Abdominal binder | A strip or roll of fabric or plastic material applied to the abdomen to support relaxed abdominal walls. |
| | Ankle binder | A strip or roll of fabric or plastic material designed to support the ankle joint. |
| | Breast binder | A strip or roll of fabric or plastic material designed to support the breasts. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | Chest binder | A strip or roll of fabric or plastic material designed to support the ribs and chest. |
| | Binder, sternum | A strip or roll of fabric or plastic material designed to support the sternum. |
| | Wrist binder | A strip or roll of fabric or plastic material designed to support the wrist joint. |
| Board | Board, arm | A firm device in which a patient's arm is placed for stabilization to maintain the patency of an intravascular catheter, e.g. those connected to an intravenous or intra-arterial line. It is typically constructed of expanded polystyrene with a plastic coating and can be straight or curved to accommodate the patient's arm/wrist. |
| | Board, cardiac Compression <i>Board, cardiopulmonary Cardiac compression board CPR board cardiopulmonary resuscitation)</i> | A flat, rigid device that is placed under a patient to instantly give the necessary support required for the application of cardiopulmonary resuscitation. This device is typically suitable for use when an acute situation has arisen and the patient is lying in his/her bed. |
| | Board, spinal <i>Spine board</i> | A flat, stiff device placed on a stretcher to ensure spinal immobilization when a spinal injury is suspected. |
| Bottle | <i>Bottle, heating/cooling Hot/cold water bottle</i> | A flexible container, typically with a relatively narrow neck, that is usually filled with either hot or cold water or ice for the purpose of |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|--|
| | | applying heat or cold therapy to an area of the body. |
| Brush | Brush, cleaning, surgical scrub <i>Brush, scrub, operating room</i> <i>Brush, surgical scrub</i> <i>Scrub brush, surgical</i> | A device used by hospital staff for the purpose of scrubbing the hands, fingers, and forearms prior to surgery or other intervention where a high degree of personal hygiene is required. It typically consists of a grip on one side, and bristles, fibers, or spines are typically mounted along a single plane. |
| Chair | Chair, bath/shower | A device designed to be set upon by a using some washing facility where there is a need to sit. The sitting requirement can be e.g. because the person is disabled or infirm, or because it is part of medical treatment. |
| | Chair , blood donor | A device used to position the patient in such a manner that a technician/nurse has easy access to the patient's arm for drawing blood. The arm board that is attached to the chair has lateral and height adjustments so that the patient's arm can be positioned in a location that is easily accessible to whoever is drawing the blood sample. This chair can typically be tilted/moved so that the donor lies in a reclining position. |
| | Chair examination/treatment | A device used to position the patient in a sitting, semi-sitting, or reclined posture for easy access and patient comfort during an examination, treatment, or surgical intervention. |
| | Chair, toilet <i>Commode, fixed, mobile;</i> | A chair designed with a toilet-like seat that allows an immobilized person/ patient to utilize a standard |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | <i>adjustable</i> | stationary toilet without leaving the chair. |
| | Chair, MRI system | A chair or stool specifically designed to support and position a patient during examinations involving the use of a diagnostic magnetic resonance imaging (MRI) system. For MRI system compatibility, these chairs/ stools are made of ferro-magnetically inactive materials. |
| Chart | Chart, dental colour discrimination <i>Shade guide, dental</i> | A device used to determine the correct shade (colour) of filling materials, artificial crowns and teeth for matching to those of the patient. |
| | Chart, eye, Amsler grid | A ophthalmic device that is a series of charts with grids of different sizes that are held at 30 centimeters distance from the patient and intended to rapidly detect central and paracentral irregularities in the visual field. |
| | Chart, eye, colour discrimination <i>Colour blindness test chart</i> Colour discrimination chart | An ophthalmic chart with coloured figures printed on coloured backgrounds, used in testing colour vision. |
| | Chart, visual acuity <i>Vision test chart</i> <i>Visual acuity chart</i> | An ophthalmic chart imprinted with block letters or other symbols in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; used in testing visual acuity. Such charts are often combined in a box where the individual letters or symbols are selected and highlighted by the optician/doctor |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | | with back ground electrical lighting. |
| Clip | Clip, nose | A device used to help prevent air movement through the nares. The device is typically constructed of plastic with rubber or foam tips and is used during pulmonary function studies to help ensure that airflow is conducted through the mouthpiece for accurate measurements. |
| | Clip, spectacle, Ophthalmic <i>Clip, lens, trial, ophthalmic</i> | A device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or set of spectacles during vision testing. |
| | Clip, surgical, towel | A surgical instrument designed with two sharply pointed blades joined at their midpoint or made out of a single “alpha” shaped part used to temporarily attach objects together, typically during surgery. These objects will typically be towels, but can be surgical drapes, or other devices, e.g. cables/leads that need fixation. |
| Compress | Compress, hot/cold Pack chemical <i>Heating pad, chemical Cooling pad, chemical</i> | A device that is intended to be applied with pressure to a body surface to provide cold therapy to that surface and/or underlying tissue, e.g. muscle. This device typically consists of a compact envelope made of plastic which is filled with special chemicals that are reactive when activated. |
| | Compress, cold pack <i>Cold compress Cold pack</i> | A device that is intended to be applied with pressure to a body surface and/or underlying tissue, e.g. muscle. This device typically |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | | consists of a compact fabric envelope containing a hydrated pliable silicate gel capable of forming to the contour of the body. |
| | Compress, hot/cold pack <i>Hot/cold pack</i> | A device that is intended to be applied with pressure to a body surface to provide cold or heat therapy to that surface and/or underlying tissue, e.g. the muscle. This device typically consists of a compact envelope containing a hydrated pliable silicate gel capable of forming to the contour of the body that can be heated or cooled. |
| | Ice collar compress | A flexible device that is intended to be applied around the body surface of the neck and throat to provide cold therapy to the surface and the underlying tissues. This will be to alleviate neck and head pain and sore throat, e.g after tonsillectomy. This device will have the appropriate size and shape to fit this part of the anatomy and can be filled with ice the coolant. |
| Case | Contact lens case | A container designed for the storage of contact lenses when the lenses are not being used by the owner. |
| Cotton | Cotton ball <i>Rayon balls</i> | A spherical mass of cotton or manmade fibers used as a swab to apply medications to or remove liquid from various parts of the body. |
| | Cotton roll, dental | A device formed as a small, short, cotton roll that is used as a saliva absorber and intended to absorb moisture from the oral cavity during dental procedures. It is |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | | usually made of cotton and is disposable. |
| | Cotton roll, general purpose | A device usually made of medical cotton or sometimes man-made fibers that have a general- purpose use throughout hospitals and other areas of the healthcare sector. |
| Cover | Cover, thermometer <i>Thermometer probe cover</i> | A device used as a physical barrier for a thermometer to prevent cross contamination between patients and/or environmental exposure. This device is single-use. |
| Depressor | Depressor, tongue <i>Wooden tongue depressors</i> | An instrument intended to displace the tongue to facilitate examination of the surrounding organs and tissues. |
| Frame | Frame, spectacle | An ophthalmic device worn by the user to hold prescription or protective spectacle lenses in front of their eyes. |
| Immobiliser | Frame, trial, ophthalmic | A device used in ophthalmic work for placing, holding and exchanging trial lenses in front of the eyes of the patient during a sight-testing procedure. |
| Immobiliser | Immobiliser, ankle | A non-rigid device, usually made of a fabric, used to temporarily render the ankle immovable (strait-jacket effect) to support the healing of an injury or surgical wound. |
| | Immobiliser, arm | A non- rigid device usually made of a fabric, used to temporarily render the arm immovable (strait-jacket effect) typically at the shoulder and elbow, to support the healing of an injury or surgical wound. |
| | Immobiliser, elbow | A non-rigid device, usually made |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---------------------------------|---|
| | | of a fabric, used to temporarily render the elbow immovable (strait-jacket effect) to support healing of an injury or a surgical wound. |
| | Immobiliser, infant, reusable | A non-rigid device, usually made of a fabric and/or plastic materials, used to temporarily render parts of an infant's body immovable (strait-jacket effect), e.g. the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care. This is a reusable device. |
| | Immobiliser, infant, single use | A non-rigid device, usually made of a fabric and/or plastic materials, used to temporarily render parts of an infant's body immovable (strait-jacket effect), e.g., the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions. It will typically be used to prevent the patient from interrupting an intravenous (IV) infusion, pulling out a catheter, or interfering with wound care. This is a single-use device. |
| | Immobiliser, knee | A rigid support used to temporarily render the knee immovable (strait-jacket effect), either pre-operatively or following injury or arthroscopy. |
| | Immobiliser, shoulder, reusable | A non-rigid device used to temporarily immobilize or limit abduction of the shoulder joint |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | | (strait-jacket effect) to support healing of an injury or a surgical wound. It is typically used postoperatively and for post traumatic treatment of injuries in the shoulder and upper arm areas (e.g., distortion/contusion, dislocation/luxation, and postoperative support). It will typically consist of layered fabric, straps, buckles, fasteners and will eliminate most of the work involved with bandaging. |
| | Immobiliser, whole body | A non-rigid device, usually made of a fabric and/or plastic materials, used to temporarily render the patient's whole body immovable (strait-jacket effect) while the patient undergoes therapeutic or diagnostic interventions. This is a reusable device. |
| | Immobiliser, wrist <i>Wrist restrainer</i> | A rigid support designed to temporarily render the wrist immovable (strait-jacket effect) as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist. It comes in a variety of sizes and is a reusable device. |
| Incontinence | Incontinence pants, liner <i>Urine absorbing aid, body-worn</i> <i>Adult diapers</i> <i>Incontinence diapers</i> | A disposable inner incontinence pants, liner composed of absorbent materials used to collect urine and faeces from the patient. |
| Lens | Lens Set, trial <i>Trial lens set, ophthalmic</i> | A set of ophthalmic lenses of various dioptric powers intended to be handled or inserted in a trial frame for vision testing to |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | | determine the required refraction. |
| Light | Light, head-worn <i>Headlamp, operating</i> <i>Headlight</i> <i>Headlight, fiberoptic</i> <i>focusing</i> <i>Light, headband, surgical</i> <i>Light, surgical headlight</i> | A device (a lamp), designed to be worn on an operator's head. It is mounted on a band or helmet frame and situated on the user's forehead providing a light direct into the field of vision during surgical, diagnostic, or therapeutic procedures. The light typically consists of a magnifying lens, a reflector and a connection for the fiber optic cable to transfer cold-light, or power supply from a battery pack. |
| | Light, surgical <i>Lamp, operating-room</i> <i>Lamp, surgical</i> <i>Lamp, surgical</i> <i>incandescent</i> <i>Light, surgical, ceiling</i> <i>mounted</i> <i>Light, surgical, connector</i> <i>Light, surgical, floor</i> <i>standing</i> <i>Light, surgical, connector</i> <i>Light, surgical, floor</i> <i>standing</i> <i>Light, surgical instrument</i> <i>Operating room light</i> <i>Operating shadowless</i> <i>light</i> <i>OR light</i> <i>Surgical lamp</i> | A device that provides a specialized light to illuminate a surgical site over a prolonged period of time providing the surgeon (s) with optimal visualization of small, low contrast objects at varying depths or through small incisions. In addition to providing enough illumination and minimizing the emission of heat to the site, the light will reduce shadows and produce minimal colour distortion, which helps the surgeon, evaluate tissues and structures. It typically consists of one or more light bulb(s), which reflects the light via reflectors or mirrors depending upon the construction. This device will typically be part of a light system comprising more than one light head. |
| | Light, examination, hand held, battery- powered <i>Light, examination,</i> | A small hand-held battery-powered light used as a personal light source to provide light for local examination, inspection and |

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GN. No. 315 (contd.)

| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | <i>medical, battery powered</i> | treatment of the patient. It may be torch-like in design and can have a magnifying lens to augment the lighting effect. It will typically be found in an examination room, doctor's surgery or office, on a medical trolley, or part of an emergency kit. |
| | <i>Light, Examination Examination light Light, examination, ceiling-mounted</i> | A device that provides light to illuminate the site of examination or treatment of the patient. It typically consists of one or more light bulb(s), which reflect the light via reflectors or mirrors depending upon the construction. This device has a variety of uses and can be fixed, e.g. to a ceiling, a wall, or supported on a mount. It can also be part of a light system comprising more than one light head. |
| | <i>Light, ear Ear light</i> | A dedicated device designed to illuminate the ear canal. |
| | <i>Light, dental, intraoral Lamp, intraoral, examination Light, dental, fibreoptic</i> | A dedicated light-conducting system with a very small dimension at the light delivery end designed for dental use and to be introduced into the oral cavity. It delivers light using fibreoptic cables. The device is typically attached to a dental hand piece and is intended to directly illuminate a patient's oral structures. |
| | <i>Light, dental, general-purpose Dental operating light Light, operating, dental</i> | A dedicated light designed for general- purpose dental use that delivers intense focused lighting to the dental operating, examination, procedure site, which usually is the oral cavity. |
| <i>Loupe</i> | <i>Loupe, binocular</i> | A system of lenses mounted onto a |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| | <i>Binoculars, surgical Loupe, binocular, low power Loupe, operating Magnifier, operating Spectacle, operating (loupe), ophthalmic</i> | pair of spectacles worn by the surgeon during surgical intervention. These function as small telescopes and provide a magnified image of the working field. They can also be connected to an external light source supplying light directly through the field of vision. |
| Mask | <i>Mask, resuscitation Mask, mouth-to-mask, Resuscitation CPR Mask Pocket Mask</i> | A malleable cone placed over the nose and mouth to administer air to a patient during cardiopulmonary resuscitation (CPR). The device is designed to replace mouth to mouth resuscitation therefore avoiding cross- contamination; The device may include an airway, one-way valve or other component. |
| | <i>Mask, surgical</i> | A device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed/ This device is disposable. |
| Mirror | <i>Mirror, ENT, Hand- held</i> | An instrument with a surface sufficiently polished to reflect enough undiffused light to form a virtual image of an object placed before it, for purpose of ear/nose/throat (ENT) examinations. This mirror is mounted on a long, slender handle, and is held by the doctor who can manipulate the mirror close to the site of interest. This is a reusable device. |
| | <i>Mirror, ENT, headband</i> | An instrument with a circular concave mirror attached to a headband acting as a reflector that |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | | is used to project a beam of deflected light to a body cavity, e.g., the nose or larynx, for purposes of ear/nose/throat (ENT) examinations. The doctor will wear this device on his/her head; place the reflector in front of one eye and view the site through a small hole in the centre of the reflector. This is a reusable device. |
| | Mirror, dental, handheld | A dental instrument for intraoral inspection or inspection and retraction generally comprising the mirror head and the mirror handle. |
| | Mirror, general & plastic surgery | A device designed to be used to assist practitioners during general/plastic surgery that display a virtual image of an object placed before it. |
| | Mirror, headband, ophthalmic | An ophthalmic instrument with a circular concave mirror attached to a headband used to project a beam of light to allow examination of the eye and its associated structures. |
| Orthosis | Orthosis, foot/ankle <i>AF (Ankle foot orthosis)</i> <i>Ankle joint orthosis</i> <i>Ankle support</i> <i>Joint, ankle, external</i> <i>Brace</i> | An externally applied orthopedic appliance or apparatus used to support, align, prevent, or correct deformities/injuries or to improve function of the ankle and/or foot. |
| | Orthosis, sacroiliac Spine Orthosis, sacroiliac, soft Sacroiliac orthosis | An externally applied orthopaedic appliance or apparatus that encompasses the thoracic spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine through compression of the abdomen. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | Orthosis, thoracic spine <i>Orthosis, thoracic TO (Thoracic orthosis)</i> | An orthopaedic corset that encompasses the thoracic spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine through compression of the abdomen. |
| | Orthosis, Cervicothoracic spine <i>CTO (Cervico/Thoracic orthosis, Orthosis, cervical-thoracic, rigid</i> | An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine. |
| | Orthosis, cervical spine <i>Cervical collar CO (Cervical orthosis) Collar, cervical Support, neck</i> | An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervical spine. |
| | Orthosis, lumbosacral Spine <i>Belt, lumbosacral LSO (Lumbosacral orthosis) Orthosis, lumbo-sacral</i> | An externally applied orthopaedic appliance or apparatus that encompasses the lumbosacral spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine. |
| Pressure pad | Pressure alleviation pad <i>Pressure pad, air Pressure pad, animal skin Pressure pad, foam Pressure pad, gel Pressure pad, soft rubber Pressure pad, water cushion Anti- decubitus pad, cushion</i> | A device designed to prevent pressure sores, e.g., bed sores or decubitus ulcers occurring on the parts of the patient's body which are prone to this. It can equally be used as an underlay for the patient when he/she is undergoing a long treatment where the body is immobilized, or for disabled, infirm persons who are confined to sitting/lying positions. This device is usually constructed as an underlay but can also be formed to accommodate the patient's body |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|---|
| | | shape, prominent or unprotected bony parts, e.g., as mattresses (both active and passive), pads or skins of different materials. |
| Protector | Finger protector <i>Finger splint</i> <i>Projector, ophthalmic</i> | A device intended to be used to protect an injured finger from further trauma during the healing process. It will typically be made of durable materials, e.g. plastic, rubber, or reinforced metal. |
| Projector | Projector, visual acuity <i>Projector, chart, eye</i> <i>Projector, ophthalmic</i> | An ophthalmic device , a kind of slide projector/beamer throwing block letters or other symbols on a screen/ wall in gradually decreasing sizes, identified according to distances at which they are ordinarily visible; used in testing visual acuity. |
| Retainer | Retainer, bandage <i>Bandage clasp</i> <i>Bandage retainer</i> <i>Bandage, elastic net</i> | A device used to stabilise, attach, or fix a bandage/ dressing in a desired location. This device can be a fastener/clasp (e.g., an elastic strip with opposing gripping teeth/ hooks), or a tubular elastic net. It is typically used on patients sensitive or allergic to adhesive tape. This device is single-use. |
| Shield | Shield, eye <i>Eye patch</i> | A mechanical shield used for protection of one or both eyes following surgery or trauma. These shields usually are plastic or metallic. |
| | Shield, face <i>Goggles</i> | A clear, transparent guard worn over the face/eyes to protect the healthcare worker from blood and other body fluid splashes while performing a clinical procedure. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|---|
| | Shield , hip | A mechanical guard worn over the hip area to prevent against hip fractures in the event of a patient fall. |
| | Shield, wound <i>Protector, wound</i> | A mechanical shield that is designed to form a protective structure over a wound. It may be cage-like and will allow exposure to air and permit access to the injured area while protecting against accidental damage. The device is disposable. |
| Shoe | Orthotic shoe <i>Orthopaedic shoe</i> <i>Orthosis, corrective shoe</i> <i>Shoe, corrective</i> | Orthopedic footwear that is intended to support, align, prevent, or correct deformities of the feet to help improve their function. |
| | Cast boot | A boot-like cover for a foot enclosed in a leg cast. This device is generally equipped with a waterproof covering, an outer sole for walking, and closures for easy application and removal. |
| | Shoe, Cast | A shoe designed to be worn over a foot/ankle that is encased in a cast, in order to protect the cast material and provide support. |
| Sling | Sling <i>Sling, arm</i> <i>Sling, knee</i> <i>Sling, leg</i> <i>Clavicle strap</i> | A hanging bandage or other material that is usually suspended from the body or another structure, and used to support and limit the range of motion of an injured limb during the healing period, or to support and limit the range of motion of a body in transport. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|---|
| Spectacles | <p>Spectacles <i>Astigmatisme spectacles</i> <i>Eyeglasses</i> <i>Farsightedness spectacles</i> <i>Nearsightedness spectacles</i> <i>Presbyopia spectacles</i> <i>Special spectacles</i> <i>Vision corrective spectacles</i></p> | <p>An optical/ophthalmic device consisting of a spectacle frame that contains a pair of spectacle lenses (eyeglasses).</p> |
| Splint | <p>Splint <i>Splint, traction</i> <i>Splint, wire board</i> <i>Splint, extremity, external</i> <i>Splint, hand/finger</i> <i>Splint, moldable</i> <i>Splint, mouldedaluminium</i> <i>Splint, moulded plastic</i> <i>Splint, padded stays</i> <i>Splint, air</i></p> | <p>A rigid or semi-rigid device that serves to immobilise an injured body or body part. It is generally placed externally along the injured body or body part. It is generally placed externally along the injured wood or metal.</p> |
| | <p>Splint, nasal, external</p> | <p>A rigid or partially rigid device intended for use externally for the immobilization of parts of the nose typically after a fracture or treatment. It may function as a truss-like support on the outside of the nose.</p> |
| Stocking | <p>Stocking, anti-oedema, arm/leg <i>Anti-oedema stocking, arm/leg</i> <i>Compression stocking</i> <i>Legging, compression, non-inflatable</i> <i>Stocking, compression</i> <i>Compression socks</i></p> | <p>A device designed like a stocking or tube-like elastic bandage for reducing or preventing swelling caused by circulation problems. It exerts a counter pressure upon the limb.</p> |
| | <p>Stocking, medical Support <i>Sock, fracture</i> <i>Stocking, elastic</i></p> | <p>An elastic limb support shaped as a stocking that is worn on the upper or lower extremity to support, correct, prevent deformity, or to align body structures for functional</p> |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|--|
| | | improvement. |
| Stretcher | Stretcher <i>Bed, stretcher</i> <i>Stretcher, mobile</i> <i>Stretcher, powered</i> <i>Stretcher, transfer</i> <i>Stretcher, wheeled, powered</i> <i>Stretcher, wheeled</i> <i>Stretcher, hospital</i> | A device on which a patient lies for transport or reclines after treatment. It may have a wheeled undercarriage, which can be foldable. |
| | Stretcher, ambulance <i>Ambulance stretcher</i> <i>Stretcher, mobile, ambulance</i> | A stretcher specially adapted for use with an ambulance vehicle including, e.g. aeroplanes, helicopters, or boats. It will typically have an undercarriage which folds automatically when it meets the vehicle as it is being pushed in, as well as locking devices that match up with the docking devices of the ambulance. |
| | Stretcher, portable <i>Stretcher, hand-carried</i> <i>Stretcher, portable, basket</i> <i>2 fold stretcher</i> <i>Pole stretcher</i> <i>Scoop stretcher</i> | A device designed for transporting the patient from an emergency site, which is not readily accessible for standard ambulance stretchers. This can be e.g. mountain or marine rescue, or difficult indoor situations, e.g narrow corridors or extremely steep stairways. It is designed to be lightweight, simple in operation and easily transported, e.g. ideally by one or two persons. The patient is often strapped to the stretcher to keep them secure during vertical or helicopter lifts. |
| Swab | Swab <i>Swab, cotton</i> <i>Swab, specimen collecting</i> | A piece of absorbent material, e.g. cotton or foam, attached to the end of a stick made of wood, plastic, or wire. It is used for the application |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|--|
| | | of medication, the removal of material, or the collection of bacteria. |
| | Swab, oral care | A piece of absorbent material, e.g. cotton or foam, attached to the end of a plastic stick that is used for dental hygiene. |
| Table | Table, examination/treatment <i>Examination bed</i> | A table or bed for examination and/or treatment purposes. It is typically of the construction where the patient lies upon it, i.e. as an operating table, but some may be designed so that the patient sits beside the table and is examined with instruments placed upon the table. This device can be manually operated or powered. It may be fitted with some basic functions, e.g. raise, lower or tilt, and is used in examination rooms, doctors surgeries and minor operating rooms. |
| | Table, instrument <i>Instrument trolley, with or without drawers</i> | A table used for laying out sterile surgical instruments, sutures, and other utensils/items required during an operation or intervention. It is designed to include an appropriate, e.g. stainless steel, top or surface with no crevices, screws or rivets, and most tables include telescoping pedestals for height adjustment and swivel caster bases. This table is used in the so-called "sterile area" of the operation site and in some cases may be attached to the operating table. |
| | Table, Operation <i>Table and attachment, operating-</i> | A device used to support the patient's body during surgical procedures, stabilizing the patient's |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|---------------------------------------|--|---|
| | <i>room</i> <i>Table, operating</i> <i>Table, operating- room</i> <i>Table, traction</i> <i>Table, operation,</i> <i>Gynecological</i> <i>Table, operation,</i> <i>ophthalmic</i> <i>Table, operation,</i> <i>orthopaedic</i> | position and providing for optimal exposure of the surgical field. Operating tables are also designed to protect the patient from excessive manipulation, trauma and abrasion. It will typically include an appropriate top surface supported by a fixed pedestal or a movable, swivel caster base. Most tables are divided into three or more hinged sections, e.g. head body and legs, and are raised and lowered by hydraulic systems using manual or electric controls. |
| | <i>Table, birthing</i> <i>Birthing table</i> <i>Table, obstetrical</i> | An adjustable table designed to support a woman's body in an appropriate position during labour and delivery and in other examination/ treatment procedures related to pregnancy. This table will typically include, receptacle for afterbirth. |
| Traction unit, non-active | Traction unit, no-active <i>Apparatus, traction, non-Powered</i> <i>Unit, traction, hip, nonpowered, non-penetrating</i> <i>Extension and traction equipment</i> <i>Static traction unit</i> <i>Traction unit, static, bed</i> <i>Traction unit, static, chair</i> | A device used to apply a tensile force in order to create a distraction on body parts by means of harnesses attached the head or pelvic area. It is non-active (static) in operation. It consists of a rigid frame with non-powered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system. |
| Traction Unit, non-invasive component | <i>Frame, traction</i> <i>Head halter, traction</i> <i>Pelvic traction belt</i> <i>Tong, skull for traction</i> <i>Weights</i> <i>Water bag</i> | A non invasive traction device, e.g. a head halter, pelvic belt or a traction splint that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|--|--|
| Transfer Aid | Transfer aid, person <i>Board, patient transfer</i> <i>Board, patient transfer</i> <i>Patient transfer aid</i> <i>Sliding board/mat</i> <i>Sheet, patient turning</i> <i>Turning sheet</i> <i>Turning carpet</i> | A technical aid used by attending personnel to assist in the physical transfer of a person/ patient, e.g. ill, disabled or infirm, from one position to another. The device has typically no lifting capabilities and uses sliding/turning techniques. This may be to change the person's position, especially for those incapable of achieving this on their own, and thus prevent bedsores; or to move the person between, e.g. an operating table and a bed, a wheel chair and a bath, or chair and toilet. |
| Walking Crutch | Walking crutch, <i>Crutch, axillary</i> <i>Crutch, elbow, Crutch, forearm</i> | A mobility aid used to assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person. It has one leg, a handle and a padded platform, which is placed under the armpit or forearm support. |
| Walking Frame | Walking Frame, Standard Walker, adjustable width Walker, folding, <i>Walker, mechanical</i> <i>Walker, standard, Walker/chair, non wheeled</i> <i>Walking chair, Walker, side</i> <i>Walking frame, rigid,Adjustable</i> <i>Walking frame, folding adjustable</i> | A mobility aid used to assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person. It is a non-wheeled frame with built-in handgrips and legs, which provide support whilst walking. It can be of fixed or adjustable height and collapsible or non-collapsible. |

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| <i>Keyword</i> | <i>Device identifier</i> | <i>Description/Intended Use</i> |
|----------------|---|---|
| | Walking table | A mobility aid used to assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person. It is a chest height wheeled frame with a horizontal forearm support, which is pushed along using the arms and/or upper body. It can be of fixed or adjustable height and collapsible and non collapsible. |
| Walking Stick | Walking Stick <i>Cane , Cane, adjustable length Cane, adjustable-length, standard-handle Cane, adjustable length, T-handle Cane, adjustable length, Crook handle Walking cane seat Cane, fixed-length, standard-handle Cane, pedestal base Walking sticks with three or more legs/handle and/or forearm support Quad cane, adjustable Height Quad stick, adjustable All rights reserved.</i> | A mobility aid used to assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person. It is a wooden or metal rod with either one leg, a tripod or quadripod base (three or four legs). It has a handle and/or forearm support. It can be of fixed or adjustable length and collapsible or non- collapsible. |

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GN. No. 315 (contd.)

THIRD SCHEDULE

FORMS

Form No. 01

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FORM FOR MEDICAL DEVICES PREMISE PERMIT

[Made under Regulation 32(2)]

PART A: PARTICULARS OF OWNER(S), PREMISE AND SUPERVISOR

| Particulars owner(s) | |
|-----------------------------------|--------------------------|
| A1 | Name of owner(s) |
| | Postal address: |
| | Telephone: |
| | Fax: |
| | E-mail |
| Information of the premise | |
| A2 | Name of the premise: |
| | Postal Address: |
| | Physical Address: |
| | Telephone: |
| | E-mail: |
| | Fax: |
| Name of Contact Person: | |
| E-mail of Contact Person | |
| Telephone: | |
| Information of Supervisor | |
| A3 | Name of Supervisor(s): |
| | Academic Qualifications: |

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PART B: DECLARATION OF APPLICATION

| | |
|-----------|---|
| B1 | <p><i>(Please tick as appropriate)</i></p> <p>I/We hereby apply for a new permit / renewal to:-</p> <p><input type="checkbox"/> Manufacture</p> <p><input type="checkbox"/> Import</p> <p><input type="checkbox"/> Wholesale</p> <p><input type="checkbox"/> Retail</p> |
| B2 | <p>Existing Permit No: Dated</p> <p>Expiring on</p> <p>My/our financial resources committed for this business amount to.....and my/our annual projected turnover is Tshs.....</p> |

PART C: ENCLOSURE

| | |
|-----------|--|
| C1 | <p><i>(Please tick as appropriate)</i></p> <p>Find enclosed the following supporting documents:-</p> <p><input type="checkbox"/> Business/company registration certificate</p> <p><input type="checkbox"/> Sketchy Design of the Premise</p> <p><input type="checkbox"/> Certified Copies of Academic Certificates of Supervisor</p> <p><input type="checkbox"/> List of class A Exempted Medical Devices Imported</p> <p><input type="checkbox"/> List of class A Exempted Medical Devices Manufactured</p> |
|-----------|--|

PART D: ATTESTATION

| | |
|-----------|--|
| C1 | <p><i>(Please tick as appropriate)</i></p> <p>The establishment has documented procedures in place for:-</p> <p><input type="checkbox"/> Distribution records</p> <p><input type="checkbox"/> Complaint handling</p> <p><input type="checkbox"/> Recalls</p> <p><input type="checkbox"/> Adverse event reporting</p> |
|-----------|--|

"As owner(s) of the premise name in this application,

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GN. No. 315 (contd.)

- a) I/We hereby attest that the information provided in this application is correct and complete.*
- b) I/We hereby attest that I have direct knowledge of the documented post- market procedures in place in respect to distribution records, complaint handling, recalls and adverse event reporting.*
- c) I/We hereby attest that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the premise.*
- d) I/We acknowledge that it is a serious offence to knowingly make false attestations on this application.*
- e) I/We acknowledge that knowingly making false attestations is grounds for refusal to issue a permit.*
- f) I/We acknowledge that the discovery, at some future time, that false attestations were knowingly made in this application is grounds for suspension or revocation of my premise permit.*

| | |
|----------------------------------|---|
| _____ Name of Owner(s) | _____ Official Stamp of the Company |
| _____ Signature | _____ Date |

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No..... of

Permit granted/not granted because

.....

Permit No.:

Approved by meeting

No.....of.....

Signature of Director General and

stamp.....

Date:

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GN. No. 315 (contd.)

Form No.02

TANZANIA FOOD AND DRUGS AUTHORITY



**IMPORTER/SUPPLIER FORM FOR REPORTING PROBLEMS AND/OR
ADVERSE EVENTS RELATED TO IN VITRO DIAGNOSTIC MEDICAL
DEVICES**

{Made under Regulation 43(2)(b)(ii)}

Note: identities of reporter, patient and institution will remain confidential.

| | |
|--|--|
| TFDA Internal Use Only | |
| Report Number: | Date received: |
| 1. Contact details of the reporting company | |
| Name of company: | Importer/supplier/distributor (Please specify) |
| Postal address: | Street Name: |
| City: | District/Region: |
| Tel: | Mob: Fax: |
| Name and position of contact person: | |
| Email of contact person: | |
| 2. Product details | |
| Product /commercial /brand name: | |
| Catalogue/Model number: | Serial /batch /lot number: |
| Manufacturing date: | Expiry date: |
| Name of associated devices/accessories: | Instructions for use version number: |
| Name of shop where the product was purchased: | |
| Manufacturer name and address: | |
| 3. Event/problem details | |
| Event/problem description narrative (explain what went wrong with the product and the observed or likely/probable consequences): | |
| Date : place of the event/problem: | |
| Number of cases involved: | Are cases from different units involved? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Operator at the time of the event/problem (please choose): | <input type="checkbox"/> Laboratory personnel <input type="checkbox"/> Non-laboratory personnel <input type="checkbox"/> other |
| Has more than one customer experienced the problem with the product? <input type="checkbox"/> Yes <input type="checkbox"/> No | |

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| | | |
|---|--|--------------|
| <i>Type of specimen used (please specify):</i> | <i>Reading time observed:</i> | |
| | <i>Date:</i> | |
| <i>Have you informed the vendor? <input type="checkbox"/> Yes <input type="checkbox"/> No</i> | | |
| <i>What measures have been recommended?</i> | | |
| <i>Have you informed the manufacturer?</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No | <i>Date:</i> |
| <i>What measures have been recommended?</i> | | |
| <i>Measures taken by the Importer/supplier:</i> | | |
| <i>Date of report:</i> | <i>Signature:</i> | |

Send to:

*The Director General, Tanzania Food and Drugs Authority (TFDA) Fax: +255
22 2450 793
Along Nelson Mandela Road, opp EPI
Email: info@tfda.or.tz
P.O.Box 77150, Dar Es Salaam, Tanzania*

REPORTING GUIDE

Why should one report adverse events?

The reported events will assist TFDA to take regulatory actions such as updating device labeling information, communicating new safety information to the public or removing a device from the market so as to ensure that devices circulating in the Tanzanian market are of acceptable quality, safety and performance.

What to report?

Any event that meets the following criteria should be reported to TFDA,

1. Malfunction or deterioration in the characteristics or performance of a medical device/IVDDs
(Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions)
2. Design or manufacturing of a device is found to be deficient
3. Inaccuracy (including *omissions and deficiencies*) in the labeling, Instructions for Use and/or promotional materials.
4. Significant public health concern
If a failure of a device has or potentially poses a threat of misdiagnosis and mismanagement of a disease e.g. false positive/negative results.
5. Any unexpected event regardless of its severity

When is an adverse event reported?

The adverse event shall be reported according to the following time lines after the reporter becomes aware of the event:

Serious threat to public health - not later than 24hours.

Death/serious injury- not later than 14 days

Others- not later than 30 days

What should you do with the device?

Devices and its associated packaging should not be discarded or repaired and shall be returned to the supplier.

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How to report?

Report of an Adverse Event shall be submitted to TFDA through postal mail, e-mails or fax. It may also be delivered to TFDA offices.

What happens to your report?

The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be conveyed to other relevant institutions. Depending on the outcome of the investigation necessary regulatory actions will be taken.

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GN. No. 315 (contd.)

Form No.03

TANZANIA FOOD AND DRUGS AUTHORITY



**MEDICAL DEVICES ADVERSE EVENT/INCIDENT REPORTING FORM FOR
MANUFACTURER**

[Made under Regulation 43(2)(b)(i)]

Note: identities of reporter, patient and institution will remain confidential.

| | |
|---|--|
| TFDA Internal Use Only | |
| Report Number: | Date received: |
| 1. Administrative information | |
| Date of this report: | Reference number assigned by the manufacturer: |
| Type of report | Initial report <input type="checkbox"/> Follow-up report <input type="checkbox"/> Combined Initial and final report <input type="checkbox"/> Final report <input type="checkbox"/> |
| Does the incident represent a serious public health threat? Yes <input type="checkbox"/> No <input type="checkbox"/> | Please explain..... |
| 2. Manufacturer information | |
| Name: | Postal address |
| Email | Physical address |
| Phone | Fax |
| Contact person's name | Postal address |
| Email | Physical address |
| Phone | Fax |
| 3. Local Representative information | |
| Name: | Postal address |
| Phone | Physical address |
| Fax | Email |
| Contact person's name | |
| Phone | Email |
| 5. Device details | |
| Brand name | Catalogue number: |

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| | |
|--|--|
| | Model number: |
| Manufacturing date: | Serial number: |
| Expiry date: | Lot/batch number: |
| Is the Device CE marked? Yes <input type="checkbox"/> No <input type="checkbox"/> | Instructions for use provided(<i>where possible please attach a copy</i>) Yes <input type="checkbox"/> No <input type="checkbox"/> |
| 6. Event/Incident details | |
| User facility report reference number, (<i>if applicable</i>) | |
| Manufacturer's awareness date | Date the incident occurred |
| Incident description narrativ | |
| Number of patients involved | Number of products involved |
| Current location of the device | |
| Usage of the medical device | <input type="checkbox"/> Initial use <input type="checkbox"/> Reuse of a single use , <input type="checkbox"/> Reuse of a reusable, <input type="checkbox"/> Re-serviced/refurbished <input type="checkbox"/> Problem noted prior use <input type="checkbox"/> other (please specify) |
| 7. Manufacturer's preliminary comments (Initial/Follow-up report) | |
| Manufacturer's preliminary analysis (Narrative) | |
| Initial corrective actions/preventive actions implemented by the manufacturer | |
| Expected date of next report | |
| 8. Results of manufacturers final investigation (Final report) | |
| The manufacturer's device analysis results | |
| Remedial action/corrective action/preventive action/ Field Safety Corrective Action | |
| Action taken to prevent further risk to the patient (Narrative) | |
| Time schedule for the implementation of the identified actions | |
| Final comments from the manufacturer | |

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| | |
|--|---|
| Further investigations | |
| Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause? | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Number of similar incidents. | |
| If yes, state in which countries and the report reference numbers of the incidents. | |
| Has a similar event occurred in these regions? | <input type="checkbox"/> EAC <input type="checkbox"/> EU <input type="checkbox"/> |
| 9. Conclusion I affirm that the information given above is correct to the best of my knowledge Name..... Signature.....Date..... | |

Send to:

The Director General, Tanzania Food and Drugs Authority (TFDA) Tel: +255 22 2450751/2450108

*Along Nelson Mandela Road, opp EPI
+255 22 2450 793*

*P.O.Box 77150, Dar Es Salaam, Tanzania
info@tfda.or.tz*

Fax:

Email:

REPORTING GUIDE

Why should one report adverse events?

The reported events will assist TFDA to take regulatory actions such as updating device labeling information, communicating new safety information to the public or removing a device from the market so as to ensure that devices circulating in the Tanzanian market are of acceptable quality, safety and **performance**.

What to report?

Any event that meets the following criteria should be reported to TFDA,

1. Malfunction or deterioration in the characteristics or performance of a medical device/IVDDs

(Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions)

2. Design or manufacturing of a device is found to be deficient

3. Inaccuracy (including *omissions and deficiencies*) in the labeling, Instructions for Use and/or promotional materials.

4. Significant public health concern

If a failure of a device has or potentially poses a threat of misdiagnosis and mismanagement of a disease e.g. false positive/negative results.

5. Any unexpected event regardless of its severity

When is an adverse event reported?

The adverse event shall be reported according to the following time lines after the reporter becomes aware of the event:

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Serious threat to public health - not later than 24hours

Death/serious injury- not later than 14 days

How to report?

Adverse event/incident reporting form may be downloaded from the TFDA website at www.tfda.or.tz. The duly filled in form should be sent via email info@tfda.or.tz or by post addressed to the Director General, TFDA.

What happens to your report?

The report will be evaluated by the Authority and if practicable advise as appropriate and intervene if necessary.

*The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices)
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GN. No. 315 (contd.)

Form No.04

TANZANIA FOOD AND DRUGS AUTHORITY



**MEDICAL DEVICES ADVERSE EVENT/INCIDENT REPORTING FORM FOR
CONSUMERS AND FACILITIES**

[Made under Regulation 42]

Note: identities of reporter, patient and institution will remain confidential

| | |
|--|---|
| TFDA Internal Use Only | |
| Report Number: | Date received: |
| 1. Device details | |
| Brand name: | Catalogue: |
| | Model number: |
| Manufacturing date: | Serial number: |
| Expiry date: | Batch /lot number: |
| Is the Device CE marked? Yes <input type="checkbox"/> No <input type="checkbox"/> | Instructions for use provided (where possible please attach a copy) Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Manufacturer name : | Address: |
| Name of supplier | Address: |
| | Telephone: |
| Current location of the device: | |
| 2. Event/Incident details | |
| | Date of incident: |
| Type of incident (patient related): Death <input type="checkbox"/> Serious <input type="checkbox"/> Distress <input type="checkbox"/> Minor <input type="checkbox"/> None <input type="checkbox"/> Others <input type="checkbox"/> | |
| Type of incident (device related): Inadequate design <input type="checkbox"/> Inaccurate labeling <input type="checkbox"/> malfunction <input type="checkbox"/> deterioration <input type="checkbox"/> other <input type="checkbox"/> | |
| Event/Incident description narrative (explain what went wrong with the product) | |
| Number of patients involved | Operator at the time of the event/incident (please choose): (check the appropriate answer): Laboratory personnel <input type="checkbox"/> Other Health care personnel <input type="checkbox"/> Other <input type="checkbox"/> |
| Measures taken by the user | |
| Have you informed the supplier /manufacturer? Yes <input type="checkbox"/> No <input type="checkbox"/> | Date: |

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| 3.Reporter details | |
|---------------------------------|---------------------------------|
| <i>Name of Person/facility:</i> | <i>Postal address:</i> |
| <i>Street Name:</i> | <i>City:</i> |
| <i>District/Region:</i> | <i>Mobile phone:</i> |
| <i>Telephone:</i> | <i>Fax:</i> |
| <i>Name of contact person:</i> | <i>Email of contact person:</i> |
| <i>Date of report:</i> | <i>Signature:</i> |

Send to: *The Director General, Tanzania Food and Drugs Authority (TFDA) Tel:*
+255 22 2450751/2450108

Along Nelson Mandela Road, opp EPI

Fax: +255 22 2450 793

P.O.Box 77150, Dar Es Salaam, Tanzania

Email: info@tfda.or.tz

REPORTING GUIDE

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2. Design or manufacturing of a device is found to be deficient

3. Inaccuracy (including *omissions and deficiencies*) in the labeling, Instructions for Use and/or promotional materials.

4. Significant public health concern

If a failure of a device has or potentially poses a threat of misdiagnosis and mismanagement of a disease e.g. false positive/negative results.

5. Any unexpected event regardless of its severity

When is an adverse event reported?

The adverse event shall be reported according to the following time lines after the reporter becomes aware of the event:

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Serious threat to public health - not later than 24 hours.

Death/serious injury- not later than 14 days impose

Others- not later than 30 days

What should you do with the device?

Devices and its associated packaging should not be discarded or repaired and shall be returned to the supplier.

How to report?

Report of an Adverse Event shall be submitted to TFDA through postal mail, e-mails or fax. It may also be delivered to TFDA offices.

What happens to your report?

The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be conveyed to other relevant institutions. Depending on the outcome of the investigation necessary regulatory actions will be taken.

The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices) Regulations, 2015

GN. No. 315 (contd.)

Form No.05

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FOR IMPORTATION OF MEDICAL DEVICES/SUPPLIES (Made under Regulation 46)

To: Director General Tanzania Food and Drugs Authority P.O Box 77150 Dar-es-salaam

I/We... of (postal address)... undertaking the business of Wholesale/ manufacturing/Other (Specify)... hereby apply for importation permit for Medical Devices/Supplies into the United Republic of Tanzania. License Number... issued on... Location of Business... Name of the Owner of the business...

- Purpose of importation permit, for: (Tick whichever is applicable) [] Spare parts for Medical Devices/Supplies for human use; [] Finished Medical Devices/Supplies products for human use; [] Clinical Trial of a specified product (only one product per application)

- Checklist for completeness of proforma invoice (Tick as appropriate) [] Name and adress of the supplier [] Name and adress of the importer [] Name and country of the manufacturer [] Invoice number [] Invoice date [] Unit price of each item [] Quantity of each item [] Mode of transport [] Clear description of items including brand names and common names as declered in information of medical devices submitted to TFDA [] Stamp and/or signature of supplier [] Stamp and/or signature of importer [] Certificate of donation (for donated medical devices) [] FoB and CIF value of the items [] Port of discharge of goods

Attached herewith the Proforma Invoice No... of (date)...

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Declaration:

I certify that the information provided in the application form and proforma invoice is true and correct.

Date of application... .. Signature of Applicant.....

Stamp.....

| |
|--|
| <p>For official use only:</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>Name of Officer : Signature.....</p> <p>Stamp.....</p> |
|--|

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GN. No. 315 (contd.)

Form No.6

TANZANIA FOOD AND DRUGS AUTHORITY



MEDICAL DEVICES SAMPLE COLLECTION FORM

[Made under Regulation 56(2)]

Name of Institution/Company/(under inspection)

Physical Address

Postal Address

Phone

Mobile

E-Mail

Date of Inspection

Time of sample collection

Name of products or supplies

Reason for collection

Size of batch/Lot from which sample was
obtained.....

Name and Address of
manufacturer.....

Batch/Lot No. Manufacturing Date.....

Expiring Date.....

Serial No.

Model.....

Place sampled (Port of Entry, Manufacturing Plant, Retail/Wholesale
Shop).....

Number of samples taken (tins, packets, equipment, glassware etc
(specify).....

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Form No.7

TANZANIA FOOD AND DRUGS AUTHORITY



REJECTION FORM FOR IMPORT PERMIT APPLICATION OF MEDICAL DEVICES

[Made under Regulation 57(2)]

TFDA Serial Number _____ of _____

Proforma Invoice Number _____ Dated _____

Reasons for rejection (Tick as appropriate)

- Importation/Consignee is not registered
Manufacturer(s) of the product is not indicated
Number of Proforma Invoice is not shown
Name and/or identity of items is not clear
The product (s) is/are not regulated by the Authority
The Proforma Invoice is not signed and/or stamped by supplier
The Proforma Invoice is not counter signed and or stamped by Importer
Certificate of Donation is not attached
Product(s) registration number is not shown
Proforma Invoice is not original

Others.....

Due to the above-mentioned reasons, the following products have to be cancelled before your profoma invoice is approved

- 1.
2.
3.
4.
5.

Name of officer rejecting Signature Date

Name of Person collecting Signature Date

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Form No. 08

TANZANIA FOOD AND DRUGS AUTHORITY



CERTIFICATE OF REGISTRATION

(Made under Section Regulation 14)

Registration number

This is to certify that the medical device described below has been registered in Tanzania.

Name of the device

Common name

Class of the device

GMDN Code and Term

Commercial

Presentation

Name of registrant

Name and address of the

Manufacturer

Country of manufacturer

Local Responsible

Person

Issued on

Expires on

The above medical device is registered in Tanzania subject to conditions prescribed at the back of the certificate.

.....
DIRECTOR GENERAL

Conditions of registration

1. Registrant and Local Responsible Person shall retain records of the distribution of all medical devices registered. The distribution records for class B, class C and class D shall be retained for a minimum of 3 years.

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2. The registrant shall ensure that the manufacturing facilities where a registered medical device is produced comply at all times with Good Manufacturing Practices and Quality Management System requirements.
3. Registrant and Local Responsible Person shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.
4. All changes with regard to a registered medical device should be notified to the Authority by the registrant for approval prior to their implementation.
5. Registered device can not be advertised without prior approval from the Authority.

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Form No.9

TANZANIA FOOD AND DRUGS AUTHORITY



REQUEST FORM FOR DISPOSAL OF MEDICAL DEVICES
[Made under Regulation 60]

I/We.....of (postal address)..... with premises
registration number.....of 20.....hereby apply for the disposal of unfit medical
devices as per attached list.

Physical address of the Premises.....

Name of the supplier.....Registration number (if applicable).....

Reason(s) for disposal.....

Weight (Kg).....

Market value (in Tshs).....

Declaration:

I certify that the information provided in the application form is true and correct.

Date of application.....Signature of applicant.....

Stamp.....

For Official use only:

Received by.....signature.....

Stamp.....Date.....

TANZANIA FOOD AND DRUGS AUTHORITY



THIRD SCHEDULE
[Made under Regulation 63(2)]

MEDICAL DEVICES VERIFICATION FORM

Name of applicant.....of postal
address..... undertaking the business of medical devices as per attached
list.

Physical address of the Premises

Weight (Kg).....

Market value (in Tshs).....

Does the actual product(s) tally with the list of product(s) submitted to TFDA? YES/NO

Other observation(s).....

Suggested mode of destruction.....

Name of applicant.....Signature.....

Date of verification.....

Name of Inspectors

1. Signature.....
2. Signature.....

TANZANIA FOOD AND DRUGS AUTHORITY



Disposal form for medical devices

(Regulation 60)

The Tanzania Food and Drugs Authority declares to have supervised the disposal of unfit product (as per attached list) belonging to

M/S.....

...

of postal address.....

The destruction exercise was conducted at (location, site)

.....on this date by the following method(s)

(state clearly):-

1.....

2.....

3.....

The total weight of the products destroyed is Kg and value is Tshs.

Name and signature of owner/in charge/representative of the organization:

.....

(Name)

(Signature)

Names, title and signatures of Inspector(s), other supervisor(s) and witness of the disposal exercise:-

Name:

Title/Position:

Signature & Date:

1.....

2.....

3.....

4.....

5.....

TANZANIA FOOD AND DRUGS AUTHORITY



(Regulation 63(3))

TANZANIA FOOD, DRUGS COSMETICS ACT,2003
CERTIFICATE OF MEDICAL DEVICES DESTRUCTION

I, being the person in-charge with the administration of the law relating to the control of medical device products to which the Tanzania Food, Drugs and Cosmetics Act, 2003 apply, hereby certify the destruction of expired medical devices belonging to of (Postal Address) which took place on The said consignment was destroyed by at under the witness and supervision of TFDA Inspector, Environmental Officer, Health Officer and Police as specified in the attached disposal form with S.No. The weight of the whole lot disposed is Kg and its value is T.Shs.

.....
Name and Signature of Director General

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GN. No. 315 (contd.)

Form No. 13

THE TANZANIA FOOD AND DRUGS AUTHORITY



PERMIT FOR ADVERTISEMENT

[Made under Regulation 70(8)]

Permit No.....

Permit is hereby granted to M/Sfor
advertisementof.....
...through..... subject to the maintenance
of records such as required by the law and it shall not be transferable.

The validity of this permit expires on
.....

Granted by the Tanzania Food and Drugs Authority this
.....day of
.....20.....

.....
Name and Signature of Director General

The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices)
Regulations, 2015

GN. No. 315 (contd.)

Form No.14

THE TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS
[Made under Regulation 70(5)]

(All information supplied in this form must be either typed or written in block capital letters.)

Applicant Particulars

| |
|---|
| Name of applicant: |
| Address: |
| |
| Contact person: E-mail: |
| Telephone Number: Fax Number: |
| |

Local Responsible Person (LRP) particulars (if different from the applicant)

| |
|---|
| Name of LRP: |
| Address: |
| Contact person: Email: |
| Telephone Number: Facsimile Number: |

Product particulars

| |
|---|
| Distribution category (please tick the appropriate box) In Vitro Diagnostics [] Medical Devices [] |
| Product Name/s |
| Registration number |
| Name of registration holder |
| Type of material: (please tick the appropriate box) Poster [] Leaflet [] Cinema [] Outdoor/Billboard [] In/On Public Transport[] Magazines/Newspaper[] Literature [] Radio [] Television [] Other [] please specify |

This form shall be accompanied by:

NB: Please tick or mark X on Checklist

| |
|--|
| [] A copy of the proposed advert (Script, Audio tape, CD, VCD, Video cassette.) |
| [] Current indications of use as indicated on Certificate of Registration (where applicable). |
| [] Copy of any research/surveys/data mentioned in advertisement (Note – further evidence to be provided if requested). |
| [] Copy of previous approval (If the advert is a reminder) |
| [] Copy of approval for the use of a restricted/prohibited claim (if applicable). |
| [] Application fee. |

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Applicant Declaration

| |
|---|
| I,declare that the information contained within this application is true and correct. Signed: Date:..... |
|---|

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No..... of
Permit granted/not granted
because.....
.....
Permit No..... Approved byof
.....

Date

Director General

The Tanzania Food, Drugs and Cosmetics (Control of Medical Devices)
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GN. No. 315 (contd.)

FORM No. 15

TANZANIA FOOD AND DRUGS
AUTHORITY



(Made under Remulation 23(1))

**APPLICATION FORM FOR VARIATION OF A REGISTERED MEDICAL
DEVICE**

| | |
|---|--|
| 1. Brand name | |
| 1.1 Device classification | |
| 1.2 Intended use: | |
| 2. Model/series/system (If applicable) | |
| 3. Type of change(s) (State which type of Variation): | |
| 3.1 Scope (Please specify scope of the change(s) in a concise way) | |
| 3.2 Background for change & Justification for change(s) (If applicable) Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s) | |
| 3.5 Present (Please specify precise current wording or specification) | Proposed (Please specify precise proposed wording or specification) |

Registrant should always enclose a working model clearly showing the differences between the proposed version and the current version.

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GN. No. 315 (contd.)

| | | |
|--------------------------|-------------|-----------------------------|
| 4. Details of Registrant | | |
| Name: | | |
| Business Address: | | |
| Postal Address: | | |
| Country: | | |
| Phone: | Fax: | Email: |
| | | |
| Name | Date | Signatures and stamp |

Dar es Salaam,
10th May, 2015

SEIF SULEIMAN RASHID
Minister for Health and Social Welfare