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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

(Made under Section 52(1) of the Tanzania Food, Drugs and Cosmetics Act, 2003)

SECOND EDITION

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CONTENTS

AKNOWLEDGEMENTS ..... **iv**
FOREWORD ..... **v**
INTRODUCTION **1**
DEFINITION OF TERMS **2**
1.0 GENERAL REQUIREMENTS **6**
1.1 Language 6
1.2 Applicant 6
1.2.1 Responsibility of applicant **6**
1.2.2 Responsibility of Local Responsible Person **6**
1.3 Applications 6
1.3.1 Medical devices classified into four risk classes (A, B, C and D) described below:- **7**
1.4 New application 7
1.5 Application for Variation of a registered medical device (s) 8
1.6 Application for renewal of registration 9
1.7 Payment of fees 9
1.8 Data presentation 10
1.9 Product Dossier 10
1.10 Processing of applications 10
1.11 Registration of the Device 11
1.12 Validity of registration 11
1.13 Termination of registration 11
1.14 Appeals 11
1.15 Medical devices exempted from registration 11
1.15.1 All other medical devices **12**
2. DEVICE DETAILS **13**
3. SUMMARY TECHNICAL DOCUMENTATION **15**
3.1 Device description and features **15**
3.2 Evidence of Conformity to Essential Principles 15
3.3 Materials 16
3.4 Device Specification 16
3.5 Device Verification and Validation 16
4. LABELLING REQUIREMENTS **22**
5.0 REQUIREMENTS FOR REGISTRATION OF SPECIALIZED MEDICAL DEVICES SUCH AS MRI, DIAGNOSTIC ULTRASOUND SYSTEMS AND TRANSDUCERS, X-RAY MACHINES, ECHO AND OTHER SIMILAR MACHINES **24**
6.0 BORDERLINES MEDICAL DEVICES **25**
7.0 SOFTWARE **26**
8.0 ACCESSORIES **26**
9.0 OTHER MEDICAL DEVICES **27**
ANNEX I **29**
ANNEX II **35**
ANNEX III **37**
ANNEX IV **42**
ANNEX V **44**
ANNEX VI **78**
ANNEX VII **80**

ABBREVIATIONS

AHWP	-	Asian Harmonization Working Party
CSDT	-	Common Submission Dossier Template
DoC	-	Declaration of Conformity
EPSP	-	Essential Principles of Safety and Performance
GHTF	-	Global Harmonization Task Force
GMDN	-	Global Medical Devices Nomenclature
GMP	-	Good Manufacturing Practices
HAS	-	Health Sciences Authority
IFU	-	Instructions for Use
IMDRF	-	International Medical Devices Regulators Forum
ISO	-	International Organization for Standardization
AR	-	Authorized Representative
MoHCDGEC	-	Ministry of Health, Community Development, Gender, Elderly and Children
MSD	-	Medical Stores Department
QMS	-	Quality Management System
TFDA	-	Tanzania Food and Drugs Authority
TFDCA	-	Tanzania Food, Drugs and Cosmetic Act, Cap 219

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The International Medical Devices Regulators Forum (IMDRF) formerly known as Global Harmonization Task Force **(GHTF),** United States Food and Drug Administration **(USFDA),** Medicines and Healthcare Products Regulatory Authority **(MHRA)**, Medical Devices regulations of Canada, Asian Harmonization Working Party **(AHWP)**, World Health Organization **(WHO)** and Health Sciences Authority **(HSA)** of Singapore are also acknowledged for making their guidelines available for reference.

Adam Mitangu Fimbo
Director, Medicines and Complementary Products

FOREWORD

Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 of 2003 to regulate among other products, the quality, safety and performance of medical devices.

The regulation of medical devices involves amongst other things, registration which is an official authorization for the purpose of marketing a medical device for free distribution after assessment of safety and performance.

In order to address various concerns from stakeholders and the general public, the TFDA has set up a framework for regulating medical devices in Tanzania. The first edition of the guidelines was developed in 2009. Since then, a number of technological advancements have been recorded particularly in the area of medical devices and IVDs. To keep pace with the changes, these guidelines have been reviewed and it is now ready for dissemination.

The guidelines are the first of its kind and together with other requirements; it provides guidance on classification of devices depending on their level of risk. The Authority will therefore take risk-based approach when regulating medical devices.

The guidelines have adapted key elements of the Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) promulgated by GHTF. This is in line with the need for global convergence of regulatory systems for medical devices.

Applicants are encouraged to familiarize with these guidelines and follow them when preparing and submitting applications for registration of medical devices. However, the requirements highlighted are minimum and whenever there will be additional information; these may be submitted to TFDA.

Adherence to these guidelines will ensure that all relevant information is provided in the dossiers submitted for registration. This will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which results n unnecessary delays in giving approvals.

The TFDA will continue to review and update these Guidelines in line with the current international and national requirements.

Hiiti B. Sillo
Director General

INTRODUCTION

These guidelines have been reviewed to provide further clarity during submission of device information to demonstrate conformity to the essential principles of safety and performance of medical devices. This is in accordance with provisions of the Tanzania Food, Drugs and Cosmetic Act, Cap 219 and its corresponding of devices in Tanzania.

The conditions include documented evidence that the medical device is safe with good performance, the premises and manufacturing operations comply with the current Quality Management System (QMS) i.e. ISO 13485:2012 and ISO 9001:2015 or any other requirements as may be prescribed by the Authority.

In developing the guidelines, reference was made from the following GHTF guidance documents:-

a) Principles of Medical Device Classification: GHTF/SG1/N 15: 2005
b) Essential Principle of Safety and Performance of Medical Devices: GHTF/SG1/N41R9:2005
c) Principles of Conformity Assessment of Medical Devices: GHTF/SG1/N40:2006
d) Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices: GHTF/SG1/NO11:2008

In addition, the Medical Devices Regulations of Canada, the Common Submission Dossier Template (CSDT) of the Asian Harmonization Working Party (AHWP) and the Medical Devices Regulations – Global overview and guiding principles of WHO were also used.

These guidelines apply to products that fall within the definition of medical devices or devices except in – vitro diagnostic devices. The guidelines are divided into the following sections:

a) General Requirements
b) Device Details
c) Summary Technical Documentation
d) Labeling Requirements
e) Annexes

It should be noted that the amount of detail and information that will be needed in the Summary Technical Documentation may vary considerably with the risk class of the device concerned.

Assessment of dossiers submitted will be based on these guidelines. Applicants are also requested to read the guidelines together with the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and its Regulations made there under.

DEFINITION OF TERMS

In the context of these guidelines, the following terms shall be defined as follows:

Authority

Means the Tanzania Food and Drugs Authority

Conformity Assessment

Means a systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

Certified Copy

Means a true copy of the original document certified by a person registered to practice law in the manufacturer's country of origin and endorsed with the practitioner's official stamp and signature.

Clinical Evaluation

Means the review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

Clinical Investigation

Means any designed and planned systematic study in human subjects undertaken to verify performance of specific device.

Dossier

Means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device.

General Medical Device

Means products falling within the definition of medical devices except in vitro diagnostic medical device.

In Vitro Diagnostic Medical Device

Means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Label

Means written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

Labeling/information supplied by the manufacturer

Means written, printed or graphic matter affixed to a medical device or any of its containers or wrappers or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Manufacture

Means all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labeling of medical devices.

Manufacturer

Means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and / or manufactured by that person himself or on his behalf by another person (s).

Medical Device or Devices

Means an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part of accessory, which is:-

a) Recognized in the official National Formulary, or Pharmacopoeia or any supplement to them;
b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
c) Intended to affect the structure or any functions of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not depended upon being metabolized for the achievement of any of its principle intended purposes.

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 a collection of medical devices, such as a procedure pack or tray that is sold under a single name.

Medical Device System

Means a number of components or parts intended to be used together to fulfill some or the entire device's intended functions and that is sold under a single name.

National Standard

Means a standard as prescribed by the Tanzania Bureau of Standards (TBS) under the Standards Act of 2009.

Objective Evidence

Means information that can be proved true based on facts obtained through observation, measurement, testing or other means.

Performance Evaluation

Means review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

Process Validation

Means confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements

Quality System

Means a system which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives

Quality Management System

Means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

Recall

Means any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to recall or correct the device, or notify its owners and users its defectiveness or potential defectiveness, after being aware that the device may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or may not meet requirements of the Act or regulations.

Recognized Standards

Means national or international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Registrant

Means any person who may either be the trademark or person authorized by him, who has rights to sale the product and is responsible for placing the device on the Tanzanian market

Technical Documentation

Means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices

Verification

Means confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled

1.0 GENERAL REQUIREMENTS

This section describes application procedures and provides other useful information to applicants. Applicants are therefore advised to read carefully this section before compiling dossiers and assemble applications ready for submission to TFDA.

1.1 Language

All applications and supporting documents shall be in Kiswahili or English.

1.2 Applicant

The applicant shall be a person who is resident in Tanzania and must be licensed by TFDA as medical device dealer.

If the applicant is not resident in Tanzania then he shall appoint a Local Responsible Person **(LRP)** also referred to as Authorized Representative who must be residing in Tanzania or company incorporated in Tanzania and authorized by TFDA to deal in medical devices. Proof of official appointment shall be submitted to TFDA.

1.2.1 Responsibility of applicant

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

Whenever any serious safety concerns are noted the applicant shall take appropriate actions including but not limited to informing the Authority, withdrawing registration, recalling the product from the market or revising labels by adding precautions or warnings.

1.2.2 Responsibility of Local Responsible Person

The Local Responsible Person shall be responsible for:

a) Monitoring the device on the market and inform the Authority immediately after the detection of any problem relating to a registered device such as serious manufacturing defects which may endanger public health.

b) Facilitating communication between the applicant and the Authority on matters relating to the product.

c) Handling device recalls.

d) Providing technical support and services to users of registered device (s).

1.3 Applications

An application consists of documentation in hard copies and electronic form, samples and fees. The applicant should have the following information before submitting the dossier to TFDA:-

(i) Class of the device

(ii) Intended purpose of the device

(iii) GMDN code and term

(iv) Conformity assessment certification

(v) Declaration of conformity

Medical devices are classified into four (4) classes based on the level of risk and the intended purpose of the device. In accordance to a set of 16 classification rules **(Annex III)** the higher the risk class, the more regulatory control is required. The manufacturer is responsible for classifying the device.

1.3.1 Medical devices classified into four risk classes (A, B, C and D) described below:-

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low- moderate Risk	Hypodermic Needles/suction equipment
C	Moderate – high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

If more than one classification rule is applicable to the device, the rules resulting to the highest risk classification shall be applicable to the device. However, the Authority reserves the right to decide on the class of the device.

Each submitted application shall contain only one of the following:-

(i) A single medical device

(ii) One medical device family

(iii) One medical device system

(iv) One medical device group

For purposes of submission to TFDA, applications are categorized as follows:

1.4 New applications

These are applications for registration of medical devices that are intended to be placed on the Tanzanian market for the first time. A new application may only be made by the applicant and he shall be the person who signs the application form. A separate application is required for each medical device.

Devices that are manufactured from different sites are considered to be different devices and hence require separate applications.

A new application for registration shall include submission of:

(a) Covering letter;

(b) A duly filled in application form as provided in **Annex I** of these guidelines; Submission shall be both in hard copy and in electronic form on a CD-Rom in a MS word format, Bookman Old style point 12;

(c) A table of contents listing all sections of the dossier and documents and their corresponding page numbers;

(d) Copies of referenced literature and other supporting documents;

(e) Two samples of the commercial pack(s);

(f) A non-refundable application fee for registration of medical devices in Tanzania as provided in the Fees and Charges Regulations currently in force.

Note: For CE marked devices, the declaration of conformity by the manufacturer must be submitted, in addition to the EC certificate issued by the notified bodies.

1.5 Applications for Variation of a registered medical device (s)

The Authority should be informed on any significant change(s) that could reasonably be expected to affect the safety or effectiveness of a medical device. Significant change(s) may include any of the following:

(a) The manufacturing process, facility or equipment;

(b) The manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;

(c) The design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories;

(d) The intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device and any change to the period used to establish its expiry date.

These changes will require TFDA approval before they can be implemented.

Before approval can be granted, any application for variation to a registered device shall be accompanied with the following:-

(i) Dully filled in application form for variation (Annex II);

(ii) Covering letter;

(iii) Re-submission of all parts of the dossier that are affected by variations according to the structure of these guidelines;

(iv) A non-refundable variation fee as prescribed in the TFDA Fees and Charges Regulations currently in force;

(v) A detailed documentation along with samples.

Certain changes are so fundamental that they alter the terms of the registered medical device and consequently cannot be considered as a change. For these

cases a new dossier must be submitted. Any other change(s) should be notified immediately to the Authority.

1.6 Applications for renewal of registration

Applications for renewal of registration shall be made at least 90 days before the expiry of existing registration by submitting the following:-

(i) A dully filled in application form for renewal of registration as outlined in **Annex I** of these guidelines;

(ii) Two samples of the commercial pack(s) from the same batch;

(iii) Specifications of the device along with batch certificates of analysis;

(iv) Artwork or mock up label of the device;

(v) A non-refundable application fee for renewal registration of medical devices in Tanzania as prescribed in the TFDA Fees and Charges Regulations currently in force.

The application may be delivered physically to TFDA head office. An application shall only be accepted by TFDA upon payment of the fees.

1.7 Payment of fees

i. Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations currently in force at the time of application.

ii. Evaluation fees shall be paid at the time of lodging an application.

iii. Any application that will not be accompanied by appropriate fees will not be accepted.

iv. The fees shall be paid by bank transfer to:

Tanzania Food and Drugs Authority, Account Details.: For Foreign Currency: Citibank, Tanzania Ltd. Dar es Salaam – Head Office Peugeot House, 36 Upanga Road, P. O. Box 71625, Dar es Salaam, Tanzania, Swift Code: CITITZTZ, A/c No. 100380013 and CRDB Holland House Branch – A/c No. 02J1021399100.

Local applicants can deposit into Account No.: 6503900110 at National Microfinance Bank, Kariakoo Branch OR by banker's draft.

v. When payment is made by bank transfer all bank charges shall be borne by the applicant who shall also make sure he sends an advice note giving details of the payment in particular the name of the applicant, the medical device paid for and the amount of fees paid. If the device is already registered in addition to the aforementioned details, the registration number of the device must also be quoted.

vi. For each registered device an annual retention fees shall be paid on or before the end of January of each calendar year for which the fees are due. The registration number of the device must be quoted at the time of payment.

vii. All fees are non-refundable once paid to the Authority.

1.8 Data presentation

Data shall be presented on a paper with readily readable letters of at least 12 font size. Every page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

All parts must be bound separately and arranged sequentially in spring file covers with flexible seat. Lever arch files are not permissible. One or more spring file covers may be used depending on the number of pages contained in a part.

The file cover should be made of hard, non-collapsible biodegradable material. The thickness should be expandable or reducible depending on the total thickness of the contents.

1.9 Product Dossier

A separate and complete product dossier in both hard copy and electronic form are required for each single medical device or a medical device or a medical device group or medical device family or a medical device system. Applicants are required to arrange the application dossier as follows:

Class A	Class B, C and D
The application form (annex I)	The application form (annex I)
Letter of authorization	Letter of authorization
-	Information on Device details (item 2 of the guidelines)
IFU, patient information leaflet and promotional material (including brochures and catalogues)	Summary technical documentation (item 3 of the guidelines)
Labeling information (item 4 of the guideline)	Labeling information (item 4 of the guidelines)
Information on sterilization method (s) and validation standards used (where applicable)	Essential requirements checklist (annex II of the dossier)
Proof of Quality Management System (QMS) e.g. ISO 13485 certificate	Proof of Quality Management System (QMS) e.g. ISO 13485 certificate.

Failure to arrange the application dossier accordingly will lead to rejection of the application at the time of submission.

1.10 Processing of applications

i. Once an application has been accepted and evaluation fees paid the processing of application for **class A** will take **90 calendar days** and for class B, C and D it will take **240 calendar days**.

ii. Once a query or a request has been raised, the processing shall halt until after the response to the query has been received. If no response to the query or request has been received within **90 calendar days**, it will be deemed that the application has been withdrawn by the applicant.

iii. If the applicant experiences difficulty in responding in full or within the specified timeframe, he should contact the Authority to discuss the queries as soon as possible after receipt of the input request for information/clarification.

iv. If the applicant wishes to resubmit the application in future, it will be processed as a new application. As part of evaluation of the medical device, Quality System audit of the manufacturing site may be conducted to verify compliance thereof.

1.11 Registration of the device

When a device is found to have complied with all the prescribed registration requirements, the applicant will be informed to that effect. A certificate of registration together with such conditions as the TFDA may determine shall be issued. Registration of a device shall be site specific.

1.12 Validity of registration

The registration of a medical device shall be valid for five (5) years unless suspended or revoked by TFDA or terminated by the registrant. The validity of registration shall be subject to:-

i. Payment of annual retention fees as prescribed in the current Fees and Charges Regulations in force;

ii. Submission of biannual post-marketing surveillance reports;

iii. Submission of adverse effect reports associated with the use of device.

1.13 Termination of registration

The TFDA may by giving reasons in writing suspend or revoke the registration of a device, or amend the conditions of its registration. The registrant may issue TFDA 60 days written notice and reasons to terminate registration of a device.

1.14 Appeals

Any person aggrieved by a decision of the Authority in relation to any application for registration of a medical device may make representations in writing to TFDA. If after consideration of the representations, the Authority is satisfied it may approve registration of a medical device and if not satisfied it shall reject the application. In case the applicant is not satisfied with the decision, he may appeal to the Minister responsible for Health.

1.15 Medical devices exempted from registration

All medical devices exempted from registration should be notified to the Authority by submitting the following:

i. A dully filled in application form for medical device notification as outlined in **Annex IV** of these guidelines

ii. Manual, Catalogue of IFU of the device

iii. A non-refundable notification fee of medical device as prescribed in the TFDA Fees and Charges Regulations currently in force.

Certain medical devices, due to the low risk associated with their use, are exempted from product registration. The list of medical devices exempted from registration and their intended purpose is provided in **Annex VII** of these guidelines.

The medical devices are solely exempted for a specific intended purpose as specified in the list. If the proposed intended purpose of a medical device shall require registration.

Exemption from product registration does not exempt the dealers of these medical devices from their legal obligations of keeping distribution and complaints records, reporting adverse events and recalling defective and unsafe products from the market.

1.15.1 All other medical devices

All other medical devices shall require registration or approval from the Authority before they can be imported or supplied to Tanzania. Application for registration of Class B, C and D medical devices shall be prepared in accordance to requirements prescribed in item 2, 3, 4 and Annexes I and IV of these guidelines.

2. DEVICE DETAILS

2.1 Name(s)

State the generic and brand name of the device.

2.2 Description

Provide a summary of information on design, characteristics and performance of the device. The description should also include information on device packaging.

2.3 Category

State the GMDN category of the device. If the device is not categorized according to GMDN and is coded based on other system, please specify.

2.4 Intended Use/Indication(s)

State the intended use(s) of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate. The description of the target patient population for which the device is intended should also be included.

The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used and whether the device is intended for single use or multiple uses.

2.5 Instructions for Use

Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

2.6 Contraindications

State conditions under which the device should not be used. The statement should specify the clinical conditions of a patient that would make use of the device inadvisable.

2.7 Warnings

State the specific hazard alert information that a user needs to know before using the device.

2.8 Precautions

State briefly precautions to be taken and any special care necessary for the safe and effective use of the device.

2.9 Adverse Effects

Describe all adverse and side effects associated with the device under normal conditions of use.

2.10 Alternative Use

Describe any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

2.11 Storage conditions

State the storage conditions for the device. This should be based on results of stability studies conducted (where applicable).

2.12 Recommended shelf-life (where applicable)

State the recommended shelf-life of the device.

3. SUMMARY TECHNICAL DOCUMENTATION

3.1 Device description and features

Provide the name of the device and detailed description of the device attributes that are necessary to explain how the device functions. If it is part of a system, the relationship of the components in the system should also be described. The details should include:-

i. The principle of operation of the device;

ii. Risk class and applicable classification rule for the medical device;

iii. Description of the key functional elements of the device including software and its release version, if applicable. e.g. its parts/components, formulation, composition and functionality;

iv. A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device.

v. Components or accessories that can be sold separately and used with other medical devices, systems or units should be identified. Variants of the device must be identified, as well as the parameter ranges of variants [for example (e.g.), hip implants with varying coatings].

vi. Labeled pictorial representation of the device in the form of diagrams, photographs or drawings with sufficient explanation should be provided.

3.2 Evidence of Conformity to Essential Principles

Provide evidence of conformity to Essential Principles of Safety and Performance (EPSP) by completing the checklist appended as **Annex V.**

Note:

i. Manufacturer should identify the essential principles of safety and performance that are applicable to the device and the general methods used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include:-
   - Compliance with a recognized or other standard(s)
   - Internal industry methods
   - Comparison to other similar marketed device

ii. When the manufacturer uses national, international or other standards to demonstrate conformity with the Essential Principles, full title of the standard, identifying numbers, date of the standard and the organization that created the standard should be provided.

3.3 Materials

Details of material identifications and specifications including raw materials and components should be provided. The description of the materials of the device and their physical properties should be sufficient to demonstrate the conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device especially for materials contacting the patient or when the material chosen is considered critical for the design or function of that component. Reference to applicable material standards may be useful in this description.

3.4 Device Specification

Describe functional characteristics and technical performance specifications for the device including as relevant, accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.

Note: A list of the features, dimensions and performance attributes of the medical device, its variants and accessories that would typically appear in the product specification should be made available to the end user e.g in brochures and catalogues.

3.5 Device Verification and Validation

Summarize the results of verification and validation studies undertaken to demonstrate compliance of the device with Essential Principles that apply.

The following documentation should be submitted;

i. Declarations/ certificates of conformity to the recognized standards listed as applied by the manufacturer; and

ii. Summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests or alternative ways of demonstrating compliance.

Whenever applicable the information should cover:

(a) Engineering tests
(b) Laboratory tests
(c) Biocompatibility tests
(d) Animal tests
(e) Simulated use
(f) Soft-ware validation

3.5.1 For sterile medical devices the following information should be provided in this section:

i. Detailed information of the initial sterilization validation including bio-burden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilization validation is not performed, adequate justification must be provided. For example, if reference to the sterilization validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the

previously conducted validation to the current medical device must be provided. In addition, the initial sterilization validation report for the reference medical device must be provided

ii. Evidence of the ongoing revalidation of the process; typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes

iii. Detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with those standards, and a summary of results

iv. Post-sterilization functional test on the medical device;

v. If the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.

3.5.2 Shelf life of the device

For medical devices with a shelf-life, data demonstrating that the relevant performances and characteristics of the medical device are maintained throughout the claimed shelf-life which the "expiry" date reflects is to be provided under this section. This may include:

i. Prospective studies using accelerated aging, validated with real time degradation correlation; OR

ii. Retrospective studies using real time experience, involving e.g. testing of stored samples, review of the complaints history or published literature etc.; OR

iii. A combination of (i) and (ii)

3.5.3 If real time shelf-life data is not available, shelf-life data collected from accelerated studies can be used to support the initial shelf-life claim. The rationale for the parameters selected for the accelerated studies must be provided. Shelf-life data collected from accelerated studies must be supported by real time testing to confirm the initial shelf-life claim. The final real time study report must be submitted when completed.

3.5.4 As the absence of an "expiry" date constitutes an implicit claim of an infinite shelf-life, evidence demonstrating the following shall be provided:

i. That there are no safety-related performances or characteristics which are likely to deteriorate over time; OR

ii. That the extent of any likely deterioration does not represent an unacceptable risk; OR

iii. That the period over which unacceptable deterioration occurs is far beyond the likely time of the first use of the medical device e.g. 30 years.

3.5.5 For devices that do not have expiry dates (e.g. infusion pump, digital thermometer), the projected useful life of the medical device must be provided. Manufacturers may refer to the current TS/ISO 14969 (Medical devices – Quality Management Systems – Guidance on the application of ISO 13485) for information on how to determine the projected useful life.

3.5.6 For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.

3.5.7 If the device requires special packaging (e.g. considerations related to sterility, humidity, light sensitivity, pressure or oxidative reaction under irradiation), evidence should be provided that this has been addressed. Likewise, evidence should be provided to demonstrate that the integrity of the device and the internal environment can be maintained by the device packaging during handling, transport and storage (i.e., for claimed shelf life). In the case of sterility, ensure that the test methods address both seal integrity and sterility (e.g., bubble tests, dye penetration test, etc.).

3.6 Biocompatibility (if applicable)

Biocompatibility testing characterizes the biological response to the material. If the device comes in contact with the patient then the biocompatibility of all materials which are potentially patient contacting is required. Tests should be conducted on samples from the final product after all manufacturing and processing has been completed (e.g., sterilization). Deviations from this should be justified; generic claims from the raw material supplier are generally insufficient.

Reports describing the tests, the results and the analyses of data should be presented. For each test, the predefined acceptance criteria and the results should be clearly provided (e.g., tabular form). In general, ISO 10993 standards are taken as the gold standards for biocompatibility. If testing was not conducted from a currently recognized standard, the validated alternative method should be provided along with a justification for its use (e.g., devices incorporating nanotechnology). Any deviations from a standard method should also be specified.

3.7 Software Verification and Validation (if applicable)

Provide information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verifications, validation protocols and report and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and where applicable, operating systems identified in the labeling.

3.8 Devices containing Biological Material (if applicable)

Provide results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents. This will include viral clearance results for known hazards. Donor screening concerns must be fully

addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.
To fulfill the requirements under this section, the following information shall be submitted:

i. A list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin;

ii. Detailed information concerning the selection of sources/donors;

iii. Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

iv. Process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents;

v. Full description of the system for record keeping allowing traceability from sources to the finished medical device.

vi. Evidence that demonstrates a system is in place for animals and tissue traceability; and quality control processes and procedures are in place to prevent contamination with potential infectious/transmissible agents, including Transmissible Spongiform Encephalopathies (TSEs) should be provided. Disinfection/decontamination procedures in the event of contamination should also be outlined along with appropriate validation.

3.9 Pre – clinical Studies (if applicable)

Provide detailed information on pre-clinical animal studies conducted to justify the probability of effectiveness in humans. These studies must follow Good Laboratory Practices. The objective, methodology, results, analysis and manufacturers conclusions must be presented. The study conclusion should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

3.10 Clinical Evidence (if applicable)

An evaluation of clinical evidence is necessary to help establish the clinical safety and effectiveness of a medical device for each claimed indication for use. A clinical evaluation considers available, relevant clinical data from published sources, or device-related investigations. It may be necessary to generate additional clinical data to address specific issues for certain medical devices.

If a clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review of relevant publications in the peer-reviewed scientific literature. Reference to devices other than the subject device in support of safety or effectiveness requires a thorough comparison

to the subject device design, features and performance capabilities to demonstrate relevance. This may be provided in a table format.

The clinical evaluation report should be summarized as per the current IMDRF guidance documents.

3.11 Risk Analysis

A risk assessment should be based on an analysis and an evaluation of the risks inherent in the use of the device, as well as the risk reduction measures adopted to satisfy safety and effectiveness requirements. The manufacturer should identify the individual or organization that carried out the risk analysis and it should be conducted on the version of the device under review.

The information provided should include a description and identification of the devices and accessories under consideration in a risk assessment. Design aspects should be evaluated. The method of risk analysis must be appropriate for the device and the level of risk involved. A brief description of the technique used to perform the risk assessment, definitions of risk and any standards used in this process should be stated. A list of critical hazards should be provided, which includes how the risks associated with these hazards have been evaluated and what risk reduction measures have been taken. An evaluation of the risks as compared with the claimed benefits of the device and steps taken to reduce the risks to acceptable levels should also be presented.

3.12 Manufacturing Information

Provide details of the manufacturing process for the device in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or conditions and the facilities and controls used for the manufacturing, processing, packaging, labeling and storage of the device. A manufacturing process flow chart should be submitted.

Sufficient details must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place

If multiple facilities are involved in the manufacture of the device, the physical address of the manufacturing site and manufacturing activities for each facility should be provided. The sites where design and manufacturing activities are performed shall be identified. For example:

(i) if the manufacturing process of a product consists of a number of subassembly processes, the manufacturing sites where each of these subassembly processes are carried out must be identified, and the relationship between these processes must be shown; or

(ii) If multiple sites manufacture the same product, each of these sites must be identified.

The sites (including contract manufacturers) where design and manufacturing activities are performed shall be identified. Quality Management System certificates

are to be provided for the design and manufacturing sites (including contract manufacturers as an **Annex** to the submission).

For those multiple facilities involved in the manufacture of medical device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the medical device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the medical device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical device) that contributes towards the manufacture of the finished medical device itself.

Details of the sterilization method and processing should be included, if the device is sold sterile or is to be sterilized, process validation data should include sterility test data, reference to a standardized test method, and attestation or evidence of successful validation under real-life conditions under which the product is to be sterilized. Bioburden determination, culture media used, time and temperature of incubation, controls, number of samples examined and frequency of testing should also be presented. A Sterility Assurance Level (SAL) of 10-6 is generally required.

If a biological indicator was used, its placement needs to be described and rationalized (e.g., most difficult to sterilize location). If a group of devices are to be sterilized together, the worst-case scenario or most difficult to sterilize product should be validated. Attestation of validation may be used. The manufacturer should also demonstrate that they have a process in place to monitor bioburden levels on a regular basis to confirm that the sterilization method remains valid.

Alternatively, a method of parametric release may be proposed and validated. If a process challenge device was used to assess the sterilization process it must be shown to have comparative resistance or a greater challenge to sterilization than the biological indicators placed inside the product/packaging.

If the product is to be re-sterilized by the end-user, a description of the recommended sterilization process for the end-user should be provided, and evidence of validation provided. Validation should be for sterility and also to confirm that the process does not compromise integrity or performance of the product. The recommended, validated sterilization method should be stated in the device labeling information.

4. LABELLING REQUIREMENTS

Labeling information shall be in English and/or Kiswahili and shall be expressed in a legible, permanent manner that can be easily understood by the intended user.

Depending on the type of device, the following minimum information should be provided on the label:-

i. The name of the device.

ii. Manufacturer's name and address.

iii. Manufacturing site name and physical address ***(if different from ii).***

iv. The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device family or medical device group family.

v. Batch or lot number if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units.

vi. The word **"Sterile"** if the manufacturer intends to sell the device in a sterile condition.

vii. Devices sold in non-sterile condition, but intended to be used sterilized, must specify the recommended sterilization process in the labeling.

viii. The words **"For single use only"** if the device is intended for that purpose.

ix. The expiry date of the device expressed in month and year.

x. Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use.

xi. The directions for use, unless directions are not required for the device to be used safely and effectively.

xii. Storage conditions applicable to the device.

xiii. Amount of DEHP (di-(2-ethylhexyl) phthalate) on packaging material (where applicable).

xiv. Medical devices marketed submitted in a kit, system or package should declare their components.

In case the device is intended to be sold to the general public, labeling information:-

i. Shall be set out on the outside of the package that contains the device; and be visible under normal conditions of sale

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

Specimen label(s), promotional material(s) and user manual(s) should be provided.

Note: Requirements that have been described in a respective standard should also be followed when labeling a device.

5.0 REQUIREMENTS FOR REGISTRATION OF SPECIALIZED MEDICAL DEVICES

Special requirements are prescribed in this section for certain specialized devices such as MRI, Diagnostics Ultrasound Systems and Transducers, X-ray machines, ECHO and other similar machines. These devices are classified in either class B, C and D but their documentation requirements differ from other devices due to their complexity. TFDA require the applicants who intend to register such devices in Tanzania to submit the following minimum information as applicable to the device.

i. Submit a dully filled in application form as prescribed in the guidelines **(Annex I).**

ii. Certificate of market approval from any other country and market history. Brief description of the foreign marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.

iii. Manufacturer's Declaration of Conformity.

iv. Certificate of Analysis to confirm safety and performance of the device.

v. Operator's manual.

The User or Operator's Manual of the devices must address the contraindications, warnings, precautions, and general risks associated with the device. Moreover, the User or Operator's Manual for a Device should contain the following. The indications for use statement in the user manual should be identical to the Indications for Use statement in application form and device details section.

vi. Summaries of non-clinical and clinical data supporting the intended use and performance characteristics;

vii. A label must provide sufficient details to satisfy the requirements prescribed in the Tanzania Regulation of Medical Devices, 2015 and section 4.0 of these guidelines.

viii. In case of medical device adverse report. TFDA requires manufacturer/ importers who have received complaints of device malfunctions, serious injuries or deaths associated with medical devices to notify TFDA of the incident. The requirements for medical device reporting are defined in Tanzania Medical Device Regulation, 2015.

ix. All other details as per section 3 of these guidelines.

5.1 Cleaning, Disinfection, Sterilization, and Pyrogenicity for Specialized Medical Devices

If the transducer supplied is non-sterile or is intended to be reused between patients, you should provide clearly written recommended procedures on how to clean, disinfect and sterilize the transducer between uses if necessary. These recommended procedures should be validated and summary validation procedures provided in the submission. The level of disinfection or sterilization should be appropriate for the intended clinical use. For sterilization, which should be used for transducers in contact with the bloodstream or normally sterile tissues, the use of an appropriate sterilization process should be recommended and its use validated.

For device components or accessories provided sterile to the user, TFDA recommends that the applicant should provide sterilization information (Sterilized with a sterility assurance level (SAL) of 1×10^{-6}).

If the device is labeled pyrogen-free, then the applicant must provide a description of the method (standard method) used to assess pyrogenicity. TFDA recommends the following endotoxin endpoint: 0.5 EU/ml for general medical devices (e.g. blood contacting) and 0.06 EU/ml for devices that contact cerebrospinal fluid.

6.0 BORDERLINE MEDICAL DEVICES

Many manufacturers have difficulty in interpreting whether or not their product would be considered a medical device within the terms defined in these guidelines. Manufacturers should always refer to the definition of a medical device when making any borderline determinations. Any such decision will be based on the stated intended purpose of the product and its mode of action.

6.1 Medical / cosmetic / toiletry purpose

Where there is a specific intended medical purpose, products may be considered to be medical devices. For example:

- breast pumps for treatment of inverted nipples;
- external heat pads claiming pain relief, e.g. for the treatment of period pains;
- Incontinence products (e.g. adult nappies);
- muscle toning products with medical claims (such as treatment of incontinence);
- slimming products indicated for the treatment of clinical obesity which do not act in a metabolic, pharmacological or metabolic manner;
- baby nappies;
- breast pumps;
- feminine hygiene products (sanitary towels, tampons).

6.2 Assistive technology products (aids for daily living)

Equipment intended for alleviation of, or compensation for a disability may or may not be considered as medical devices. The determining factor will be whether or not there is a direct link between the corrective function of the equipment and the individual concerned and that there is a stated medical purpose.

The following products are considered to be medical devices as there is such a direct link:

• baths with integral hoists;
• external limb prostheses and accessories;
• hearing aids;
• mobility aids for the visually impaired;
• orthopaedic footwear;
• orthoses (lower/upper limb, spinal, abdominal, neck, head);
• patient hoists;
• rehabilitation tricycles / mobility carts;
• walking / standing frames;
• walking sticks / crutches;
• wheelchairs.

6.3 Products for sports or leisure

In general, products for sport or leisure purposes are not considered to be medical devices. However, in some cases, products aimed for sports may be considered to be medical devices. This is usually the case where specific claims are made for the treatment of pain or injury and the product acts in a physical manner. Examples of products considered to be medical devices under this section:

• heat / cold pads for pain relief;
• bandages for sprains and similar;
• support bandages;
• Blood pressure monitors, even if intended to be used in a gym.

7.0 SOFTWARE

Software may be considered to be medical devices provided that the purpose fits the definition of a medical device. The definition of a medical device includes stand alone software and specifies that when software is used in combination with a device which is 'intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes' that it will be considered to be a medical device.

For example:
• Software intended to enhance images from x-ray or ultrasound would be considered to be medical devices.

• Software that is simply a patient management system or a records storage system would not, however be considered to be a medical device.

8.0 ACCESSORIES

Accessories should be classified in their own right as a medical device and do not necessarily take the classification of the device with which they are intended to be used. A product can only become an accessory to a medical device if there is an established intended use in conjunction with a medical device. The registration of accessories will follow the requirements of these guidelines.

Examples of such potential accessories are:
• steriliser for use with medical equipment;
• pouches for packaging re-sterilized medical devices;
• specific battery chargers for battery-driven electro-medical devices;
• contact lens care products;
• disinfectants specifically intended for medical devices;
• specialized water treatment devices for use with dialysis machines ;
• gas cylinders / pressure release devices for use in conjunction with anaesthesia machines.

8.1 Spare parts

Spare parts, supplied for the replacement of existing components of a medical device that has already been registered are not considered to be medical devices unless they are likely to significantly change the characteristics or performance of the finished device. If this is the case then such spare parts are likely to be considered to be medical devices in their own right and therefore may require registration.

9.0 OTHER MEDICAL DEVICES

9.1 Repairs

Where a registered device is 'repaired' and returned to its original owner after the repair the components used in the repair would not require registration. The device should not be 'placed on the market' but returned to its owner. If the repaired device was not registered then registration process will be required.

9.2 Second-hand and fully refurbished devices

Second-hand medical devices are those which are already on the market and have been 'pre-owned' and used and that are subsequently 'sold on' for the same continued use. These products are considered to be already registered and do not require second registration by their new owner.

A medical device that has been fully refurbished is not the same as one that has been repaired or undergone maintenance. Therefore, it requires to be registered as a new medical device.

They will be considered to be the 'manufacturer' under the regulations and are required to place the product on the market under their own name. 'Fully refurbished' is considered to mean that a device has been completely rebuilt / made as new from used devices and is assigned a new 'useful life'. It would also be considered as a new device if a new intended purpose was assigned.

9.3 Medical devices that require final processing

Some devices may not be supplied in their final state (i.e. may not be immediately available for use) once placed on the market. They may require some further processing prior to being 'usable', for example processing, preparation, installation, assembly or fitting. These activities are not usually undertaken by the manufacturer but are carried out by the healthcare professional or the final user.

Examples of such activities are:

- sterilisation of medical devices supplied non-sterile;
- assembly of systems;
- configuration of electronic equipment;
- preparation of dental fillings;
- fitting of contact lenses;
- adaptation of a prosthesis to the needs of the individual patient.

NOTE: The type of documentation for registration and application process for borderlines medical devices shall depend on the declared intended use and risk class declared by the manufacturer.

Majority of border line medical devices especially from item 6.1 to 6.3 falls under the list of exempted medical devices and therefore do not require registration. However, applicants must confirm the status before importation is initiated.

ANNEX I

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR REGISTRATION OF MEDICAL DEVICES

Please read this section carefully before completing the form

1. Please check the corresponding boxes in the "Encl." column if any document is enclosed and indicate the respective indexes in the submission folder

2. Please check the boxes as appropriate

Note	Part A: Particulars of Applicant		Encl.
A1	Applicant's name		
	Address of Head Office		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website:		
	Part B: Particulars of the Manufacturing Site(s)		
B1	Name		
	Physical address of the site		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website:		

	Particulars of the Manufacture (if different from manufacturing site)		
	Name		
	Physical address of the site		
	Post Code:	Country:	
	Contact Person:	Telephone:	

B2	Quality Management System Established by the Manufacturing Site(s): Mention current Standards with which the system complies : ☐ _____ ☐ _____ ☐ _____ ☐ System certified by _____ and a certified copy of the certificate is enclosed. Indicate areas covered by Quality Management System ☐ Device design, ☐ Production ☐ Post-production processes ☐ Others (***please specify***) _____		☐ _____
	Part C: Particulars of Authorized Representative (AR)		
C1	LRP's name		
	Address of the registered business premise		☐

	Contact person:	Telephone:	_____
	Fax:	E-mail:	
	Contact telephone for public enquiries **(*if different from the number given above*):**		

	☐ Certified copy of business registration certificate with business registration number: is enclosed		
C2	☐ Certified copy of Power of attorney or formal agreement or any other official authorization of the LRP is enclosed		☐ _____
C3	☐ The AR is also an importer of the device named in Part D		
	Part D: Particulars of the Device		
D1	Generic name of the Device		
D2	Brand name of the device		
D3	Model/Series/System ***(if applicable)***		
D4	Family (***if applicable***)		
D5	Country of origin		

D6	Select GMDN (Global Medical Device Nomenclature) Categories: 01 - Active implantable device 02 - Anaesthetic and respiratory devices 03 - Dental devices 04 - Electro mechanical devices 05 - Hospital hardware 06 - In vitro diagnostic devices 07 - Non-active implantable devices 08 - Ophthalmic and optical devices 09 - Reusable instruments 10 - Single use devices 11 - Technical aids for disabled persons 12 - Diagnostic and therapeutic radiation devices 13 - Complimentary therapy devices 14 - Biologically -derived devices 15 - Healthcare facility products and adaptations 16 - Laboratory equipment 17 - Others	
D7	Description of the device ***(Please enter appropriate GMDN description. If none of the descriptions in GMDN appear appropriate, enter a short description of the device)*** _____ _____ _____	
D8	GMDN Code: _____ ***(Please enter if known)***	
D9	Other common descriptions of the device: _____ _____ _____	
D10	Intended use of device	
D11	Class of the medical device: ☐ Class A ☐ Class B ☐ Class C ☐ Class D	

D12	Reasons for classifying the device as Class A, B, C or D device: _____ _____ _____	
D13	History ☐ No previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies. ☐ Yes ***(Please tick the appropriate boxes and provide details):*** ☐ Recalls completed or in progress ☐ Any reportable adverse incidents bearing implications to the Device ☐ The device banned previously in other countries ☐ Pro-active post-market surveillance studies	
D13	Performance and safety: International or national standards with which the device complies _____ _____ (Please enclose copy of the standard)	
	Part E: Marketing Approvals in Foreign countries	
E1	Mention the countries where the device has obtained marketing approvals _____ _____ (Please enclose certified copy of valid marketing authorization)	☐ _____
E2	Mention the countries where the device approval is still pending _____ _____	
	Part F: Declaration of conformity (DoC)	
F1	Submit a written declaration of conformity. The DoC should contain the following:-	

	(i) An attestation that a device complies with the applicable EPSP, has been classified accordingly and has met applicable conformity assessment element. (ii) Information is sufficient to identify the device including its nomenclature. (iii) The risk class allocated to the device. (iv) Which of the conformity assessment elements have been applied (v) The date from which the DoC is valid. (vi) The name and address of the device manufacturer. (vii) The name, position and signature of the responsible person who has been authorized to complete the DoC.	

Declaration by applicant

I, the undersigned certify that all the information in this form and accompanying documentation is correct and true to the best of my knowledge.

Name: ----------

Position: _____

Signature: _____

Official stamp:

Date: _____

ANNEX II

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FORM FOR VARIATION OF A REGISTERED MEDICAL DEVICE

Reference Number:	
Brand name:	
Generic name:	
Risk Class:	
GMDN code	
GMDN category:	
Model/ Series/ System (if applicable)	
Type of change(s) (State which type of variation)	
Other Application(s) (Please provide brief information on any ongoing variation or other variation(s) submitted in parallel or renewal application(s) or line extension(s)).	
Scope (Please specify scope of the change(s) in a concise way)	
Background for change & Justification for consequential 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).	
Present (Please specify precise present wording)	Proposed (Please specify precise proposed change)
In the case of changes to the device detail, package leaflet, IFU or catalogue applicants should always enclose a working model clearly showing the differences (new text and deleted text) between the proposed new version and the current text, previous version or reference text.	

Details of applicant (Must be the holder of the marketing authorization/registration certificate). Name: Physical Address: Postal Address: Country: Phone: Fax: Email:
Declaration of the Applicant: I hereby submit an application for the above Marketing Authorization to be varied in accordance with the proposals given above. I declare that (Please tick the appropriate declarations): ✓There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)'); ✓Where applicable, Variation fees have been paid; ✓ Change will be implemented from: Next production run/next printing Name: Qualification: Position in the company: Signature: Date: Official stamp:

ANNEX III

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;

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,

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

unless 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 or 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

All implantable devices, and long-term surgically invasive devices, are in Class C,

Unlessthey 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:

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 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.

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 medical devices, or disinfecting as the end point of processing, are in Class C.

unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B; or

Unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C

Rule 16

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,

Unlessthey are implantable or long-term invasive devices, in which case they are in Class D.

ANNEX IV

TANZANIA FOOD AND DRUGS AUTHORITY

NOTIFICATION FORM FOR MEDICAL DEVICES

Attachments:
Please attach/enclose:-

(a) A copy of certificate of incorporation for companies or registration of the other forms of ownership of the Business in Tanzania.
(b) A copy of free sale certificate and certificate of observance to Quality Management System for imported medical device(s).
(c) Certificate of conformity
(d) Art work of immediate package, outer package, product information leaflet. Manual, catalogue or any other related document

Name of importer:	
Address:	
Telephone:	
Fax:	
E-mail:	

S/N	Brand name of the Device	Common name or preferred name	Description of the device as per GMDN or as applicable	Category of the device as per GMDN	Intended use of the device	Name and complete address of the manufacturing Site(s)	Device Class**	Marketing approval status in GHTF Member Countries and/or other countries
1								
2								
3								
4								
5								

Name of authorized person:

Signature:

Date:

Stamp:

GHTF Global Harmonization Task Force ** Classification as per GHTF Rules

GMDN Global Medical Devices Nomenclature

ANNEX V

TANZANIA FOOD AND DRUGS AUTHORITY

ESSENTIAL REQUIREMENTS CHECK LIST				
Brand name : _____		**Common name: _____**	**Risk class: _____**	
	Essential Principal	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**
	General Requirements			
1	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety			
	of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			

2	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; • eliminate risks as far as reasonably practicable through inherently safe design and manufacture; • reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and inform users of any residual risks.			
3	Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.			

4	The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.			
5	Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.			
6	All known and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.			
7	**DESIGN AND MANUFACTURING REQUIREMENTS**			

7.1	**Chemical, physical and biological properties** The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 1 to 6 of the 'General Requirements'. Particular attention should be paid to; • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, • the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
7.2	The devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.			
7.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible			

	their performance is maintained in accordance with the intended use.			
7.4	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.			
7.5	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.			
8	**Infection and microbial contamination**			
8.1	The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: • allow easy handling, and when necessary: • reduce as far as reasonably practicable and appropriate any microbial exposure during use; • prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person.			

8.2	Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.			
8.3	In some jurisdictions products incorporating tissues, cells and substances of non-human origin may be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.			
8.4	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.			
8.5	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.			

8.6	Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.			
8.7	The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.			
9	**Manufacturing and environmental properties**			
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.			
9.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,			

	electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; • the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; • the risks of accidental penetration of substances into the device; • the risk of incorrect identification of specimens; • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; • risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
9.3	Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.			
9.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.			

10	**Devices with a diagnostic or measuring function**			
10.1	Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.			
10.2	Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.			
10.3	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.			
10.4	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
10.5	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device			

11	**Protection against radiation**			
11.1 11.1.1	General Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			
11.2 11.2.1	Intended radiation Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.			
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			

11.3 11.3.1	Unintended radiation Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.			
11.4	Instruction for use			
11.4.1	The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.			
11.5	Ionizing radiation			
11.5.1	Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.			
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.			

11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.			
12	**Requirements for medical devices connected to or equipped with an energy source**			
12.1	Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.			
12.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.			
12.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.			
12.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.			

12.5	Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.			
12.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.			
12.7	Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the manufacturer.			
13	**Protection against mechanical risks**			
13.1	Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.			
13.2	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			

13.3	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
13.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.			
13.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.			
14	**Protection against the risks posed to the patient or user by supplied energy or substances**			
14.1	Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.			
14.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.			

14.3	The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.			
15	**Protection against the risks posed to the patient for devices for self-testing or self-administration**			
15.1	Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.			
15.2	Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.			
15.3	Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the manufacturer.			
16	**Information supplied by the manufacturer**			

16.1	Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood. Note: Further information is provided in GHTF/SG1/N009 *Labeling for medical Devices and in SG!/N043 Labeling for Medical Devices.)*			
17	**Performance evaluation including, where appropriate, clinical evaluation**			
17.1	All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.			
17.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.			

I declare that the information provided in this form is accurate and correct and the device conforms to all applicable requirements stipulated above.

Name:_____

Signature:_____

Position:_____

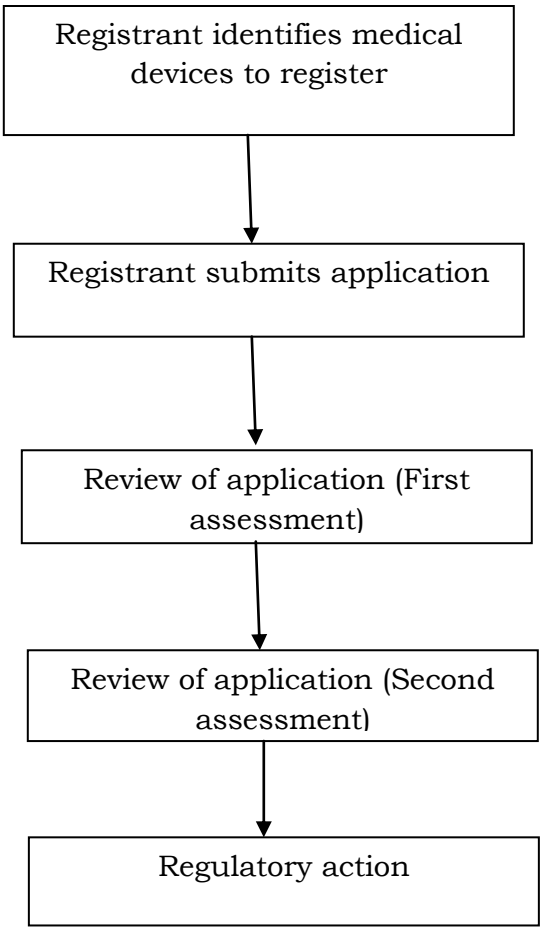
Date:_____

TANZANIA FOOD AND DRUGS AUTHORITY

ANNEX VI

THE APPLICATION PROCESS FOR REGISTRABLE MEDICAL DEVICES

The process described below is applicable to medical devices that require registration.



1.1 Submission Requirements for Class A Medical Devices

Applicants are required to submit the following data for Class A medical devices not exempted from registration along with dully filled in application form as provided in Annex I of this guideline.

1.1.1 Copies (in English and in original colour) of:

(a) The labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging.

Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated;

(b) The instructions for use (where applicable);

(c) The patient information leaflet (where applicable); and

(d) The promotional material (including brochures and catalogues).

1.1.2 For sterile medical devices: the sterilization validation report

1.1.3 For medical device with measuring function: certification on medical device metrology or equivalent.

1.1.4 For active medical devices: certification to electrical safety standards, e.g IEC 60601.

1.2 Review of application

For class A medical devices not exempted from registration, the risk associated with the use of the medical devices has been determined to be low. The Authority does not conduct a premarket evaluation of the safety, quality and performance for such medical devices.

The Authority's role in the review of the application is to determine that:

(i) The class A medical device is correctly classified

(ii) The intended purpose/indications for use for the class A medical device is appropriate for the design of the medical device, i.e. no exaggerated claims are made.

In the event that the medical device is incorrectly classified or the product claims are questionable, the Authority may request for the full technical documentation of the medical device.

ANNEX VII

TANZANIA FOOD AND DRUGS AUTHROITY

List of Medical Devices Exempted from Product Registration

Explanation of listing

The listing is tabulated with the following items:

Item	Explanation
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 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)

Keyword	Device identifier	Description/Intended Use
Adhesive	**Adhesive Bandage** Bandage/dressing, adhesive Bandage/tape, adhesive	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.

Keyword	Device identifier	Description/Intended Use
	Adhesive strip Adhesive strip, general-purpose Closure, wound, adhesive Strip, adhesive, general Purpose Adhesive strip, butterfly	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 suchas hypoallergenic or waterproof. The device is usually supplied sterile in precut sizes/shapes. This is a single –use device.
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	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 (such as waterproof, hypoallergenic) and is typically supplied in rolls. This is a single -use device.
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent	A solvent material designed to remove adhesive tape and its residue from the skin or other surfaces. This is a single-use device.

Keyword	Device identifier	Description/Intended Use
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 holder that keeps the bag in a 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.

Keyword	Device identifier	Description/Intended Use
	Bandage, gauze Cotton gauze swabs	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 Cotton gauze dressing Dressing, roller gauze	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 Compression dressing Elastic bandage Crepe Bandage	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 ostomyaids. 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** Bed, nursing	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 Bed, hospital, manual Bed, hospital, mechanical	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.
	Bed, general- purpose, hydraulically-powered Bed, hydraulic, adjustable hospital	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.

Keyword	Device identifier	Description/Intended Use
	Bed, general-purpose, electrically-powered Bed, AC-powered adjustable hospital	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.
	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.

Keyword	Device identifier	Description/Intended Use
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
		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 Board, cardiopulmonary Cardiac compression board CPR board (cardiopulmonary resuscitation)	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 Spine board	A flat, stiff device placed on a stretcher to ensure spinalImmobilization when a spinal injury is suspected.
Bottle	**Bottle, heating/cooling** Hot/cold water bottle	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 applying heat or cold therapy to an area of the body.

Keyword	Device identifier	Description/Intended Use
Brush	**Brush, cleaning surgical scrub** Brush, scrub, operating room Brush, surgical scrub Scrub brush, surgical	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 flat handle or a block with side grips on one side, and bristles, fibers, or spines are typically mounted along a single plane.
Chair	**Chair, bath/shower**	A device designed to be sat 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 Commode, fixed, mobile; adjustable	A chair designed with a toilet-like seat that allows an immobilized person/ patient to utilize a standard stationary toilet without leaving the chair.

Keyword	Device identifier	Description/Intended Use
	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** Shade guide, dental	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 Colour blindness test chart Colour discrimination chart	An ophthalmic chart with colouredfigures printed on coloured backgrounds, used in testing colour vision.
	Chart, visual acuity Vision test chart Visual acuity chart	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 with back ground electrical lighting.

Keyword	Device identifier	Description/Intended Use
	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	**Clip, spectacle, ophthalmic** Clip, lens, trial, ophthalmic	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** Heating pad, chemical Cooling pad, chemical	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 Cold compress Cold pack	A device that is intended to be applied with pressure to a body surface and/or underlying tissue, e.g muscle. This device typically consists of a compact fabric envelope containing a hydrated pliable silicate gel capable of forming to the contour of the body.

Keyword	Device identifier	Description/Intended Use
	Compress, hot/cold Pack Hot/cold pack	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** Rayon balls	A spherical mass of cotton or man-made 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 usually made of cotton and is disposable.
	Cotton roll, general purpose	A device usual made of medical cotton or sometimes man-made fibers that have a general- purpose use throughout hospitals and other areas of the healthcare sector.

Keyword	Device identifier	Description/Intended Use
Cover	**Cover, thermometer** Thermometer probe cover	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.
Couch	**Couches** 2 section, 3 section, neurology, Paediatric, Elite Aster, Elite 7-section, Bariatric, Aplit leg orthopedic, ultrasound, Podiatry couch	Very stable and rigid examination couch. These couches will provide much assistance in the reduction of manual handling issues, as well as provide a comfortable surface for the patient to be positioned. They provide smooth electric positioning of height, tilt and backrest angle, this couch features a compact base frame and is ideal for both supine and seated procedure
Depressor	**Depressor, tongue** Wooden tongue depressors	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.
	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

Keyword	Device identifier	Description/Intended Use
	Immobiliser, elbow	A non-rigid device, usually made 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.

Keyword	Device identifier	Description/Intended Use
	Immobiliser, shoulder, reusable	A non-rigid device used to temporarily immobilize or limit abduction of the shoulder joint (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 Wrist restrainer	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** Urine absorbing aid, body-worn Diapers (Infants and Adults) Incontinence diapers	A disposable inner incontinence pants, liner composed of absorbent materials used to collect urine and faeces from the patient.

Keyword	Device identifier	Description/Intended Use
Lens	**Lens Set, trial** Trial lens set, ophthalmic	A set of ophthalmic lenses of various dioptric powers intended to be handled or inserted in a trial frame for vision testing to determine the required refraction.
Light	**Light, head-worn** Headlamp, operating Headlight Headlight, fiberoptic focusing Light, headband, surgical Light, surgical headlight	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 fiberoptic cable to transfer cold- light, or power supply from a battery pack.
	Light, surgical Lamp, operating-room Lamp, surgical Lamp, surgical incandescent Light, surgical, ceiling mounted Light, surgical, connector Light, surgical, floor standing Light, surgical instrument Operating room light Operating shadowless Light OR light Surgical lamp	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), this 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.

Keyword	Device identifier	Description/Intended Use
	Light, examination, hand held, battery-powered Light, examination, medical, battery powered	A small hand-held battery-powered light used as a personal light source to provide light for local examination, inspection and 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.
	Light, Examination Examination light Light, examination, ceiling-mounted	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.
	Light, ear Ear light	A dedicated device designed to illuminate the ear canal.
	Light, dental, intraoral Lamp, intraoral, examination Light, dental, fibreoptic	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.

Keyword	Device identifier	Description/Intended Use
	Light, dental, general-purpose Dental operating light Light, operating, dental	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.
Loupe	**Loupe, binocular** Binoculars, surgical Loupe, binocular, low power Loupe, operating Magnifier, operating Spectacle, operating (loupe), ophthalmic	A system of lenses mounted onto a 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	**Mask, resuscitation** Mask, mouth-to-mask, Resuscitation CPR Mask Pocket Mask	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.
	Mask, surgical	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.

Keyword	Device identifier	Description/Intended Use
Mirror	**Mirror, ENT, Hand-held**	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.
	Mirror, ENT, headband	An instrument with a circular concave mirror attached to a headband acting as a reflector that 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, hand-held	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.

Keyword	Device identifier	Description/Intended Use
Orthosis	**Orthosis, foot/ankle** AF (Ankle/Kids foot orthosis) Ankle joint orthosis Ankle support Joint, ankle, external Brace Prostep / Equiflex Foot Orthosis	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 orthopedic 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.
	Orthosis, thoracic spine Orthosis, thoracic TO (Thoracic orthosis)	An orthopedic 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 CTO (Cervico/Thoracic orthosis, Orthosis, cervical-thoracic, rigid	An externally applied orthopedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.

Keyword	Device identifier	Description/Intended Use
	Orthosis, cervical spine Cervical collar CO (Cervical orthosis) Collar, cervical Support, neck	An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervical spine.
	Orthosis, lumbosacral spine Belt, lumbosacral LSO (Lumbosacral orthosis) Orthosis, lumbo-sacral	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** 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	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 Under-lay but can also be formed to accommodate the patient's body shape, prominent or unprotected bony parts, e.g., as mattresses (both active and passive), pads or skins of different materials.
Protector	**Finger protector** Finger splint	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.

Keyword	Device identifier	Description/Intended Use
Projector	**Projector, visual acuity** Projector, chart, eye Projector, ophthalmic Vision test projector	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** Bandage clasp Bandage retainer Bandage, elastic net	A device used to stabilize, 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.
Scale	**Scales** Weighing scale Chair weighing scale	A device used to measure weight of the person so that to enhance treatment, diagnosis etc. of the person.
Shield	**Shield, eye** Eye patch	A mechanical shield used for protection of one or both eyes following surgery or trauma. These shields usually are plastic or metallic.
	Shield, face Goggles	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.
	Shield , hip	A mechanical guard worn over the hip area to prevent against hip fractures in the event of a patient fall.

Keyword	Device identifier	Description/Intended Use
	Shield, wound Protector, wound	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** Orthopaedic shoe Orthosis, corrective shoe Shoe, corrective	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** Sling, arm Sling, knee Sling, leg Clavicle strap	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.

Keyword	Device identifier	Description/Intended Use
Spectacles	**Spectacles** Astigmatism spectacles Eyeglasses Farsightedness spectacles Nearsightedness Spectacles Presbyopia spectacles Special spectacles Vision corrective spectacles	An optical/ophthalmic device consisting of a spectacle frame that contains a pair of spectacle lenses (eyeglasses).
Splint	**Splint** Splint, traction Splint, wire board Splint, extremity, external Splint, hand/finger Splint, moldable Splint, moulded aluminium Splint, moulded plastic Splint, padded stays Splint, air	A rigid or semi-rigid device that serves to immobilize an injured body or body part. It is generally placed externally along the injured limb or body part. It is typically made of plastic, moldable plastic, wood or metal.
	Splint, nasal, external	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 atruss-like support on the outside of the nose.

Keyword	Device identifier	Description/Intended Use
Stocking	**Stocking, anti-oedema, arm/leg** Anti-oedema stocking, arm/leg Compression stocking Legging, compression, non-inflatable Stocking, compression Compression socks	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.
	Stocking, medical support Sock, fracture Stocking, elastic	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 improvement.
Stretcher	**Stretcher** Bed, stretcher Stretcher, mobile Stretcher, powered Stretcher, transfer Stretcher, wheeled, powered stretcher, wheeled Stretcher, hospital	A device on which a patient lies for transport or reclines after treatment. It may have a wheeled undercarriage, which can be foldable.

Keyword	Device identifier	Description/Intended Use
	Stretcher, ambulance Ambulance stretcher Stretcher, mobile, ambulance	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 Stretcher, hand-carried Stretcher, portable, basket 2 fold stretcher Pole stretcher Scoop stretcher	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** Swab, cotton Swab, specimen collecting	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 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.

Keyword	Device identifier	Description/Intended Use
Table	**Table, examination/ treatment** Examination bed	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 Instrument trolley, with or without drawers	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.

Keyword	Device identifier	Description/Intended Use
	Table, Operation Table and attachment, operating- room Table, operating Table, operating- room Table, traction Table, operation, gynecological Table, operation, ophthalmic Table, operation, orthopaedic	A device used to support the patient's body during surgical procedures, stabilizing the patient's 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.
	Table, birthing Birthing table Table, obstetrical	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** Apparatus, traction, non-Powered Unit, traction, hip, non-powered, non-penetrating Extension and traction Equipment Static traction unit Traction unit, static, bed Traction unit, static, chair	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.

Keyword	Device identifier	Description/Intended Use
Traction unit, noninvasive component	**Traction unit noninvasive component** Frame, traction Head halter, traction Pelvic, traction belt Tong, skull for traction Weights, Cervical traction, Lumbar traction, Over door traction, Water bag	A noninvasive 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.
Transfer Aid	**Transfer aid, person** Board, patient transfer Chair, patient transfer Patient transfer aid Sliding board/mat Sheet, patient turning Turning sheet Turning carpet	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 bedsore; or to move the person between, e.g. an operating table and a bed, a wheelchair and a bath, or chair and toilet.
Walking Crutch	**Walking crutch** Crutch, axillary Crutch, elbow Crutch, forearm	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.

Keyword	Device identifier	Description/Intended Use
Walking Frame	**Walking Frame, Standard** Standing frame, mobile Walker, adjustable width Walker, folding Walker, mechanical Walker, standard Walker/chair, non-wheeled Walking chair Walker, side Walking frame, rigid, adjustable Walking frame, folding adjustable	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.
	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 Fore arm 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.

Keyword	Device identifier	Description/Intended Use
	Walking frame, wheeled Walker, wheeled Walker/chair. Wheeled Walking frame with wheels, pushed forward by the hands	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 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.
Walking Stick	**Walking Stick** 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	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.