TFDA/DMC/DMDAE/G/001

TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

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

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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
HSA	-	Health Science Authority
ISO	-	International Organization for Standadization
LRP	-	Local Responsible Person
MoHSW	-	Ministry of Health and Social Welfare
MSD	-	Medical Store Department
PHLB	-	Private Health Laboratory Board
QMS	-	Quality Management System
STD	-	Summary Technical Documentation
TFDA	-	Tanzania Food and Drugs Authority
TFDCA	-	Tanzania Food, Drugs and Cosmetic Act of 2003

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Foreword

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, 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 or free distribution after assessment of safety and performance.

In order to address various concerns from stakeholers and the general public, the Authority has decided to set up a framework for regulating medical devices in Tanzania. To begin with, the Authority has developed this guideline which defines requirements for registration of medical devices.

The guideline is 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 guideline has 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 of medical devices.

Applicants are encouraged to familiarize with the 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 this guideline 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 in unnecessary delays in giving approvals.

Since science is always dynamic and due to the fact that the field of medical devices keeps changing overtime, the Authority will welcome inputs and comments that will help in improving the guideline.

M. Ndomondo-Sigonda
Director General
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Introduction

This guideline has been developed to provide guidance for 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 Cosmetics Act, 2003 which among other things prescribes conditions of registration of devices in Tanzania.

The conditions include; the medical device is safe and efficacious, the premises and manufacturing operations comply with the current Good Manufacturing Practices (GMP) requirements as provided in the regulations and the medical device complies with any other requirements as may be prescribed by the Authority.

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

(a) Principles of Medical Device Classification: GHTF/SG1/N15:2005
(b) Essential Principles of Safety and Perfomance 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/N011:2008

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.

This guideline apply to products that fall within the definition medical devices or devices except *in-vitro* diagnostic devices. The guideline is divided into the following sections:

(a) General Requirements
(b) Device Details
(c) Summary Technical Documentation
(d) Labelling 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 this guideline. Applicants are also requested to read the guideline together with the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made thereunder.

DEFINITION OF TERMS

In the context of this guideline, the following terms shall be defined as follows:

Authority
Means the Tanzania Food and Drugs Authority.

Conformity Assessment
The 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
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 legal practitioner's official stamp and signature.

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

Clinical Investigation
Any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.

General Medical Device
Refer to products falling within the definition of medical devices except *in-vitro* diagnostic medical device.

In Vitro Diagnostic Medical Device
A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from 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
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.

Labelling / information supplied by the manufacturer
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
Includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of medical devices.

Manufacturer
Means any natural or legal person[1] 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
Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is -

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

Medical Device Family
A group of medical devices that are made by the same manufacturer that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Medical Device Group
Medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name.

Medical Device System
A medical device comprising a number of components or parts intented to be used together to fullfill some or all of the device's intended functions and that is sold under a single name.

[1] The term "person" includes legal entities such as a corporation, a partnership or an association.

National Standard
A standard as prescribed by the Tanzania Bureau of Standards (TBS).

Objective Evidence
Information that can be proved true, based on facts obtained through observation, measurement, testing or other means.

Performance Evaluation
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
Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

Quality System
System which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System
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
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 to notify its owners and users of 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 the requirements of the Act or regulations.

Recognised Standards
National or International standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Technical Documentation
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
Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

1. GENERAL REQUIREMENTS

All applications shall be made by submitting a dully filled in application form (annex 1) accompanied with prescribed information as detailed in these guidelines.

1.1 Applicant

An application for registration of medical device(s) can be made by a manufacturer or by a person who orders the device to be manufactured for sell in Tanzania.

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

An applicant who is not a resident in Tanzania shall nominate a Local Responsible Person (LRP). A certified copy of power of attorney, formal agreement or any other official authorization shall be submitted by an applicant as official proof of nomination of a LRP.

1.2 Local Responsible Person

A local responsible person is natural person residing in Tanzania or cooperate body registered in Tanzania who has received a mandate from the applicant to act on his behalf with regard to matters pertaining to registration of devices in Tanzania.

The Local Responsible Person shall:

(a) Monitor 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) Facilitate communication between the applicant and the Authority on matters relating to the product.

(c) Handle device recalls.

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

1.3 First time application

A separate and complete product dossier in both hard copy and electronic form on a CD-ROM is required for each single medical device or a medical device group or medical device family or medical device system.

Applications shall be accompanied by the following:

(a) A non-refundable application fee.

(b) Five (5) Sample(s) of the device or artwork where applicable at the time of lodging an application for screening.

1.4 Documentation

1.4.1 Language

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

1.4.2 Paper type and binding

Data shall be presented on A4 and 80g/m^2 paper with readily readable letters of at least 12 font sizes. 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.

1.5 Classification of general medical devices other than *In-Vitro* Diagnostic (IVD) medical devices

Devices should be classified into one of the 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

Classification should be done based on classification rules promulgated by the Global Harmonization Task Force (GHTF) under the document titled "Principle of Medical Devices Classification" which can be obtained at http://www.ghtf.org/documents/sg1/SG-N15-2006-classification-FINAL.pdf. 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.

1.6 Regulatory control of medical devices

Burden of regulatory controls takes into account the risk associated with medical device. Therefore, not all medical devices shall be subjected to product registration.

1.6.1 Medical devices exempted from registration

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 IV** 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 is different from that specified in the list, then the 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.

Note:

Every importer shall be required to submit list of medical devices exempted from registration to TFDA at the time of renewing permit for medical device business. Submission of such list is a requirement for a dealer to obtain a permit.

1.6.2 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 II of this guideline.**

1.6.3 Submission requirements for Class A medical devices not exempted from registration

Submission of application in format prescribed for Class B, C and D medical devices under item 1.6.2 above is not required for Class A non-exempted medical devices. **The submission requirements for Class A medical devices not exempted from registration are stipulated in annex III of this guideline.**

1.7 Payment of fees, screening and processing of applications

1.7.1 Payment of fees

Every application shall be accompanied by appropriate fees as specified in these guidelines. The fees specified in these guidelines shall be read *mutatis mutandis* with Fees and Charges Regulations and its guidelines in force at the time of application. Any application that will not be accompanied by appropriate fees will not be screened or evaluated.

(a) Application Fees for Class A (non-exempt) Medical Devices

Screening Fees per dossier - US$ 25

(b) Application Fees for Class B, C and D Medical Devices

(i) Screening Fees per dossier - US$ 50

(ii) Evaluation Fees per dossier

Risk Class	Fees
Class B	US$ 500
Class C	US$ 750
Class D	US$ 1000

Screening fees is payable at the time of lodging an application and evaluation fee is payable once an application has been accepted for evaluation.

The fees may be paid directly to TFDA or by bank transfer to:-

Tanzania Food and Drugs Authority,
Account No. 100380013 USD, Citibank, Tanzania Ltd. Dar es Salaam – Head office Peugeot House, 36 Upanga Road, P. O. Box 71625, Dar es Salaam Tanzania Swift Code: CITITZTZ.

Local currency: Account No. 6503900110, National Microfinance Bank, Kariakoo Branch OR by banker's draft.

When payment is made by bank transfer all bank charges shall be borne by the applicant who shall also make sure that advice note is submitted to TFDA giving details of the payment in particular the name of the applicant, the device or devices paid for and amount of fees paid.

Both screening and evaluation fees are non-refundable once paid to the Authority.

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

Risk Class	**Annual Retention Fees**
Class A	US$ 25
Class B	US$ 40
Class C	US$ 60
Class D	US$ 100

1.7.2 Screening of application

The application will be screened before can be accepted for evaluation to ensure that there are no major deficiencies that would hinder the evaluation. If any major deficiencies are identified during the screening, an input request will be made to the applicant. The applicant will be required to submit all The requested information and material identified in the input request within **60 calendar days** from the date of request. Any deficiencies indicated must be adressed before the application can be accepted for evaluation.

If the applicant anticipates difficulty in responding in full or within the specified timeframe, they should contact the authority to discuss the request for information as soon as possible after receipt of the input request for information/clarification.

If the applicant fails to provide all requested information, or the submitted information is incomplete, deficient or contains unsolicited information, the application will be rejected.

If the applicant wishes to resubmit the application at a future time, it will be processed as a new application.

The following applications will be rejected at screening stage:-

(a) Application for device products that are not medical devices;
(b) Application not submitted in the prevailing required format;
(c) Low risk (Class A) medical device applications submitted via the medium (Class B and C) and high risk (Class D) product registration route, or vice versa.

1.7.3 Processing of applications

Once an application has been accepted and evaluation fees paid the processing of application will take 270 calender days. This will involve evaluation of application, request for additional data/samples and clarification of some issues where applicable.

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 six months the application will be rejected.

As part of evaluation of the medical device, pre-registration GMP inspection or Quality System audit may be conducted to verify compliance thereof.

1.8 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.

1.8.1 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:-

(a) payment of annual retention fees as prescribed in current fees and charges regulations.

(b) submission of biannual post-marketing surveillance reports.

(c) submission of adverse effects reports associated with the use of device.

1.8.2 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 by giving 60 days written notice and reasons to the TFDA terminate the registration of a device.

1.8.3 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 registation of a medical device and if not satisfied it shall reject the application. In case the applicant is not satisfied with the decision, may appeal to the Minister responsible for Health.

1.9 Application for variation of a registered device

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; and

(d) the intended use of the device, including any new or extend 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. Any other change(s) should be notified immediately to the Authority and may be implemented without prior approval.

All applications for variation to a registered device shall be made in writing and shall be accompanied by variation fee as prescribed in Fees and Charges Regulations and its Guidelines in force at the time of application.

1.10 Applications for renewal of registration

Applications for renewal of registration shall be made at least 90 days before the expiry date of registration of the device. The application shall include submission of filled in application form (annex 1) and information pertaining to changes that were made to a registered device.

1.11 Compilation of the dossier

Applicants are required to arrange the application dossier for Class B, C and D in the format described below:-

(a) The application form (annex I)
(b) Device Details (item 2 of the guideline)

(c) Summary technical documentation (item 3 of the gudeline)
(d) Labelling information (item 4 of the guideline)
(e) Essential requirement checklist (annex II of the dossier)

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

2. DEVICE DETAILS

2.1 Name(s)

State the generic and brand name of the device.

2.2 Description

Provide a general description 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

State the intended use 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.

2.5 Instruction 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.

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.

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 a detailed description of the device attributes that are necessary to explain how the device functions. The details should include:-

(a) The principle of operation of the device

(b) Description of the key functional elements of the device e.g. its parts/components, formulation, composition and functionality.

(c) 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 II.**

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:-

(a) Compliance with a recognized or other standard(s)

(b) Internal industry methods

(c) 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.

Reference:

- Essential Principles of Safety and Performance of Medical Devices

  http://www.ghtf.org/documents/sg1/sg1n41r92005.pdf

3.3 Materials

Provide description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device.

3.4 Device Specifications

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.

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. Whenever applicable the information should cover:-

(a) Engineering tests.

(b) Laboratory tests.

(c) Simulated use testing.

(d) Animal tests for demonstrating feasibility or proof of concept of the finished device.

(e) Any published literature regarding the device or substantially similar devices.

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

Declarations/certificate of compliance to a recognized standard as applied by the manufacturer should be provided.

3.5.1 Biocompatibility (if applicable)

Provide details of all biocompatibility tests conducted on materials used in a device. At a minimum, tests must be conducted on samples from the finished and sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the analysis of data must be presented.

3.5.2 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 verification, validation protocol 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 labelling.

3.5.3 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.

3.5.4 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 manufacture's 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.

3.5.5 Clinical Evidence (if applicable)

Provide detailed information on clinical evaluation studies undertaken to demonstrate compliance of the device with the Essential Principles of Safety and Performance. The clinical evaluation report should be summarized as per current GHTF guidance documents.

Reference:

- Clinical Evaluation

  http://www.ghtf.org/documents/sg5/sg5_n2r8_2007final.pdf

3.6 Risk Analysis

Provide a summary of the risks identified during the risk analysis process and how such risks have been controlled to an acceptable level. Preferably, the risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.

3.7 Manufacturing Information

Provide details of 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. A brief summary of the sterilization method and processing should be included, if any.

If multiple facilities are involved in the manufacture of device, the physical address and overview of activities for each facility should be provided.

4. LABELLING REQUIREMENTS

Labelling information shall be in English and/or Kiswahili and shall be expressed in a legible, permanent and prominent 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:-

(a) the name of the device
(b) the name and address of the manufacturer
(c) 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
(d) batch or lot number
(e) if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units
(f) the words "Sterile" if the manufacturer intends to sale the device in a sterile condition
(g) the words "for single use only" if the device is intended for that puporse
(h) the expiry date of the device expressed in month and year
(i) 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
(j) the directions for use, unless directions are not required for the device to be used safely and effectively and
(k) any special storage conditions applicable to the device

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

(a) shall be set out on the outside of the package that contains the device; and be visible under normal conditions of sale
(b) 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 sell

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 labelling a device.

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 Manufacturer		
B1	Manufacturer's name		
	Address of Head Office		
	Physical address of the site		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	

	Website:	
B2	Quality Management System Established by the Manufacturer Standards with which the system complies: ☐ ISO 9001:2000 ☐ ISO 13485:2003 ☐ ISO 9001:2008 ☐ GMP ☐ Others _____ **(*please specify)*** ☐ 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 Local Responsible Person (LRP)	
C1	LRP's name Address (*Please give the registered place of business, if any*) 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 LRP 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	
D11	Reasons for classifying the device as Class A, B, C or D device: _____ _____ _____	

D12	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 elements. (ii) Information 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

ESSENTIAL REQUIREMENTS CHECK LIST		
Brand name : _____	**Common name: _____**	**RISK CLASS: _____**

	Essential Principal	Applicable to the device?	Method of Conformity	Identity of specific Documents
1.	**<u>GENERAL REQUIREMENTS</u>** The device must be designed & manufactured in such a way that, when used under the conditions & for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety & health of users or, where applicable, other persons, provided 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 & safety.			
2.	The solutions adopted by the manufacturer for the design& construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently			

	safe design & construction) - where appropriate take adequate protection measures including alarms, if necessary, in related to risks that cannot be eliminated - inform users of the residual risks due to any shortcomings of the protection methods adopted.			
3.	The devices must achieve the performance intended by the manufacturer and be designed, manufactured & packaged in such a way that they are suitable for one or more of the functions referred to as specified by the manufacturer.			
4.	The characteristics & performances referred to in sections 1,2 & 3 must not be adversely affected to such a degree that the clinical condition & safety of the patients & 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.			
5.	The devices must be designed, manufactured & packed in such a way that their characteristics & performances during their intended use will not be adversely affected during transport & storage taking account of the instructions & information provided by the manufacturer.			
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.			
7.	**DESIGN AND MANUFACTURING REQUIREMENTS**			

7.1	Chemical, physical & biological properties The devices must be designed & manufactured in such a way as to guarantee the characteristics & performance referred to in Section 1 on the " General Requirements" Particular attention must be paid to: - choice of materials used, particularly as regards toxicity and, where appropriate flammability; - the compatibility between the materials used and biological tissues, cells& body fluid, taking account of the intended purpose of the device;			
7.2	The devices must be designed, manufactured & packed in such a way as to minimise the risk posed by contaminants & residues to the persons involved in the transport, storage & use of the devices & to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed & the duration & frequency of the exposure.			
7.3	The devices must be designed & manufactured in such a way that they can be used safely with the materials, substances& gases with which they enter into contact during normal use or during routine procedures; if they are intended to administer medicinal products they must be designed & manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.			
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered			

	to be a medicinal product & which is liable to act upon the body with action ancillary to that of the device, the safety, quality & usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods			
7.5	The devices must be designed & manufactured in such a way as to reduce as much possible, risks posed by the unintentional ingress of substances into the device taking into account the device & the nature of the environment in which it is intended to be used.			
8. 8.1	**<u>Infection & microbial contamination</u>** The devices & their manufacturing processes must be designed in such a way as to eliminated or reduce as far as is possible the risk of infection to the patient, user & third parties, the design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.			
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls & surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, prevention, testing & handling of tissues, cells & substances of animal origin must be carried out so as to provide optimal security. In particular, safety with regard to viruses & other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.			

8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non- reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market & remain sterile, under the storage & transport conditions laid down, until the protective packaging is damaged or opened.			
8.4	Devices delivered in a sterile state must have been manufactured & sterilised by an appropriate, validated method.			
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.			
8.6	Packaging systems for non-sterile devices must keep the product without deterioration in the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.			
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in sterile and non- sterile condition.			
9. 9.1	**<u>Manufacturing and environmental properties</u>** If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must specified performance of the			

	devices. Any restrictions on use must be indicated on the label or instruction for use.			
9.2	Devices must be designed & manufactured in such a way as to remove or minimise as far as possible: - the risk of injury, in connection with their physical features, including the volume/ pressure ratio, dimension, and where appropriate the ergonomic features, - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration - 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 the materials used or loss of accuracy of any measuring or control mechanism.			
9.3	Devices must be designed & manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use included exposure to flammable substance 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			
10.	**Devices with a measuring function.**			

10.1	Devices with a measuring function must be designed & manufactured in such a way as to provide sufficient accuracy & stability within appropriate limits of accuracy & taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.			
10.2	The measurement, monitoring & display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.			
10.3	The measurements made by devices with a measurements made by devices with a measuring function must be expressed in legal units conforming to the metric system.			
11. 11.1 11.1.1	**<u>Protection against radiation</u>** General Devices shall be designed & manufactured such that exposure of patients, users& other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic & diagnostic purposes.			
11.2 11.2.1	**<u>Intended radiation</u>** Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks			

	inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed & manufactured to ensure reproducibility & tolerance of relevant variable parameters.			
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warning of such emissions.			
11.3 11.3.1	**Unintended radiation** Devices shall be designed & manufactured in such s way that exposure of patients, users and other persons to the emission if unintended, stray or scattered radiation must be reduced as far as possible.			
11.4 11.4.1	**<u>Instructions</u>** The operating instructions for devices emitting radiation must 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 & of eliminating the risks inherent in installation.			
11.5 11.5.1	**<u>Ionising radiation</u>** Devices intended to emit ionising radiation must be designed & manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied & controlled taking account of the intended uses.			

11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed & 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 ionising radiation, intended for therapeutic radiology shall be designed & manufactured in such a way as to enable reliable monitoring & control of the delivered dose, the beam type & energy & where appropriate the quality of the radiation.			
12. 12.1	**<u>Requirements for medical devices connected to or equipped with an energy source</u>.** Devices incorporating electronic programmable systems must be designed to ensure the repeatability & performance of these systems according to their 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 possible consequent risks.			
12.2	Devices where safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.			
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.			
12.4	Devices intended to monitor one or more clinical			

	parameters of a patient must 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 must be designed & manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.			
12.6 12.6.1	**<u>Protection against electrical risks</u>** Devices must be designed & manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use& in single fault condition, provided that the devices are installed correctly.			
12.7 12.7.1	**<u>Protection against mechanical & thermal risks</u>** The devices must be designed and manufactured in such a way as to protect the patient & user against mechanical risks connected with, for example, resistance, stability & moving parts.			
12.7.2	The devices must be designed & manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress & of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			

12.7.3	The devices must be designed & manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress & of the means available to reduce noise, particularly at source, unless the emitted is part of the specified performance.			
12.7.4	The terminals& connectors to the electricity, gas or hydraulic & pneumatic energy supplies which the user has to handle must be designed & constructed in such a way as to minimise all possible risks.			
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) & their surroundings must not attain potentially dangerous temperatures under normal use.			
12.8 12.8.1	**Protection against the risks posed to the patient by energy supplies or substances** Devices for supplying the patient with energy or substances must be designed & constructed in such a way that the flow rate can be set & maintained accurately enough to guarantee the safety of the patient & the user.			
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow –rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			

12.9	The function of the controls & indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operation or adjustment parameters by means of a visual system, such information must be understandable to the user &, as appropriate, the patient.			
13. 13.1	**Information supplied by the manufacturer** 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.			
14.	**Performance evaluation including, where appropriate, clinical evaluation**			
14.1	All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable			
14.2	Clinical investigation 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: _____

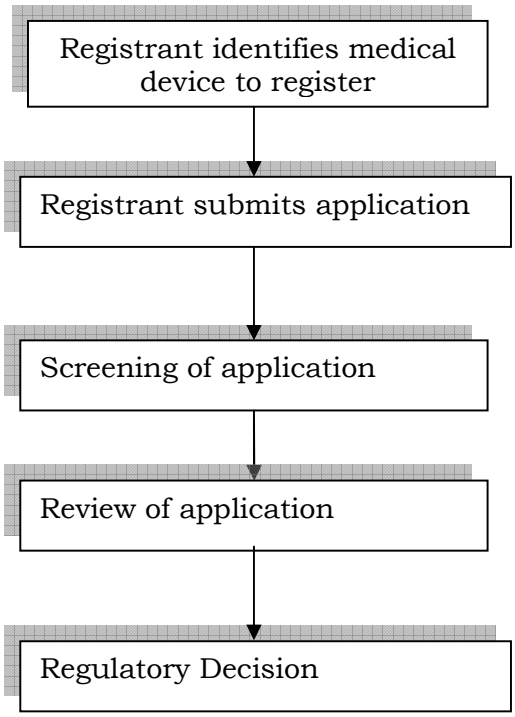
Position: _____

Date: _____

Annex III

THE APPLICATION PROCESS FOR CLASS A MEDICAL DEVICES NOT EXEMPTED FROM REGISTRATION

The process described below is applicable solely to Class A medical devices that are not exempted from medical device product 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:

- The class A medical device is correctly classified, i.e it is not a class B, C or D medical device;
- 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 IV

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 hat 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.
	Adhesive strip *Adhesive strip, general-purpose* *Closure, wound, adhesive* *Strip, adhesive, general purpose*	A small, narrow flexible band (of fabric, plastic, paper, or other material) coated on one side with a pressure- sensitive adhesive, used to cover or approximate the edges of superficial wounds or fix dressings to skin. The device may include an adhesive pad and have qualities such as hypoallergenic or

Keyword	Device identifier	Description/Intended Use
	Adhesive strip, butterfly	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 pressure-sensitive adhesive, used to cover a surface (e.g. small wound), fix a dressing, or bind/attach objects (e.g. a venflon to a patient's body part). The device may also be applied in several layers, one overlapping the other, to cover and exert pressure on a body part (e.g. a limb). The device may have additional properties (e.g., waterproof, hypoallergenic) and is typically supplied in rolls. This is a single –use device.
	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.
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

Keyword	Device identifier	Description/Intended Use
		walls. The device may include a holder that keeps the bag in place.
Bandage	**Bandage, self-adherent**	A flexible piece, strip, or roll of fabric or plastic material that is applied to (typically wrapped around) a part of the body to secure a dressing, maintain pressure over a compress, or immobilize a limb or other body part. This is usually a single-use device.
	Bandage, clavicle	A strip or roll of fabric or webbed material that is wrapped around the shoulder girdle to maintain fixation and longitudinal extension of the clavicle during a period of treatment. This is a single-use device.
	Bandage, elastic	An elasticized fabric (e.g., polyamide, lycra) used to provide support or local pressure to a part of the body, especially a joint, while allowing movement. It may have various configurations (e.g. long flat strip, tubular) to accommodate various body parts (e.g. ankles, knees, wrists, neck). This is a reusable device.
	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*	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

Keyword	Device identifier	Description/Intended Use
	Elastic bandage *Crepe Bandage*	support for varicose veins or ostomy aids. This is a single-use device.
	Bandage, traction	A large strip of fabric or plastic material used to assist in exerting desirable tensile (pulling) forces on the body. This is a single-use device.
Bed	**Bed, hospital** *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.
	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

Keyword	Device identifier	Description/Intended Use
		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.
Board	**Board, arm**	A firm device in which a patient's arm is placed for stabilization to maintain the patency of an intravascular catheter, e.g those connected to an intravenous or intra-arterial line. It is typically constructed of expanded polystyrene with a plastic coating and can be straight or curved to accommodate the patient's arm/wrist.
	Board, cardiac	A flat, rigid device that is placed

Keyword	Device identifier	Description/Intended Use
	compression *Board, cardiopulmonary* *Cardiac compression board* *CPR board (cardiopulmonary resuscitation*)	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 spinal immobilization 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.
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

Keyword	Device identifier	Description/Intended Use
		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.
	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	An ophthalmic chart with coloured figures printed on coloured

Keyword	Device identifier	Description/Intended Use
	Colour blindness test chart *Colour discrimination chart*	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.
Clip	**Clip, nose**	A device used to help prevent air movement through the nares. The device is typically constructed of plastic with rubber or foam tips and is used during pulmonary function studies to help ensure that airflow is conducted through the mouthpiece for accurate measurements.
	Clip, spectacle, ophthalmic *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**	A device that is intended to be applied with pressure to a body surface to provide cold therapy to that surface and/or underlying

Keyword	Device identifier	Description/Intended Use
	Heating pad, chemical *Cooling pad, chemical*	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.
	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.

Keyword	Device identifier	Description/Intended Use
	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.
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.
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

Keyword	Device identifier	Description/Intended Use
		injury or surgical wound.
	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.
	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

Keyword	Device identifier	Description/Intended Use
		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* *Adult diapers* *Incontinence diapers*	A disposable inner incontinence pants, liner composed of absorbent materials used to collect urine and faeces from the patient.
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*	A device (a lamp), designed to be worn on an operator's head. It is mounted on a band or helmet frame

Keyword	Device identifier	Description/Intended Use
	Headlight *Headlight, fiberoptic focusing* *Light, headband, surgical* *Light, surgical headlight*	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), which reflects the light via reflectors or mirrors depending upon the construction. This device will typically be part of a light system comprising more than one light head.
	Light, examination, hand held, battery-powered *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

Keyword	Device identifier	Description/Intended Use
		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.
	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*	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

Keyword	Device identifier	Description/Intended Use
	Magnifier, operating *Spectacle, operating (loupe), ophthalmic*	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.
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

Keyword	Device identifier	Description/Intended Use
		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.
Orthosis	**Orthosis, foot/ankle** *AF (Ankle foot orthosis)* *Ankle joint orthosis* *Ankle support* *Joint, ankle, external brace*	An externally applied orthopedic appliance or apparatus used to support, align, prevent, or correct deformities/injuries or to improve function of the ankle and/or foot.
	Orthosis, sacroiliac spine *Orthosis, sacroiliac, soft* *Sacroiliac orthosis*	An externally applied orthopaedic appliance or apparatus that encompasses the thoracic spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine through compression of the abdomen.
	Orthosis, thoracic spine *Orthosis, thoracic* *TO (Thoracic orthosis*)	An orthopaedic corset that encompasses the thoracic spine region of the trunk and is used to support or immobilize deformities, fractures, sprains, or strains of the spine through compression of the abdomen.

Keyword	Device identifier	Description/Intended Use
	Orthosis, cervicothoracic spine *CTO (Cervico/Thoracic orthosis,* *Orthosis, cervical-thoracic, rigid*	An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.
	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 underlay 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.

Keyword	Device identifier	Description/Intended Use
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.
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 stabilise, attach, or fix a bandage/ dressing in a desired location. This device can be a fastener/clasp (e.g., an elastic strip with opposing gripping teeth/ hooks), or a tubular elastic net. It is typically used on patients sensitive or allergic to adhesive tape. This device is single–use.
Shield	**Shield, eye** *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.
	Shield, wound *Protector, wound*	A mechanical shield that is designed to form a protective structure over a wound. It may be

Keyword	Device identifier	Description/Intended Use
		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*	Orthopaedic 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.
Spectacles	**Spectacles** *Astigmatism spectacles* *Eyeglasses* *Farsightedness spectacles* *Nearsightedness spectacles*	An optical/ophthalmic device consisting of a spectacle frame that contains a pair of spectacle lenses (eyeglasses).

Keyword	Device identifier	Description/Intended Use
	Presbyopia spectacles *Special spectacles* *Vision corrective spectacles*	
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 immobilise 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 a truss-like support on the outside of the nose.
Stocking	**Stocking, anti-oedema, arm/leg** *Anti-oedema stocking, arm/leg* *Compression stocking* *Legging, compression, non-inflatable*	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.

Keyword	Device identifier	Description/Intended Use
	Stocking, compression *Compression socks*	
	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.
	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*	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

Keyword	Device identifier	Description/Intended Use
	Pole stretcher *Scoop stretcher*	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.
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

Keyword	Device identifier	Description/Intended Use
		and in some cases may be attached to the operating table.
	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.
Traction unit,	**Traction unit noninvasive component**	A noninvasive traction device, e.g., a head halter, pelvic belt or a traction

Keyword	Device identifier	Description/Intended Use
noninvasive component	*Frame, traction* *Head halter, traction* *Pelvic traction belt* *Tong, skull for traction* *Weights* *Water bag*	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.
Walking Frame	**Walking Frame, Standard** *Standing frame, mobile* *Walker, adjustable width* *Walker, folding*	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

Keyword	Device identifier	Description/Intended Use
	Walker, mechanical *Walker, standard* *Walker/chair, non-wheeled* *Walking chair* *Walker, side* *Walking frame, rigid, adjustable* *Walking frame, folding adjustable*	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 forearm support, which is pushed along using the arms and/or upper body. It can be of fixed or adjustable height and collapsible and non-collapsible.
	Walking 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*	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

Keyword	Device identifier	Description/Intended Use
	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*	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.