ZANZIBAR FOOD AND DRUGS BOARD

Document number: ZFDB/004

GUIDELINE ON APPLICATION OF SUBMISSION OF MEDICAL DEVICES.

(Made under section 53 (1) of Zanzibar Food, Drugs and Cosmetics Act, 2006)

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ZANZIBAR FOOD DRUGS AND COSMETICS BOARD

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Protect and Enhance Health Care of Public Health

Acknowledgement:

This work has been developed with the input of ZFDB staff and pharmaceutical experts in the country whose contribution is greatly appreciated for enabling the development of this guideline of registration of human medicine.

I am most grateful to the following individuals who worked tirelessly in the preparation of these guidelines: Ms. Mayasa Ali Salum, Mr. Zahran Ali Hamad, Mr. Emmanuel Temu Joachim and Mr.Abdulrazak Juma Fakih. The contribution of all other staff of the Unit of Product Evaluation and Registration is very much acknowledged.

We would like to convey special thanks to WHO for financial support which helped us to accomplish this work.

We would also like to acknowledge Ms. Sophia Ali of TFDA for her technical assistance and guidance provided in developing this guideline.

Lastly but not the least, the assistance of Ms Salma Yussuf for typing and putting the guidelines into the present shape is highly appreciated.

Dr. Burhan Othman. Simai

Registrar

Zanzibar Food and Drugs Board.

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 Standardization
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
ZFDB	-	Zanzibar Food and Drugs Board
ZFDCA	-	Zanzibar Food, Drugs and Cosmetic Act of 2006

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

(i) Screening Fees per dossier (ii) Evaluation Fees per dossier - US$ 50

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

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.

Generic Name	

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 Zanzibar Food, Drugs and Cosmetics Act, 2006 which among other things prescribes conditions of registration of medical devices in Zanzibar.

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 Board.

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

(a) Principles of Medical Device Classification: GHTF/SG1/N15:2005
(b) Essential Principles of Safety and Performance of Medical Devices: GHTF/SG1/N41R9:2005
(c) Principles of Conformity Assessment of Medical Devices: GHTF/SG1/N40:2006
(d) Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices: GHTF/SG1/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 Labelling Requirements(d)
(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 Zanzibar Food, Drugs and Cosmetics Act, 2006 and Regulations made thereunder.

DEFINITION OF TERMS

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

Board
Means the Zanzibar Food and Drugs Board.

Conformity Assessment
The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Board, 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 person1 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, or use for any medical purposes 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 metabolized 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, color, flavor 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 intended to be used together to fulfill some or all of the device's intended functions and that is sold under a single name.

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.

Recognized 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, donation or use for medical purpose in Zanzibar.

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 Zanzibar shall nominate a Local or Resident Responsible Person (LRP/ RRP). 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 Zanzibar or cooperate body registered in Zanzibar who has received a mandate from the applicant to act on his behalf with regard to matters pertaining to registration of devices in Zanzibar.

The Local Responsible Person shall:

(a) Monitor the device on the market and inform the Board 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 Board 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 specified in Fee and Charges regulations

(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, including Technical documents shall be made in Kiswahili or English.

1.4.2 Paper type and binding

Data shall be presented on A4 and 80g/m 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.

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ISO	-	International Organization for Standardization
LRP	-	Local Responsible Person
MoHSW	-	Ministry of Health and Social Welfare
MSD	-	Medical Store Department
PHLB	-	Private Health Laboratory Board
QMS	-	Quality Management System

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 ZFDB 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 Board before they can be imported or supplied to Zanzibar. **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

very (Each) 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

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GMP	-	Good Manufacturing Practices
HSA	-	Health Science Authority
ISO	-	International Organization for Standardization
LRP	-	Local Responsible Person
MoHSW	-	Ministry of Health and Social Welfare

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) (shall) be paid directly to ZFDB or by bank transfer to:-

Zanzibar Food and Drugs Board, Account No. 021103000579, People's Bank of Zanzibar, – Head Office Mnazi Mmoja area, Kaunda road, P. O. Box 71625, Zanzibar – Tanzania.

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 ZFDB 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 Board.

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 annual retention fee is US$ 100 The registration number of the device must be quoted at the time of payment.

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 addressed 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 board 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 and language;

(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 place within 270 calendar (within 90) 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 ZFDB 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 ZFDB or terminated by the registrant. The validity of registration shall be subject

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HSA	-	Health Science Authority
ISO	-	International Organization for Standardization

1.8.2 Termination of registration

The ZFDB 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 ZFDB terminate the registration of a device.

1.8.3 Appeals

Any person aggrieved by a decision of the Board in relation to any application for registration of a medical device may make representations in writing to ZFDB.

If after consideration of the representations, the Board 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 Board 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 ZFDB approval before they can be implemented. Any other change(s) should be notified immediately to the Board 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 applicableEssential 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 recognized 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

Labeling 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 users.

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.
(d) Family or medical device group family.
(e) Batch or lot number.
(f) 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.

(g) The words "Sterile" if the manufacturer intends to sale the device in a sterile condition.

(h) The words "for single use only" if the device is intended for that purpose.
(i) The expiry date of the device expressed in month and year 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.

(j) If those specifications are necessary for proper use 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, labeling 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 labeling a device.

ZANZIBAR FOOD AND DRUGS BOARD

E-mail: znzfdb@yahoo.com

Tel No: +255-24-2233959

Fax No:+255-24-2233959

Website ; www .zanzhealth.info/zfdb

All letters should be addressed to the Registrar

Kaunda Road,

Mnazi Mmoja Area,

P.O. BOX 3595,

ZANZIBAR,

TANZANIA.

APPLICATION FORM FOR REGISTRATION OF MEDICAL DEVICES

Under Section No. 53 of the Zanzibar Food, Drugs and Cosmetics Act, 2006

Date: …… Application Number (for official use only)……

1. Particulars of Applicant

Name: ……..

Physical Address: …….. Postal

Address: ……..

Telephone:……...Fax:……..

Email:……

2. Particulars of a Resident Responsible Person

Name: ……..

Physical Address (*Please, the place of business should be registered, if any*)

…… Postal

address ……. Phone:

……. Fax: …… Email:

…….. …… Certified copy

of business registration certificate with business registration number

…….. is enclosed. Certified copy of Power of attorney or formal

agreement or any other official

Authorization of the Resident Responsible Person is enclosed. Please also state if this person is an importer of the device named in section 4.

3. Manufacturer and qualified person for manufacture of the product

3.1: Manufacturer

Name: …… Address of Head Office……... Physical Address: …… Postal Address: …… Website: …….. Contact Person: …… Phone: …… Fax: …… . Email: …….. ……

3.2: Quality Management System Established by the Manufacturer

Standards with which the system complies:

ISO 900:2000

ISO 13485:2003

ISO 9001:2008

GMP

Others _____ (Please specify)

System certified by _____ and certified copy of the certificate is enclosed.

Indicate areas covered by Quality Management System

Device design

Production

Post-production processes

Others (Please specify)

1. Particulars of the Device

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 Standardization
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
ZFDB	-	Zanzibar Food and Drugs Board
ZFDCA	-	Zanzibar Food, Drugs and Cosmetic Act of 2006

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

(i) Screening Fees per dossier (ii) Evaluation Fees per dossier - US$ 50

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

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.

Generic Name	29
Brand Name	
Model /Series / System	

	08.	Opthalmic and Optical devices
	09.	Reusable instruments
	10.	Single use devices
	11.	Technical aids for disabled person
	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 (*Please specify*)

ESSENTIAL REQUIREMENTS CHECK LIST

Brand name :	Common name:	RISK CLASS:

	Essential Principal	**Applicable to the device?**	**Method of Conformi**
1.	**GENERAL REQUIREMENTS** The device must be designed & manufactured in such a way that, when used under the		

4.2: Description of the device (*Please enter appropriate GMDN description. If none of the descriptions in the GMDN appears appropriate, enter a short description of the device)*

4.3: GMDN Code: …….. (Please enter if known)

4.4: Other common descriptions of the device

4.5: Intended use of device

4.6: Class of the medical device

Class A

Class B

Class C

Class D

4.7: Reasons for classifying the device as A, B, C or D Device:

4. 8: History

Is there any previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies?

Yes No

If *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

4.9: Performance and Safety International or National Standards with which the device complies (Please enclose the copy of standards)

5.Marketing Approvals in Foreign countries

5.1: Mention the countries where the device has obtained marketing approvals (Please enclose certified copy of valid marketing authorization)

5.2: Mention the countries where the device approval is still pending

6: Declaration of conformity (DoC)

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.

7.Declarations by an applicant

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

I also agreed that I am obliged to comply with Zanzibar Food, Drugs and Cosmetics Act No. 2, 2006 requirements related to Medical devices.

Name:…….

Position in the Company:……..

Signature and official stamp:…….....

Date:……

	08.	Opthalmic and Optical devices
	09.	Reusable instruments

	08.	Opthalmic and Optical devices
	09.	Reusable instruments
	10.	Single use devices
	11.	Technical aids for disabled person
	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 (*Please specify*)

ESSENTIAL REQUIREMENTS CHECK LIST

Brand name :	Common name:	RISK CLASS:

	Essential Principal	**Applicable to the device?**	**Method of Conformity**	**Identity of specif Documents**
1.	**GENERAL REQUIREMENTS** 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			

	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 minimize 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.	**Infection & microbial contamination** 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, minimize 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 & sterilized by an appropriate, validated method.			
8.5	Devices intended to be sterilized 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 sterilized prior to use, minimize the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilization 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.	**Manufacturing and environmental properties.** 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 minimize 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 minimize 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**	**Protection against radiation** **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.			
11.2 **11.2.1**	**Intended radiation** 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	**Unintended radiation**			

11.3.1	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**	**Instructions** 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**	**Ionizing radiation** Devices intended to emit ionizing 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 ionizing 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			

	minimizing radiation exposure of the patient and user.			
11.5.3	Devices emitting ionizing 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**	Requirements for medical devices connected to or equipped with an energy source. 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 minimize 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**	**Protection against electrical risks** 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**	**Protection against mechanical & thermal risks.** 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 minimize 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.	**Information supplied by the**			

13.1	**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. **14.1**	**Performance evaluation including, where appropriate, clinical evaluation.** 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 stip

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.

Registrant identifies medical device to register

Registrant submits application

Screening of application

Review of application

Regulatory Decision

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 color) 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 The name (presented in bold) that is selected to represent a generic identifier 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 Adhesive strip Adhesive strip, general-purpose Closure, wound, adhesive Strip, adhesive, general purpose	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. 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
Keyword	**Device identifier**	
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	

below)

Keyword	Device identifier	Description/In	**Description/Intended Use**
Adhesive	Adhesive Bandage Bandage/dressing, adhesive Bandage/tape, adhesive Adhesive strip Adhesive strip, general- purpose Closure, wound, adhesive Strip, adhesive, general purpose	A piece of a f strip) that is a a pressure-se not used to e absorbent pac wounds, to su part of the bo the skin. This A small, narr plastic, paper side with a pr sensitive adhe approximate t or fix dressin device may ir and have speci	waterproof. The device is usually supplied sterile in precut sizes/shapes. This is a single – use device. 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.

Keyword	**Device identifier**	
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	A solvent material designed to remove adhesive tape and its residue from the skin or other surfaces. This is a single-use device.
Applicator		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

Keyword	**Device identifier**
Bandage	Bandage, self-adherent
	Bandage, clavicle
	Bandage, elastic

below)

Keyword	Device identifier	Description/Intended Use
Adhesive	Adhesive Bandage	A piece of a f strip) that has flexible walls. The device may a pressure-sh not include a absorbent pac
	Bandage/dressing, adhesive	pressure holder that keeps the bag in place
	Bandage/tape, adhesive	wound dressin part of this bo the skin. This
	Adhesive strip Adhesive strip, general-purpose	A small, narr plastic, paper side with a pr sensitive adhe
	Closure, wound, adhesive	approximate t or fix dressin
	Strip, adhesive, general purpose	device may h and have qual

Keyword	Device identifier	Description/Intended Use
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	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.
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	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.
Applicator		
Bag	Ice bag	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).
Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	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
	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	A 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.

below)

Keyword	Device identifier	Description/In	**Description/Intended Use**
Adhesive	Adhesive Bandage	A piece of a f	
	Bandage/dressing, adhesive	strip, part is a a pressure-sen	p) part is a ades. This is a single-use device.
	Bandage/tape, adhesive	not include a absorbent pac wounds, to su part of the bo the skin. This	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.
	Adhesive strip Adhesive strip, general-purpose	A small piece plastic, paper side with a pr sensitive adhe	A device upon which a patient rests or sleeps, or upon which a patient is examined. 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.
	Closure, wound, adhesive	approximate t or fix a dressing	
	Strip, adhesive, general purpose	device may ir and have addi	

Keyword	**Device identifier**	
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	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.
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	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.
Applicator		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.
Bag	Ice bag	

Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	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
	Bandage, clavicle	
	Bandage, elastic	

below)

Keyword	Device identifier	Description/Intended Use
Adhesive	Adhesive Bandage	A piece of a f
	Bandage/dressing, adhesive	strip with plas
		a pressure-sen
		not include a
	Bandage/tape, adhesive	absorbent pac
		wound to su
		part of the bo
		the skin. This
	Adhesive strip Adhesive strip, general-	A small, narr
		plastic, paper
	purpose	side with a pr
		sensitive adhe
	Closure, wound, adhesive	approximate t
		or fix dressin
	Strip, adhesive, general purpose	device may in
		and have qual

Keyword	**Device identifier**	**Description/Intended Use**
	Adhesive strip, butterfly	A strip or roll of fabric or plastic material applied to the abdomen to support relaxed abdominal walls.
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	A strip or roll of fabric or plastic material designed to support the ankle joint.
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	A strip or roll of fabric or plastic material designed to support the breasts.
Applicator		A strip or roll of fabric or plastic material designed to support the ribs and chest.
Bag	Ice bag	A strip or roll of fabric or plastic material designed to support the sternum.
		A strip or roll of fabric or plastic material designed to support the wrist joint.
		A firm device in which a patient's arm is placed for stabilization to maintain the patency of an intravascular catheter,
		e.g those connected to an intravenous or intra-arterial line. It is typically constructed of expanded polystyrene with a plastic coating and can be straight or curved to accommodate the patient's arm/wrist.
	Board, cardiac compression	A flat, rigid device that is placed

Keyword Device identifier		Description/Intended Use
	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 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
		Brush, surgical scrub Scrub brush, surgical
Chair	Chair, bath/shower	A device designed to be set upon by a using some washing facility where there is a need to sit. The sitting requirement can be e.g. because the person is disabled or infirm, or because it is part of medical treatment.
	Chair , blood donor	A device used to position the patient in such a manner that a technician/nurse has easy access to the patient’s arm for drawing

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 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 color discrimination	A device used to determine the correct shade (color) of filling materials, artificial crowns and teeth for matching to those of the patient.
	Shade guide, dental	
	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. An ophthalmic chart with colored Figures printed on colored
	Chart, eye, color discrimination	

	Keyword Device identifier	Description/Intended Use
		backgrounds, used in testing color vision.
	Color blindness test chart Color discrimination chart	
	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 mouth piece 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. 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. A container designed for the storage of contact lenses when the lenses are not being used by the owner.
	Ice collar compress	
Case	Contact lens case	
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.

below)

Keyword	Device identifier	Description/I
Adhesive	Adhesive Bandage	A piece of a strip that is a pressure-sl not include a absorbent pa wounds, to su part of the bo the skin. This
	Bandage/dressing, adhesive	
	Bandage/tape, adhesive	
	Adhesive strip Adhesive strip, general-purpose	A small, flat plastic, paper side with a p sensitive adh approximate or fix dressin device may i and have qua
	Closure, wound, adhesive	
	Strip, adhesive, general purpose	

Keyword	**Device identifier**	**Description/Intended Use**
	Adhesive strip, butterfly	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.
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	An instrument intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	An ophthalmic device worn by the user to hold prescription or protective spectacle lenses in front of their eyes.
Applicator		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.
Bag	Ice bag	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.

Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	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
	Bandage, clavicle	
	Bandage, elastic	

Keyword **Device** identifier	**Description/Intended Use**
	support the healing of an 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 (straitjacket 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
		Post operatively 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	A disposable inner incontinence pants, liner composed of absorbent materials used to collect urine and faeces from the patient.
Adult diapers	Incontinence diapers	
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. A device (a lamp), designed to be worn on an operator's head. It is mounted on a
	Light, head-worn	
Light		
Headlamp, operating		

Keyword	**Device** identifier	**Description/Intended Use**
	Headlight Headlight, fiberoptic focusing Light, headband, surgical	band or helmet frame and situated on the user's forehead providing a light direct into the field of vision during surgical, diagnostic, or therapeutic procedures. The light typically consists of a magnifying lens, a reflector and a connection for the fiberoptic cable to transfer cold- light, or power supply from a battery pack.
	Light, surgical headlight 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 shadow less light OR light	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 color 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.
	Surgical lamp 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,

Keyword Device identifier	Description/Intended Use
Light, Examination Examination light Light, examination, ceiling- mounted	medical trolley, or part of an emergency kit. 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 Light, dental, intraoral Lamp, intraoral, examination Light, dental, fibreoptic	A dedicated device designed to illuminate the ear canal. 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 Loupe Loupe, binocular	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.
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 vision

below)

Keyword	Device identifier	Description/In	**Description/Intended Use**
Adhesive	Adhesive Bandage	A piece of a f	
	Bandage/dressing, adhesive	strip) that is a	
		a pressure-ser	
		not include a	
	Bandage/tape, adhesive	absorbent pad	
		wounds, to su	
		part of the bo	
		the skin. This	
	Adhesive strip Adhesive strip, general-	A small, flat(	
		plastic, paper,	
	purpose	side with a pr	
		sensitive adhe	
	Closure, wound, adhesive	approximate t	
		or fix dressing	
	Strip, adhesive, general	device may in	
	purpose	and have qual	

Keyword	**Device identifier**	
	Adhesive strip, butterfly	
	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. 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
	Mirror, ENT, headband	

A manmade 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.

A device made from fabric or other material placed over the nose and mouth by medical personnel to preventthetransmissionof airborne organisms while surgery is being performed/ This device is disposable.

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	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.
	brace 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 or s et 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,	An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.
Orthosis, cervical-thoracic, rigid Orthosis, cervical spine Cervical collar CO (Cervical orthosis) Collar, cervical	An externally applied orthopaedic appliance or apparatus used to support or immobilize deformities, fractures, sprains, or strains of the cervical spine.
Support, neck 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	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.
Pressure pad , foam Pressure pad, gel Pressure pad, soft rubber Pressure pad, water cushion Anti-decubitus pad, cushion	

below)

Keyword	Device identifier	Description/In	**Description/Intended Use**
Adhesive	Adhesive Bandage	A piece of a f	
	Bandage/dressing, adhesive	strip) that is a	
		a pressure-sen	
		not an included	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.
	Bandage/tape, adhesive	absorbing pa	
		wounds; it may	
		part of the bo	
		the skin. This	
	Adhesive strip Adhesive strip, general-purpose	A small, narro	
		plastic, paper	
		side with a pr	
		sensitive adhe	
	Closure, wound, adhesive	approximate t	
	Strip, adhesive, general purpose	or fix dressin	
		device may in	
		and have qual	

Keyword	**Device identifier**	
	Adhesive strip, butterfly	A device used to stabilize, attach, or fix a bandage/ dressing in a desired location. This device can be a fastener/clasp (e.g., an elastic strip with opposing gripping teeth/ hooks), or a tubular elastic net. It is typically used on patients sensitive or allergic to adhesive tape. This device is single–use.
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	A mechanical shield used for protection of one or both eyes following surgery or trauma. These shields usually are plastic or metallic.
Applicator		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.
Bag	Ice bag	
Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	A mechanical guard worn over the hip area to prevent against hip fractures in the event of a patient fall.
	Bandage, clavicle	A mechanical shield that is designed to form a protective structure over a wound. It may be
	Bandage, elastic	

Bandage, gauze

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.
below)		
Keyword	Device identifier	Descri
Adhesive	Adhesive Bandage	A pie
	Bandage/dressing, adhesive	strip) h a press
	Bandage/tape, adhesive	not in absorb wound part of
	Adhesive strip Adhesive strip, general-purpose	the ski A soft plastic sides;
	Closure, wound, adhesive	sensiti approx
	Strip, adhesive, general purpose	or fix device
Keyword	**Device identifier**	and ha
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	
Applicator		
Bag	Ice bag	
Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	

Orthopaedic footwear that is intended to support, align, prevent, or correct deformities of the feet to help improve their function.

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.

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.

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.

Anoptical /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 Splint, nasal, external	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.
	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,	A device on which a patient lies for Transport or reclines after treatment. It may have a wheeled under carriage, which can be foldable.
powered Stretcher, wheeled Stretcher, hospital 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. 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
Stretcher, portable Stretcher, hand-carried Stretcher, portable, basket 2 fold stretcher	

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	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,
Examination bed	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 labor 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

below)

Keyword	Device identifier	Descri	**Description/Intended Use**
Adhesive	Adhesive Bandage	A piec	
	Bandage/dressing, adhesive	strip li	
		a pers	
		not pa	
	Bandage/tape, adhesive	absorb	
		wound	
		part of	
		the ski	
	Adhesive strip Adhesive strip, general-	A sma	
	purpose	plastic	
		side w	
		sensiti	
	Closure, wound, adhesive	approx	
		or fix	
	Strip, adhesive, general	device	
	purpose	and ha	

Keyword	**Device identifier**	
	Adhesive strip, butterfly	
	Adhesive tape First-aid adhesive tape Tape, adhesive Tape, cotton Tape, gauze, self-adhesive Tape, adhesive, hypoallergenic Tape, adhesive, waterproof	
	Adhesive tape remover Adhesive solvent Degreaser, skin, surgical Solvent, adhesive type Tape adhesive removing solvent Applicator, absorbent tipped	
Applicator		
Bag	Ice bag	

Keyword	**Device identifier**	
Bandage	Bandage, self-adherent	
	Bandage, clavicle	
	Bandage, elastic	
	Bandage, gauze	

A 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.

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.

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.

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

Keyword	Device identifier	Description/Intended Use
		support whilst walking. It can be of fixed or adjustable height and collapsible or non-collapsible.
	Walker, mechanical Walker, standard Walker/chair, non-wheeled Walking chair Walker, side Walking frame, rigid, adjustable Walking frame, folding adjustable 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.