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THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR NOTIFICATION OF MEDICAL DEVICES EXEMPTED FROM REGISTRATION

(Made under Regulation 13 of the Tanzania Medicines and Medical Devices (Control of Medical Devices), Regulations, 2015, GN 315)

FIRST EDITION

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ABBREVIATIONS

CAB	-	Conformity Assessment Body
DoC	-	Declaration of Conformity
IFU	-	Instructions for Use
ISO	-	International Organization for Standardization
QMS	-	Quality Management System
TMDA	-	Tanzania Medicines and Medical Devices Authority
TMDCA	-	Tanzania Medicines and Medical Devices Act, Cap 219
ENT	-	Ear, Nose and Throat (Otorhinolaryngology)
IVDs	-	In Vitro Diagnostics
IMDRF	-	International Medical Devices Regulatory Forum
GHTF	-	Global Harmonization Task Force
WHO	-	Word Health Organization
USFDA	-	United States Food and Drug Administration
HSA	-	Health Sciences Authority
MA	-	Market Authorization
LRP	-	Local Representative Person

ACKNOWLEDGEMENTS

These guidelines were developed in order to provide applicants with precise information on documentations and requirements for submitting applications for notifications of medical devices and in vitro diagnostics exempted for registration in Tanzania. Such Guidelines were not present before thus making this a first edition.

I wish to express my gratitude to TMDA staff who worked diligently and tirelessly in successful development of these guidelines. Acknowledgements are particularly extended to Ms. Rehema Mariki, Mr.Sunday Kisoma, Mr. Bryceson Kibasa, Mr. David Mwakyoma, Ms. Gudula Mpanda, Ms.Jeniva Jasson, Ms. Rose Maingu, Ms. Engerasia Mtui, Ms. Edina Zebedayo, Ms. Marina Sapali and Dr. Shani Maboko for drafting and finalizing the guidelines.

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Kissa W. Mwamwitwa

Acting Director of Medical Devices and Diagnostics Control

FOREWORD

All health technologies such as medical devices and in vitro diagnostics to be marketed in the country must meet acceptable standards of quality, safety and performance and are produced by facilities that meets the acceptable standards for manufacturing of such products.

The guidelines are applicable for medical devices for both human and veterinary, in vitro diagnostics, veterinary medical devices, and Laboratory equipment which are considered to be of low risk and hence are exempted from registration, unlike devices of higher risk classes such as class B, C and D that follow a separate guideline.

In addition to risk classification, products have been further categorised into seven (7) specialised groups which place together products based on their relationship and intended uses. Groups consists of the following:

a. Group 1: Ophthalmic, Anesthesia, Respiratory, Ear Nose Throat **(**ENT) and Dental Device
b. Group 2: Cardiovascular Devices, Radiological Health, Neurological, Orthopedic Devices and Physical Medicine Devices
c. Group 3: Gastro-renal, obstetrics-gynecology (ObGyn) General Hospital, and Urology Devices
d. Group 4: Surgical and Infection Control Devices,
e. Group 5: In Vitro Diagnostics, laboratory equipment and veterinary devices
f. Group 6: Medical gases
g. Group7: Blood and blood products

These guidelines are therefore developed to provide comprehensive guidance to applicants intending to notify their products in Tanzania. Requirements for notification were previously included under the guidelines for Submission of Documentation for Registration for both medical devices and in vitro diagnostic in summary. This document provides guidance on principle issues to consider under each category of the devices.

The guidelines will provide understanding to applicants towards meeting the notification requirements, identifying relevant information required for notification and therefore facilitate the approval process and consequently avoid unnecessary delays in product accessibility.

The guidelines will be revised regularly to respond to any new requirements addressing the challenges for notification process as may arise from time to time in line with legal framework for notification of medical devices and IVDs.

These guidelines should be read in conjunction with TMDA Laws and Regulations.

Adam M. Fimbo
Director General

DEFINITION OF TERMS

Active Medical Devices

Means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity.

Applicant

Means a person who owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications, the product is manufactured and who shall be the marketing authorization holder and have the primary responsibility of the product on the Tanzanian market.

Authority

Means the Tanzania Medicines and Medical Devices Authority.

In Vitro Diagnostic Medical Device

Means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived 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

Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embosed or impressed on or attached to a container of any medical devices;

Labeling/ Information Supplied by the Manufacturer

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

Local Responsible Person (LRP)

Means a person residing in Tanzania mainland or coorporate body registered in Tanzania mainland who has received a mandate from the Applicant to act on his behalf with regard to matters pertaining to registration of medical devices.

Manufacturer

Means a person who sells medical devices under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Manufacturing Site

Means an authorized space where designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the device take place.

Medical Device or Devices

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

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

Medical Devices with Measuring Function

Device has a measuring function if;

a. The device is intended by the manufacturer to measure: - quantitatively a physiological or anatomical parameter, or - a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.

b. The result of the measurement - is displayed in legal units or other internationally acceptable units or - is compared to at least one point of reference indicated in legal units or other acceptable units.

c. The intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.

Medical Device Accessories

Means a separate, finished device intended to "support, supplement, and/or augment the performance" of at least one parent device. Accessories might be marketed individually for use with a specific device type and may be a different class than their parent device.

Medical Device Family

Means a group of medical devices that are made by the same manufacturer that differ only in shape, color, flavor or size, that have the same design and manufacturing process and that have the same intended use.

Medical Device Group

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

Medical Device Procedure Pack

Means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

Medical Device Spare Parts / Components

Means "any, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." For example, a stethoscope contains multiple parts, including a diaphragm, bell, and tubing. When packaged in whole with the stethoscope, these parts would be considered medical device components that comprise a finished medical device.

Medical Device System

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

Medical Gases

Means any gases that are intended for therapeutic use for:

a. Treatment and prevention of diseases;
b. Performing diagnostic tests;
c. Calibrating machines used for making diagnostic tests; and/or
d. Restoration, correction and modification of physiological functions in human beings

These include oxygen, medical air, nitric oxide, and mixtures of helium and oxygen and oxygen and carbon dioxide.

Notified Products

Means medical devices, in -vitro diagnostic devices, medical gas, veterinary medical devices that has been granted market authorization through notification process.

Quality Management System

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

Recognized Standards

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

1.0 INTRODUCTION

Registration of Medical Devices and IVDDs is a legal requirement, therefore the sale, supply or importation of any medical devices and in vitro diagnostics within Tanzania is prohibited unless one has obtained market authorization from the Authority. This is in pursuant to regulation 6 of the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, GN 315.

Market authorization of medical devices and IVDDs in Tanzania is divided into two categories depending on the risk classification. Medical devices and IVDDs that belong to higher risk classes such as class B, C and D must obtain full registration of which they must comply with technical requirements prescribed under relevant registration guidelines and must be manufactured by facilities that complies with requirements of ISO 13485 Quality management systems for regulatory purposes.

“On the other hand, medical devices and In vitro diagnostic that are supplied in non-sterile state, non-active and without measuring function as well as medical devices for veterinary use are exempted from registration and must obtain market authorization from the Authority in form of notification.”

The conditions under which a medical device and IVDD may obtain market authorization in the country include: -

a. The availability of the devices is in the public interest;
b. The medical device is safe, performs as intended and of acceptable quality;
c. The premises and manufacturing operations comply to National and International standards as provided in the regulations;
d. The medical devices and IVDDs complies with any other requirements as may be prescribed by the Authority

These guidelines therefore prescribe information required to apply for notification of devices under specific categories of the seven groups thus demonstrates that a device which is the subject of notification conforms to the requirements of the quality, safety and performance.

a. Group 1: Ophthalmic, Anesthesia, Respiratory, Ear Nose Throat **(**ENT) and Dental Device
b. Group 2: Cardiovascular Devices, Radiological Health, Neurological, Orthopedic Devices and Physical Medicine Devices
c. Group 3: Gastrorenal, obstetrics-gynecology (ObGyn), General Hospital, and Urology Devices

d. Group 4: Surgical and Infection Control Devices,
e. Group 5: In Vitro Diagnostics, Laboratory Equipment and Veterinary Devices
f. Group 6: Medical Gases
g. Group 7: Blood and Blood products

The guidelines are comprised of three (3) main sections namely General requirements, Documentation requirements and Labelling requirements. Furthermore, it includes list of medical devices and in vitro diagnostics exempted for registration. The devices are grouped in accordance with the above listed categories. The lists will be updated from time to time when a need arise

2.0 GENERAL INFORMATION

This section provides valuable information that will enable applicant(s) to comply with the requirements for notification of their product(s).

2.1 Language

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

2.2 Applicant Responsibility

The applicant shall be responsible for the product, information supplied in support of the application for notification thereof.
Shall also;

a. Provide authentic scientific documents to support their applications;
b. Ensure that all submissions (of additional data) are submitted within the deadlines;
c. Ensure that their product meets all requirements to be retained in the register of notified products;
d. Submit any variations to the Authority in line with the requirements stated in the variation guides;
e. Re-new their notification every 3 years

2.3 Local Responsible Person (LRP) Responsibility

The Local Responsible Person shall be responsible for:

a. Monitoring the device on the market and inform the Authority immediately after the detection of any problem relating to a notified products such as serious manufacturing defects which may endanger public health.
b. Facilitating communication between the applicant and the Authority on matters relating to the product.
c. Handling product recalls.
d. Providing technical support and services to users of notified device (s).

2.4 Applications

All applications for notification shall be made online through *TMDA Customer Self-Service Portal* https://imis2.tmda.go.tz.

2.4.1 Acceptable Products for Notification

a. Medical devices and In-vitro diagnostics (IVDDs) in class A that are not active, non-sterile or without measuring function as per the rules of classifications prescribed in part one (1), and part two (2) of the First Schedule of TMDA (Control of Medical Devices), Regulation – GN 315;
b. Veterinary medical devices covered in this guideline.
c. Medical gases.
d. Laboratory equipment and apparatus.
e. Blood and Blood Products

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

a. A single medical device
b. One medical device family
c. One medical device system
d. One medical device group

2.4.3 Types of applications

a. New notification applications. For the documentation requirements refer to Section 3.0 of this guideline.
b. Renewal applications. During renewal/ re-notification, applicant shall submit an application form and product label(s) including instructions for use.
c. Variation applications. For the documentation requirements refer to the Guidelines for Changes of Approved Medical Devices.

2.5 Payment of Fees

a. Every application shall be accompanied by notification fees as specified in the Fees and Charges Regulations currently in force at the time of application.
b. All payments shall be made using control number indicated on the Invoice generated against the application.

2.6 Processing of Applications

a. Authority shall conduct screening of submitted applications to confirm completeness of submission before issuing invoice for payment of notification fees within 24 hours.
b. Incomplete applications will be queried for additional data, and returned back to the applicant for rectifications.

c. Applications for incorrect products applied for notifications will be rejected and returned to the applicant.
d. Once application has been accepted and appropriate fees paid, the processing of application will be within five (5) working days.
e. Once a query or a request has been raised, the processing shall halt until after the response to the query has been received.

2.7 Notification Approval

When a product is found to comply with all prescribed requirements of safety, quality and performance, it will be notified and approval letter issued.

2.8 Validity of Notification

Notified product shall be valid for three (3) years end of which is viable for renewal/re-notification unless suspended or revoked by TMDA or terminated by the applicant. The notification of product shall continue to be valid provided that annual retention fees is paid before 31st January each year.

2.9 Appeals

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

3.0 DOCUMENTATION REQUIREMENTS

Documentation requirements applies to all acceptable products for notification stated in section 2.4.1.

3.1 General requirements

3.1.1 Application form

A completely filled in application form (*Annex I*) for notification should be provided in each application. The form shall be signed, dated and stamped by the official stamp of the applicant.

3.1.2 Appointment Letter for Local Responsible Person (LRP)

Applicant who is not resident of Tanzania should appoint LRP who is residing in Tanzania and who is registered by TMDA as dealer of Medical Devices.

Imported product submitted by local applicants should include an official letter from the manufacturer of the product as a testimony of no objection to notification of their product in Tanzania.

The letters should bear company letter head, signed, stamped and dated by the applicant or manufacturer (*applies for local applicants*).

3.2 Medical Devices, In-Vitro Diagnostic Devices and Laboratory Equipment

3.2.1 Product details

a. Description of the product including features, accessories and intended uses and users. The description should state;
    i. The intended uses of the product (i.e conditions that require its usage)
    ii. The intended users (i.e professional or general users)
    iii. The targeted population (Children, Adults, Elderly, any Gender criteria)
    iv. Any associated products that work together with the product (examples; reagents, controls, accessories etc)
    v. The number of unit products in a commercial pack

b. Pictures of the device in the commercial pack whereas, all sides of the devices are clearly visible.

3.2.2 Product label

Labelling of products should comply with the requirements stated in **section 4.0** of this guidelines.

3.2.3 Manufacturer Information

Provide valid certificate of compliance to ISO 13485 standards or its equivalent from the manufacturer(s) of the devices. Certificate should be issue by recognized Conformity Assessment Body (CAB).

Manufacturers in Tanzania have to be registered by TMDA prior to notification of their products. This also applies to the manufacturers involved in the final manufacturing process like assembly, resizing, cutting, and or packing.

Used product which have been refurbished by a third party who is not the original manufacturer of the devices, then, that third party shall bear the responsibility of the manufacturer described in this guideline.

3.2.4 Other Requirements

a. Declaration of Conformity (DoC) to TMDA Control of Medical Devices Regulations. The declaration (annex II) should be filled, signed and stamped by the manufacturer.

b. Medical Devices Specifications including list of standards that the product complied with.

c. Two (2) product samples in their commercial presentation. This requirements applies for the products identified in the ***annex III***.

d. Instructions for use or user manual.

3.3 Medical devices and IVD groups, family and kits

Medical device groups, family or kits may be notified under a single application. In addition to the technical requirements outlined in section 2.2 above, the applicant is also required to:

a. Provide a complete description of each component of the group, family or kit;

b. State the intended use of each component of the group, family or kit; and

c. For kits or groups that contain devices that require registration (such as sutures), state the registration number issued by TMDA for the product.

d. Co-packed medical devices (kits) manufactured locally by domestic facilities such as maternity kits, first aid, male circumcision kits

Applications for medical devices kits that are made locally by co-packing of various medical devices intended for a certain use requires submission of the following:

i. Product requirements
   a) All medical devices intended to be included in a co-packaging kit must be authorized by TMDA either through notification or registration process

   b) Medical devices in a co-packaging kit must maintain the brands that are initially approved by TMDA throughout validity period of three years

   c) If an applicant is intended to change a brand of a devices in the kit different from the one approved, must submit application for a change to TMDA

   d) Each medical devices to be included in the kit should have a valid shelf life

ii. Document requirements
   a) Dully filled in and signed application form
   b) Authorization letters from the distributors of the products intended to be co-packed in a kit
   c) Evidence of authorization from TMDA (A copy of registration certificate or notification letter)
   d) Evidence of premise registration by TMDA where the packing is performed

iii. Labelling requirements

Kits' label

The label on the co-packaging kit must contain the following information
   a) Name of the co-packaging kit
   b) Intended use of the kit
   c) List of medical devices in the kit
   d) Expiry date (as per shortest expiry medical device)
   e) Name and address of the manufacturer who conduct co-packing of devices
   f) Batch number
   g) Manufacturing date
   h) Storage conditions

Products' label

All medical devices to be included in the kit should have an intact label with all required information as per TMDA requirements

iv. Samples

Two commercial samples with brands of medical devices intended for approval

Note:

1: *The classification of the co-packed kit will be determined by the product in the package with the highest risk class according to the rules of classifications of medical devices and diagnostics.*

2: *The imported kit shall be approved the Authority in line with the requirements for market approval prescribed in the regulations*.

3.4 Medical Gases

a. Medical gases are gases for therapeutic purposes that are used within healthcare facilities. They include the following elements and compounds:

i. **Oxygen**, used to provide supplemental oxygen to the respiratory system; in dentistry in combination with nitrous oxide; and as an emergency standby;
ii. **Nitrous oxide**, used as an anesthetic agent in surgery; mixed with oxygen to help patients relax during dental procedures; and in cryosurgery (the use of extreme cold to destroy tissue);
iii. **Nitrogen**, used to provide pneumatic pressure in medical equipment; to prevent combustion and other chemical reactions; and as a component of many gas mixtures;
iv. **Carbon dioxide**, used to inflate areas of the body for "keyhole" surgery (small incisions made to accommodate surgical instruments); mixed with air or oxygen to stimulate breathing; and in cryosurgery or testing tooth sensitivity in dentistry;
v. **Medical air**, used in administering breathing treatments and as a mixing component for other respiratory gases; and
vi. **Helium**, used in breathing mixtures for patients with impaired lung functions
vii. **Argon,** a non-toxic inert gas used for argon gas knife, gas knife, and other surgical instruments.

b. The following information should be submitted along with all applications for notification of medical gases:

   i. Controlled copies of the valid standard operating procedures or protocols for the production of the medical gases including procedures for storage, transportation and distribution;
   ii. Results of the daily quality of gas checks of consecutive batches manufactured over a period of at least 3 months *(if applicable*);
   iii. A comprehensive plan for ensuring tracking of the recipients of each batch to enable follow up of the product in the market;
   iv. Mockup labels of the finished product as packaged for sale/distribution; and
   v. Evidence of premises certification (domestic) or GMP compliance (foreign)

c. Notification is not applicable for aerosol preparations or mixtures of solids that are used to generate gases for fire departments, ambulance services, hospitals or health care facilities that produce medical gases for their own use or administration to a patient.

3.5 Medical Devices for Veterinary Uses

a. Medical devices and IVDDs intended to be used in animals have been exempted from registration. This applies to those products which are specifically intended by the manufacturer to be used in animal care and must be labelled on product label and manual “for animal use only”.

b. The applicant is required to submit all the technical information outlined under section 2.2 above.

4.0 LABELLING REQUIREMENT

Medical devices offered or imported for sale or use in Tanzania must meet the labelling requirements listed in Sections 74 - 75 of the TMDA (Control of Medical Devices), Regulations – GN 315. This guidance is to be used in the preparation of labelling material for regulated products in all risk classifications.

Furthermore, symbols to be included in the medical devices label shall meet the minimum requirements stated in the ISO standards for labelling requirement with examples of commonly used symbols given in the annex II.

4.1 Labels

a. Labels must minimally include the following information:

i. Product name and product identification number (product code/catalogue number),
ii. Name of manufacturing site and physical address,
iii. Contents and 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, volume after reconstitution shall be indicated,
iv. Manufacturing and expiry dates shall be indicated where applicable and shall follow the requirements of ISO 8601,
v. Storage conditions necessary to maintain the stability of the product shall be indicated. If there are any other conditions that may affect the handling or storage of the products shall be specified e.g. fragile,
vi. Warning and precautions: If a product is considered hazardous, the outer container label shall include the appropriate danger wording or symbol(s) e.g. chemical, radioactive and biological hazards,
vii. Lot/batch and/or serial number,
viii. The words "**Sterile**" if the manufacturer intends to sell the product in a sterile condition,
ix. Names of all included reagents, and components in each box on the outer package label, where possible,
x. The word "**For Single Use Only**" shall be included if the product is intended for single use,
xi. The In vitro diagnostics use of the device shall be indicated e.g. "**For In vitro diagnostics use**" or graphical symbol: "**In vitro diagnostic medical device**",
xii. All devices intended for animal uses it shall be indicated " **For Veterinary Use**" or "**Device for Veterinary Uses Only**"
xiii. Where a component is too small to contain all the above information, it must at a minimum contain Name, lot number, expiration date, volume, and storage conditions,
xiv. If the product requires associated instrumentation, the above requirements also apply to the instrument,
xv. The instrument should clearly display information regarding its status as a new or reprocessed product.

4.2 Instructions for use *(if applicable)*

A copy of the current instructions for use must be submitted along with the application and should include the following minimum information:

a. The product name and product code
b. The name and contact details of the manufacturer or an authorized representative of the

manufacturer, in order for the user to obtain assistance

c. A clearly stated intended use, including:

i. what is detected by the assay (that is, the analytical use of the assay (e.g. the marker or nucleic acid sequence being detected);
ii. the clinical indication for the test (e.g. if it is for a specific disorder, or a condition or risk factor of interest that the test is intended to detect, define or differentiate);
iii. the function of the product (screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease);
iv. the intended user (laboratory professional and/or at point-of-care);
v. the intended testing population (e.g. neonates, antenatal women);
vi. What the instrument is intended for and Whether the test is qualitative or quantitative;
vii. An indication that the product is for ***in vitro use***, ***Veterinary Uses***;
viii. A general description of the principle of the assay method or instrument principles of operation;
ix. A description of all components of the assay (e.g. reagents, assay controls and calibrators) and a description of the reactive ingredients of relevant components (e.g. antibodies, antigens, nucleic acid primers etc.);
x. A description of the specimen collection and transport materials provided with the product or recommended for use;
xi. If applicable, a description of any software to be used with the product;
xii. If applicable, a description or complete list of the various configurations/variants of product that will be made available;
xiii. If applicable, a description of the accessories, and other products that are intended to be used in combination with the product but are not provided with the product;
xiv. Storage conditions, including storage conditions and stability of both the unopened and opened product, and working solutions. When applicable, these instructions should include such information as conditions of temperature, light, humidity, and other pertinent factors;
xv. If the test kit includes sterile accessories, an indication of that condition and any necessary instructions in the event of damage to sterile packaging;
xvi. If the test kit includes accessories that have been specified by the manufacturer as intended for single-use only, an indication of that stat;
xvii. Clear instructions on how to perform the assay, including instructions on specimen collection, handling, preparation and storage of reagents, the use of assay calibrators and controls and the interpretation of results;
xviii. Recommendations for quality control procedures;
xix. Clear instructions on the correct usage of any equipment or software that is

required for the performance of the assay;

xx. Any warning and precautions to be considered related to the use of the assay including but not limited to interpreting the results, the disposal of the assay and/or its accessories (e.g. lancets), to any consumables used with it (e.g. reagents) that may be carcinogenic, mutagenic or toxic, or to any potentially infectious substances of human or animal origin;

xxi. Any residual risks;

xxii. Precautions and measures to be taken in the event of performance changes or product malfunction;

xxiii. Limitations of the assay, including information on interfering substances that may affect the performance of the assay;

xxiv. Any requirements for special training or particular qualifications of the assay user;

xxv. Any requirements for routine maintenance. Include details of frequency of maintenance and who should perform this maintenance (for example: the user, a representative of the manufacturer, or a third party;

xxvi. Where relevant, a bibliography; and

xxvii. Document control details, such as a document version number and release date.

4.3 Instrument manual

If the product requires associated instrumentation, include a hard copy and softcopy of the instrument manual and/or associated operator manuals. If the instrument manual is large, an electronic version may be included instead of a hard copy.

4.4 Any other instruction material provided to the user

a. Provide copies of any other instructional materials that need to be provided to the user.

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

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

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

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

ANNEX I: APPLICATION FORM FOR NOTIFICATION

	NOTIFICATION FORM FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTIC DEVICES	TMDA/DMD/MDA/F/006

1.	**Applicant Details**	
1.1	Status of applicant (choose one or more [√])	☐ Tanzanian
		☐ Non -Tanzania resident
1.2	Applicant address	Name
		Physical address
		Phone number
		Email
1.3	Local Responsible Person Address	Name
		Physical address
		Phone number
		Email
2.	**Details of the Manufacturer**	
2.1	Name of the Manufacturer	
2.2	Full address and contact details (*phone number, email address*) of the manufacturer	Address: Phone number: Email:
3	**Details of the product**	
3.1	Brand name	
3.2	Common name	
3.3	Intended use of the product	
3.4	Intended user	☐ Professional use
		☐ General use
3.5	Intended population	☐ Children
		☐ Adult
		☐ Elderly
		☐ General public
		☐ Female ☐ Male

3.6	Model/series/family (*list all sizes applicable*)	
3.7	Commercial presentation (*number of units presented in pack*) (*if applicable*)	
3.8	Storage condition with respect to the product (*if applicable*)	

Declaration by applicant

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

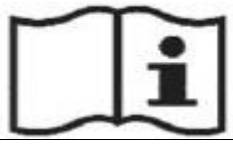
Name of authorized person:
Signature:
Date:
Stamp:

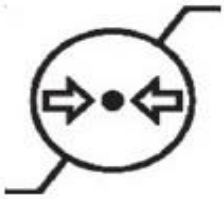
Approved by MMDA (signature): ……. Effective date: 01/04/2022

ANNEX II: EXAMPLES OF SYMBOLS USED IN MEDICAL DEVICES BASED ON ISO 15223-1

Reference symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer, as defined in TMDA Guidelines
	Date of Manufacturer	Indicates the date when the device was manufactured
	Use by Date	Indicates the date after which the device is not to be used
	EC Representative	Indicates the Authorized Representative in the European Community
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue Number	Indicates the manufacturer's catalogue number so that the device can be identified
	Serial Number	Indicates a serial number so that a specific device can be identified
	Unique Device Identifier	The unique device identification (UDI) is a unique numeric or alphanumeric code related to a medical device. It allows for a clear and unambiguous identification of specific devices on the market and facilitates their traceability.
	Medical Device	Indicates that the product is intended to be used as a medical device

Reference symbol	Title	Description
	In Vitro Diagnostic	Indicates a device that is intended to be used as an in vitro diagnostic medical device
	Sterilize Use Steam Dry heat	Indicates a device that has been sterilized using steam or dry heat
	Sterilize	Indicates a device that has been subjected to a sterilization process
	Sterilize Use Irradiation	Indicates a device that has been sterilized using irradiation
	Sterilize Use Aseptic Processing	Indicates a device that has been manufactured using accepted aseptic techniques
	Sterilize Use Ethyleneoxide	Indicates a device that has been sterilized using ethylene oxide
	Sterile fluid Path	To identify the presence of a sterile fluid pathway within a medical device that might otherwise not be supplied sterile. Understanding that such a patheway is present is important to the safe use of the medical device.
	Sterilized Vaporized Hydrogen Peroxide	Indicates the presence of a sterile fluid path within the device when other parts of the device, including the exterior, may not be supplied sterile
	No Re-sterilize	Indicates a device that is not to be re-sterilized
	No Reuse	Indicates a device that is intended for one use or for use on a single patient during a single procedure
	Natural Rubber Latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the device or the packaging of a device

Reference symbol	Title	Description
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.
	Instruction For Use	Indicates the need for the user to consult the instructions for use
	Nonsterile	Indicates a device that has not been subjected to a sterilization process
	Damaged Pack	Indicates a device that should not be used if the package has been damaged or opened
	Sunlight Away	Indicates a device that needs protection from light sources
	Heat Radioactive Away	Indicates a device that needs protection from heat and radioactive sources
	Keep Dry	Indicates a device that needs to be protected from moisture
	Temperature Low limit	Indicates the lower limit of temperature to which the device can be safely exposed

Reference symbol	Title	Description
	Temperature Upper limit	Indicates the upper limit of temperature to which the device can be safely exposed
	Temperature limit	Indicates the temperature limits to which the device can be safely exposed
	Humidity	Indicates the range of humidity to which the device can be safely exposed
	Atmospheric Pressure	Indicates the range of atmospheric pressure to which the device can be safely exposed
	Biological Risk	Indicates that there are potential biological risks associated with the device
	Non Pyrogenic	Indicates a device that is non-pyrogenic
	Sampling site	Indicates on a device or blood processing application that it includes a system dedicated to the collection of samples of a given substance stored in the device or blood container

ANNEX III: TMDA DECLARATION OF CONFORMITY

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TMDA/DMD/MDA/F/007

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA- Declaration of Conformity

We (manufacturer or authorized representative)

Business name: ……
Address: ……
Country: ……

Declare under sole responsibility for the equipment:

Equipment name: ……
Model or Type: ……
Batch or serial number: ……
Object (colour image)

That the Manufacturer shall confirm to the following sections of the *TMDA (Control of Medical Devices), Regulations, GN 315*;

(i) Restriction for sale unapproved products: *Part III, Section 9, Section 13, and Section 23.*

(ii) Prohibition to sell unfit products: *Part VI, Section 63.*

(iii)Labelling requirements: *Part IX, Section 73, and Section 74.*

And that the equipment is in conformity with the following internationally standards and /or other normative documents or technical specifications;

- ……..

Place and date of issue (of this DoC): …….

Signed by or for manufacturer: ……..

Name: …….

Function: ……

ANNEX IV: EXAMPLES OF MEDICAL DEVICES and IVDDs IN CLASS A

S/No	Device Types with examples	Description/Intended Use
GROUP 1: OPHTHALMIC, ANESTHESIA, RESPIRATORY, ENT AND DENTAL DEVICE		
OPHTHALMIC DEVICES		
1.	An ophthalmic trial lens clip	An ophthalmic trial lens clip is a device intended to hold prisms, spheres, cylinders, or occludes on a trial frame or spectacles for vision testing.
2.	An ophthalmic trial lens set	An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers intended to be handheld or inserted in a trial frame for vision testing to determine refraction.
3.	Color Vision Tester	A color vision tester is a device that consists of various colored materials, such as colored yarns or color vision plates (multicolored plates which patients with color vision deficiency would perceive as being of one color), intended to evaluate color vision.
4.	Corneal radius measuring device	A corneal radius measuring device is an AC-powered device intended to measure corneal size by superimposing the image of the cornea on a scale at the focal length of the lens of a small, hand held, single tube pen scope or eye gauge magnifier.
5.	Diagnostic Hruby fundus lens	A diagnostic Hruby fundus lens is a device that is a 55-diopter lens intended for use in the examination of the vitreous body and the fundus of the eye under slit lamp illumination and magnification.
6.	Lens measuring instrument	A lens measuring instrument is an AC-powered device intended to measure the power of lenses, prisms, and their centers (e.g., lensometer).
7.	Low-vision magnifier	A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.
8.	Maddox lens	A Maddox lens is a device that is a series of red cylinders that change the size, shape, and color of an image. The device is intended to be handheld or placed in a trial frame to evaluate eye muscle dysfunction.
9.	Ocular esthesiometer	An ocular esthesiometer is a device, such as a single-hair brush, intended to touch the cornea to assess corneal sensitivity.

S/No	Device Types with examples	Description/Intended Use
10.	Ophthalmic lens gauge	An ophthalmic lens gauge is a calibrated device intended to manually measure the curvature of a spectacle lens.
11.	Permanent Magnet	A permanent magnet is a nonelectric device that generates a magnetic field intended to find and remove metallic foreign bodies from eye tissue.
12.	Schirmer Strip	A Schirmer strip is a device made of filter paper or similar material intended to be inserted under a patient's lower eyelid to stimulate and evaluate formation of tears.
13.	Spectacle dissociation test system	A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, usually red or green filters, intended to subjectively measure imbalance of ocular muscles.
14.	Tangent, screen	A tangent screen (campimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation intended to map on a flat surface the central 30 degrees of a patient's visual field. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and stereo campimeters.
15.	Adaptometer (Bio photometer)	An adaptometer (bio photometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities intended to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.
16.	An image intensification vision aid	An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.
17.	An optokinetic drum	An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.
18.	Anomaloscope	An anomaloscope is an AC-powered device intended to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.

S/No	Device Types with examples	Description/Intended Use
19.	Bagolini lens	A Bagolini lens is a device that consists of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and intended to determine harmonious/anomalous retinal correspondence (a condition in which corresponding points on the retina have the same directional values).
20.	Closed-circuit television reading system	A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor that is intended for use by a patient who has subnormal vision to magnify reading material.
21.	Color vision plate illuminator	A color vision plate illuminator is an AC-powered device that is a lamp intended to properly illuminate color vision testing plates. It may include a filter.
22.	Contact lens inserter/remover	A contact lens inserter/remover is a handheld device intended to insert or remove contact lenses by surface adhesion or suction
23.	Corneal Inlay Inserter Handle	The corneal inlay inserter handle is a hand-held device intended to be used as an accessory to a corneal inlay inserter. The device extends the length of the inlay inserter to aid in delivering the inlay implant
24.	Diagnostic condensing lens	A diagnostic condensing lens is a device used in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye) intended to focus reflected light from the fundus of the eye.
25.	Distometer	A distometer is a device intended to measure the distance between the cornea and a corrective lens during refraction to help measure the change of the visual image when a lens is in place.
26.	Euthyscope	A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a perforated mirror device intended to inspect the interior of the eye) that projects a bright light encompassing an arc of about 30 degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).

S/No	Device Types with examples	Description/Intended Use
27.	Exophthalmometer	An exophthalmometer is a device, such as a ruler, gauge, or caliper, intended to measure the degree of exophthalmos (abnormal protrusion of the eyeball).
28.	Fixation	A fixation device is an AC-powered device intended for use as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macular retina of the eye
29.	Flexible diagnostic Fresnel lens	A flexible diagnostic Fresnel lens is a device that is a very thin lens which has its surface a concentric series of increasingly refractive zones. The device is intended to be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens of the eye).
30.	Fornixscope	A fornix scope is a device intended to pull back and hold open the eyelid to aid examination of the conjunctiva.
31.	Gonioscopic prism	A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.
32.	Haidinger brush	A Haidinger brush is an AC-powered device that provides two conical brush like images with apexes touching which are viewed by the patient through a Nicol prism and intended to evaluate visual function. It may include a component for measuring macular integrity.
33.	Haploscope	A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).
34.	Headband mirror	A headband mirror is a device intended to be strapped to the head of the user to reflect light for use in examination of the eye.

S/No	Device Types with examples	Description/Intended Use
35.	Instrument, measuring, stereopsis	A stereopsis measuring instrument is a device intended to measure depth perception by illumination of objects placed on different planes.
36.	Intraocular lens guide	An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.
37.	Keratome	A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.
38.	Keratoscope	A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.
39.	Low-power binocular loupe	A low-power binocular loupe is a device that consists of two eyepieces, each with a lens or lens system, intended for medical purposes to magnify the appearance of objects.
40.	Low-vision telescope	A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.
41.	Magnifying spectacles	Magnifying spectacles are devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images
42.	Maxwell Spot, Ac-Powered	A Maxwell spot is an AC-powered device that is a light source with a red and blue filter intended to test macular function.
43.	Near point ruler	A near point ruler is a device calibrated in centimeters intended to measure the near point of convergence (the point to which the visual lines are directed when convergence is at its maximum).
44.	Nystagmus tape	Nystagmus tape is a device that is a long, narrow strip of fabric or other flexible material on which a series of objects are printed. The device is intended to be moved across a patient's field of vision to elicit

S/No	Device Types with examples	Description/Intended Use
		optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.
45.	Ocular Surgery Irrigation device	An ocular surgery irrigation device is a device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.
46.	Operating headlamp	An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.
47.	Ophthalmic bar prism	An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.
48.	Ophthalmic bar reader	An ophthalmic bar reader is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device is placed directly onto reading material to magnify print.
49.	Ophthalmic chair	An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient is to sit or recline during ophthalmological examination or treatment.
50.	Ophthalmic eye shield (Including Sunlamp Protective Eyewear and Post-Mydriatic Eyewear)	An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.
51.	Ophthalmic Fresnel prism	An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.
52.	Ophthalmic instrument stand	An ophthalmic instrument stand is an AC-powered or non-powered device intended to store ophthalmic instruments in a readily accessible position.
53.	Ophthalmic instrument table	An ophthalmic instrument table is an AC-powered or manual device on which ophthalmic instruments are intended to be placed.

S/No	Device Types with examples	Description/Intended Use
54.	Ophthalmic prism reader	An ophthalmic prism reader is a device intended for use by a patient who is in a supine position to change the angle of print to aid reading.
55.	Ophthalmic projector,	An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing. An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing.
56.	Ophthalmic refractometer	Ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.
57.	Ophthalmic surgical marker	An ophthalmic surgical marker is a device intended to mark by use of ink, dye, or indentation the location of ocular or scleral surgical manipulation.
58.	Ophthalmic trial lens frame	An ophthalmic trial lens frame is a mechanical device intended to hold trial lenses for vision testing.
59.	Optical vision aid	Optical vision aid is a device that consists of a magnifying lens with an accompanying AC-powered or battery-powered light source intended for use by a patient who has impaired vision to increase the apparent size of object detail.
60.	Perimeter	A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.
61.	Prescription spectacle lens	A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitized.
62.	Prescription spectacle lens	A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright

S/No	Device Types with examples	Description/Intended Use
		sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitized
63.	Ptosis crutch	A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.
64.	Pupillometer	A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.
65.	Retinoscope	A retinoscope is an AC-powered or battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.
66.	Skiascopic rack	A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths intended as an aid in refraction.
67.	Spectacle frame	A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.
68.	Stereoscope	A stereoscope is an AC-powered or battery-powered device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief. It is intended to measure the angle of strabismus (eye muscle deviation), evaluate binocular vision (usage of both eyes to see), and guide a patient's corrective exercises of eye muscles.
69.	Transilluminator	A transilluminator is an AC-powered or battery-powered device that is a light source intended to transmit light through tissues to aid examination of patients.
70.	Visual acuity chart	A visual acuity chart is a device that is a chart, such as a Snellen chart with block letters or other symbols in graduated sizes, intended to test visual acuity.
EAR NOSE AND THROAT(ENT) MEDICAL DEVICES		
71.	Acoustic chamber for audiometric testing.	A room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.

S/No	Device Types with examples	Description/Intended Use
72.	Air or water caloric stimulator.	A device that delivers a stream of air or water to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient's body balance system.
73.	Ant stammering device.	An ant stammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitative or repetitive speech.
74.	Audiometer calibration set.	An electronic reference device that is intended to calibrate an audiometer. It measures the sound frequency and intensity characteristics that emanate from an audiometer earphone.
75.	Battery-powered artificial larynx.	An externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voice box, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.
76.	Bone particle collector.	A filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.
77.	Ear, nose, and throat drug administration device.	An ear, nose, and throat drug administration device are one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.
78.	Ear, nose, and throat examination and treatment unit.	An ear, nose, and throat examination and treatment unit are an AC-powered device intended to support a patient during an otologic examination while providing specialized features for examination and treatment. The unit consists of a patient chair and table, drawers for equipment, suction and blowing apparatus, and receptacles for connection of specialized lights and examining instruments.
79.	Ear, nose, and throat fiberoptic light source and carrier.	An AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or

S/No	Device Types with examples	Description/Intended Use
		throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.
80.	Earphone cushion for audiometric testing.	A device that is used to cover an audiometer earphone during audiometric testing to provide an acoustic coupling (sound connection path) between the audiometer earphone and the patient's ear.
81.	External nasal splint.	An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.
82.	Intranasal splint.	Intranasal splint is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. The intranasal splint is constructed from plastic, silicone, or absorbent material
83.	Nasal dilator.	A device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow. The device decreases airway resistance and increases nasal airflow. The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose; it acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils; it acts by pushing the nostrils open or by gently pressing on the columella.
84.	Otoscope.	A device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device provides illumination of the ear canal for observation by using an ac- or battery-powered light source and an optical magnifying system.
85.	Powered nasal irrigator.	A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The

S/No	Device Types with examples	Description/Intended Use
		device consists of a control unit and pump connected to a spray tube and nozzle.
86.	Short increment sensitivity index (sisi) adapter.	A device used with an audiometer in diagnostic hearing evaluations. A SISI adapter provides short periodic sound pulses in specific small decibel increments that are intended to be superimposed on the audiometer's output tone frequency.
87.	Toynbee diagnostic tube.	A listening device intended to determine the degree of openness of the eustachian tube.
ANESTHESIOLOGY		
88.	Airway connector.	A device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.
89.	Anesthesia stool.	A device intended for use as a stool for the anesthesiologist in the operating room.
90.	Anesthetic cabinet, table, or tray.	A device intended to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.
91.	Blow bottle.	A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.
92.	Calibration gas.	A device consisting of a container of gas of known concentration intended to calibrate medical gas concentration measurement devices.
93.	Cardiopulmonary emergency cart.	A device intended to store and transport resuscitation supplies for emergency treatment. The device does not include any equipment used in cardiopulmonary resuscitation.
94.	Dental protector.	A device intended to protect a patient's teeth during manipulative procedures within a patient's oral cavity.
95.	Gas collection vessel.	A gas collection vessel is a container-like device intended to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump
96.	Gas mask head strap.	A gas mask head strap is a device used to hold an anesthetic gas mask in position on a patient's face.
97.	Gas volume calibrator.	A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the

S/No	Device Types with examples	Description/Intended Use
		output of gas volume measurement instruments by delivering a known gas volume.
98.	Manual algesimeter.	A manual algesimeter is a mechanical device intended to determine a patient's sensitivity to pain after administration of an anesthetic agent, e.g., by pricking with a sharp point.
99.	Medical gas yoke assembly.	A device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.
100.	Nose clip.	A device intended to close a patient's external nares (nostrils) during diagnostic or therapeutic procedures.
101.	Patient position support.	A device intended to maintain the position of an anesthetized patient during surgery.
102.	Posture chair for cardiac or pulmonary treatment.	A posture chair for cardiac or pulmonary treatment is a device intended to assist in the rehabilitation and mobilization of patients with chronic heart or lung disease.
103.	Pressure tubing and accessories.	Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.
104.	Tee drain (water trap).	A device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.
105.	Tracheal tube cleaning brush.	A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.
106.	Tracheal tube stylet.	A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.
107.	Tube introduction forceps.	Tube introduction forceps (e.g., Magill forceps) are a right-angled device used to grasp a tracheal tube and place it in a patient's trachea.
	Ventilator tubing.	A device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.
DENTAL DEVICES		
108.	Abrasive device and accessories.	An abrasive device and accessories is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The

S/No	Device Types with examples	Description/Intended Use
		device is intended to remove excessive restorative materials, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece. The device includes the abrasive disk, guard for an abrasive disk, abrasive point, polishing agent strip, and polishing wheel.
109.	Calcium hydroxide cavity liner.	A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.
110.	Endosseous dental implant accessories.	Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, counter torque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, and trial abutments
111.	Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive.	An ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive is a device containing ethylene oxide homopolymer and/or carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
112.	Facebow.	A facebow is a device intended for use in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is intended for use in placing denture casts accurately into an articulator (§ 872.3150) and thereby aiding correct placement of artificial teeth into a denture base.

S/No	Device Types with examples	Description/Intended Use
113.	Gold or stainless-steel cusp.	A gold or stainless-steel cusp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group or stainless steel intended to provide a permanent cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) between the teeth and a removable denture.
114.	Powered toothbrush.	A powered toothbrush is an AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.
115.	Root canal post.	A root canal post is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be cemented into the root canal of a tooth to stabilize and support a restoration.
116.	Anesthetic warmer.	An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.
117.	Articulation paper.	Articulation paper is a device composed of paper coated with an ink dye intended to be placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.
118.	Articulator.	An articulator is a mechanical device intended to simulate movements of a patient's upper and lower jaws. Plaster casts of the patient's teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient's jaws. An articulator is intended to fit dentures or provide orthodontic treatment.
119.	Backing and facing for an artificial tooth.	A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.
120.	Base plate shellac.	Base plant shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.

S/No	Device Types with examples	Description/Intended Use
121.	Boiling water sterilizer.	A boiling water sterilizer is an AC-powered device that consists of a container for boiling water. The device is intended to sterilize dental and surgical instruments by submersion in the boiling water in the container.
122.	Bone cutting instrument and accessories.	A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw.
123.	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.	A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
124.	Dental amalgam capsule.	A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.
125.	Dental amalgamator.	A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental caries.
126.	Dental bur.	A dental bur is a rotary cutting device made from carbon steel or tungsten carbide intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.
127.	Dental cement.	Zinc oxide-eugenol is a device composed of zinc oxide-eugenol intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp.
128.	Dental chair and accessories.	A dental chair and accessories is a device, usually AC-powered, in which a patient sits. The device is

S/No	Device Types with examples	Description/Intended Use
		intended to properly position a patient to perform dental procedures. A dental operative unit may be attached.
129.	Dental diamond instrument.	A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth.
130.	Dental floss.	Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.
131.	Dental hand instrument.	A dental hand instrument is a hand-held device intended to perform various tasks in general dentistry and oral surgery procedures. The device includes the operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative amalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operative explorer surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative margin finishing periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, surgical osteotome chisel, endodontic broach, dental wax carver, endodontic pulp canal file, hand instrument for calculus removal, dental depth gauge instrument, plastic dental filling instrument, dental instrument handle, surgical tissue scissors, mouth mirror, orthodontic band driver, orthodontic band pusher, orthodontic band setter, orthodontic

S/No	Device Types with examples	Description/Intended Use
		bracket aligner, orthodontic pliers, orthodontic ligature tucking instrument, forceps, for articulation paper, forceps for dental dressing, dental matrix band, matrix retainer, dental retractor, dental retractor accessories, periodontic or endodontic irrigating syringe, and restorative or impression material syringe.
132.	Dental handpiece and accessories.	A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.
133.	Dental injecting needle.	A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs
134.	Dental operating light.	A dental operating light, including the surgical headlight, is an AC-powered device intended to illuminate oral structures and operating areas.
135.	Dental operative unit and accessories.	A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, and oral cavity evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.
136.	Dental sonography device.	A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.
137.	Dental x-ray exposure alignment device.	A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.
138.	Dental x-ray film holder.	A dental x-ray film holder is a device intended to position and to hold x-ray film inside the mouth.
139.	Dental x-ray position indicating device.	A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray

S/No	Device Types with examples	Description/Intended Use
		beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.
140.	Disposable fluoride tray.	A disposable fluoride tray is a device made of styrofoam intended to apply fluoride topically to the teeth. To use the tray, the patient bites down on the tray which has been filled with a fluoride solution.
141.	Electrode gel for pulp testers.	An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current
142.	Endodontic paper point.	An endodontic paper point is a device made of paper intended for use during endodontic therapy to dry, or apply medication to, the root canal of a tooth.
143.	Endodontic silver point.	An endodontic silver point is a device made of silver intended for use during endodontic therapy to fill permanently the root canal of a tooth.
144.	Mercury and alloy dispenser.	A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.
145.	Ethylene oxide homopolymer and/or karaya denture adhesive.	Ethylene oxide homopolymer and/or karaya denture adhesive is a device composed of ethylene oxide homopolymer and/or karaya intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
146.	Fiber optic dental light.	A fiber optic dental light is a device that is a light, usually AC-powered, that consists of glass or plastic fibers which have special optical properties. The device is usually attached to a dental handpiece and is intended to illuminate a patient's oral structures.
147.	Gingival fluid measurer.	A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.
148.	Gutta percha.	Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

S/No	Device Types with examples	Description/Intended Use
149.	Heat source for bleaching teeth.	A heat source for bleaching teeth is an AC-powered device that consists of a light or an electric heater intended to apply heat to a tooth after it is treated with a bleaching agent.
150.	Impression tube.	An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.
151.	Intraoral dental drill.	An intraoral dental drill is a rotary device intended to be attached to a dental handpiece to drill holes in teeth to secure cast or preformed pins to retain operative dental appliances.
152.	Intraoral dental wax.	Intraoral dental wax is a device made of wax intended to construct patterns from which custom-made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is intended to make a pattern of a patient's bite to make study models of the teeth.
153.	Jaw tracking device.	A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three-dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.
154.	Karaya and sodium borate with or without acacia denture adhesive.	A karaya and sodium borate with or without acacia denture adhesive is a device composed of karaya and sodium borate with or without acacia intended to be applied to the base of a denture before the denture is inserted into patient's mouth to improve denture retention and comfort.
155.	Lead-lined position indicator.	A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental x-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the x-rays by absorbing divergent radiation, and to prevent leakage of radiation.

S/No	Device Types with examples	Description/Intended Use
156.	Manual toothbrush.	A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.
157.	Massaging pick or tip for oral hygiene.	A massaging pick or tip for oral hygiene is a rigid, pointed device intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition.
158.	Mechanical denture cleaner.	A mechanical denture cleaner is a device, usually AC-powered that consists of a container for mechanically agitating a denture cleansing solution. The device is intended to clean a denture by submersion in the agitating cleansing solution in the container.
159.	Oral cavity abrasive polishing agent.	An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).
160.	Oral irrigation unit	An oral irrigation unit is an AC-powered device intended to provide a pressurized stream of water to remove food particles from between the teeth and promote good periodontal (gum) condition.
161.	Orthodontic appliance and accessories.	An orthodontic appliance and accessories are a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.
162.	OTC denture cleanser.	An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

S/No	Device Types with examples	Description/Intended Use
163.	OTC denture cushion or pad.	An OTC denture cushion or pad is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter.
164.	Pantograph.	A pantograph is a device intended to be attached to a patient's head to duplicate lower jaw movements to aid in construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient's mouth opens, the pen records on graph paper the angle between the upper and the lower jaw.
165.	Posterior artificial tooth with a metal insert.	A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).
166.	Precision attachment.	A precision attachment or preformed bar is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use in prosthetic dentistry in conjunction with removable partial dentures. Various forms of the device are intended to connect a lower partial denture with another lower partial denture, to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a partial denture.
167.	Preformed anchor.	A preformed anchor is a device made of austenitic alloys or alloys containing 75 percent or greater gold or metals of the platinum group intended to be incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient's mouth.
168.	Preformed clasp.	A preformed clasp or a preformed wire clasp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be incorporated into a dental appliance, such as a partial

S/No	Device Types with examples	Description/Intended Use
		denture, to help stabilize the appliance in the patient's mouth by fastening the appliance to an adjacent tooth.
169.	Preformed crown.	A preformed crown is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is intended for use as a functional restoration until a permanent crown is constructed. The device also may be intended for use as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.
170.	Preformed cusp.	A performed cusp is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) before permanent restoration of a tooth.
171.	Preformed gold denture tooth.	A preformed gold denture tooth is a device composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use as a tooth or a portion of a tooth in a fixed or removable partial denture.
172.	Preformed impression tray.	A preformed impression tray is a metal or plastic device intended to hold impression material, such as alginate, to make an impression of a patient's teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient's teeth and gums.
173.	Preformed tooth positioner.	A preformed tooth positioner is a plastic device that is an impression of a perfected bite intended to prevent a patient's teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.
174.	Prophylaxis cup.	A prophylaxis cup is a device made of rubber intended to be held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the

S/No	Device Types with examples	Description/Intended Use
		polishing agent and the user applies it to the teeth to remove debris.
175.	Resin applicator.	A resin applicator is a brush like device intended for use in spreading dental resin on a tooth during application of tooth shade material.
176.	Resin impression tray material.	Resin impression tray material is a device intended for use in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray for use in cases in which a preformed impression tray is not suitable, such as the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.
177.	Retentive and splinting pin.	A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.
178.	Rubber dam and accessories.	A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting a tooth through a hole in the center. The device includes the rubber dam, rubber dam clamp, rubber dam frame, and forceps for a rubber dam clamp. This classification does not include devices intended for use in preventing transmission of sexually transmitted diseases through oral sex; those devices are classified as condoms
179.	Saliva absorber.	A saliva absorber is a device made of paper or cotton intended to absorb moisture from the oral cavity during dental procedures.

S/No	Device Types with examples	Description/Intended Use
180.	Silicate protector.	A silicate protector is a device made of silicone intended to be applied with an absorbent tipped applicator to the surface of a new restoration to exclude temporarily fluids from its surface.
181.	Teething ring.	A teething ring is a device intended for use by infants for medical purposes to soothe gums during the teething process. Class I if the teething ring does not contain a fluid, such as water
GROUP 2: CARDIOVASCULAR DEVICES, RADIOLOGICAL HEALTH, NEUROLOGICAL, ORTHOPEDIC DEVICES AND PHYSICAL MEDICINE DEVICES		
CARDIOVASCULAR DEVICES		
182.	Recorder, Paper Chart	A paper chart recorder is a device used to print on paper, and create a permanent record of the signal from, for example, a physiological amplifier, signal conditioner, or computer.
183.	Recorder, Magnetic Tape, Medical	A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.
RADIOLOGICAL HEALTH,		
184.	Medical image hardcopy device.	A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multiformat cameras and laser printers
185.	Medical image digitizer	A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include Systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices
186.	Nuclear scanning bed	A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure
187.	Personnel protective shield	A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.
188.	Pneumoencephalographic chair	A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain)

S/No	Device Types with examples	Description/Intended Use
189.	Radiation therapy beam-shaping block	A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source
190.	Radiographic film	Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.
191.	Radiographic film cassette	A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.
192.	Radiographic film/cassette changer	A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.
193.	Radiographic grid	A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.
194.	Radiologic patient cradle	A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.
195.	Radiologic table	A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.
NEUROLOGICAL		
196.	Ataxiagraph	An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed
197.	Bite Block	A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions
198.	Clip Rack	A clip rack is a device used to hold or store surgical clips during surgery.

S/No	Device Types with examples	Description/Intended Use
199.	Computerized Cognitive Assessment Aid	The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.
200.	Evoked Photon Image Capture Device	An evoked photon image capture device is a prescription, electrically powered device intended for use as a noninvasive measurement tool that applies electricity to detect electrophysiological signals emanating from the skin, which are reported numerically and as images without clinical interpretation. The device is not intended for diagnostic purposes.
201.	Neurosurgical Chair	A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery
202.	Neurosurgical Headrests	A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.
203.	Percussor	A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.
204.	Pinwheel	A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.
205.	Skull Plate Anvil	A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.
206.	Tuning Fork	A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.
207.	Ultrasonic Scanner Calibration Test Block.	An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).
PHYSICAL MEDICINE DEVICES		

S/No	Device Types with examples	Description/Intended Use
208.	Arm sling.	An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.
209.	Cane, crutch, and walker tips and pads.	Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.
210.	Cane.	A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end
211.	Chilling unit.	A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.
212.	Cold pack.	A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.
213.	Congenital hip dislocation abduction splint.	A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).
214.	Crutch.	A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.
215.	Daily activity assist device.	A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.
216.	Denis Brown splint.	A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.
217.	Exercise component.	An exercise component is a device that is used in conjunction with other forms of exercise and that is intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an

S/No	Device Types with examples	Description/Intended Use
		adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.
218.	External limb orthotic component.	An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.
219.	External limb prosthetic component.	An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.
220.	Flotation cushion.	A flotation cushion is a device intended for medical purposes that is made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.
221.	Force-measuring platform.	A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time
222.	Hot or cold disposable pack.	A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.
223.	Limb orthosis.	A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

S/No	Device Types with examples	Description/Intended Use
224.	Mechanical chair.	A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.
225.	Mechanical table.	A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.
226.	Mechanical wheelchair	A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.
227.	Miniature pressure transducer.	A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.
228.	Moist heat pack.	A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.
229.	Nonmeasuring exercise equipment.	Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.
230.	Nonpowered communication system.	A nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

S/No	Device Types with examples	Description/Intended Use
231.	Nonpowered lower extremity pressure wrap.	A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary restless leg syndrome.
232.	Nonpowered sitz bath	A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.
233.	Physical Medicine Prosthetic Devices	A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance
234.	Plinth.	A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.
235.	Powered exercise equipment.	Powered exercise equipment consists of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.
236.	Powered finger exerciser.	A powered finger exerciser is a device intended for medical purposes to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.
237.	Powered heating unit.	A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.
238.	Powered table.	A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.
239.	Powered wheelchair.	A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

S/No	Device Types with examples	Description/Intended Use
240.	Powered wheeled stretcher.	A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).
241.	Pressure-applying device.	A pressure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.
242.	Prosthetic and orthotic accessory.	A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.
243.	Special grade wheelchair.	A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadriplegics, and amputees.
244.	Stair-climbing wheelchair.	A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.
245.	Standup wheelchair.	A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.
246.	Therapeutic massager.	A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

S/No	Device Types with examples	Description/Intended Use
247.	Therapeutic vibrator.	A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.
248.	Traction accessory.	A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.
249.	Truncal orthosis.	A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.
250.	Wheelchair accessory.	A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: arm board, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.
251.	Wheelchair component	A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.
252.	Wheelchair platform scale.	A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.
GROUP 3: GASTRORENAL, OBGYN, GENERAL HOSPITAL, AND UROLOGY DEVICES		
GASTROENTEROLOGY-UROLOGY DEVICES		

S/No	Device Types with examples	Description/Intended Use
253.	Biliary stent, drain, and dilator accessories.	Biliary stent, drain, and dilator accessories are manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.
254.	Colostomy rod.	A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.
255.	Continent ileostomy catheter.	A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.
256.	Enema kit.	An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing.
257.	Esophageal dilator.	An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).
258.	Fiberoptic light ureteral catheter.	A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.
259.	Gastroenterology-urology accessories to a biopsy instrument.	A gastroenterology-urology accessory to a biopsy instrument is an accessory used to remove a specimen of tissue for microscopic examination by cutting or aspiration. This generic type of device

S/No	Device Types with examples	Description/Intended Use
		includes a syringe for specimen aspiration and a biopsy channel adaptor. This device does not include accessories to biopsy instruments used in other medical specialty areas.
260.	Gastroenterology-urology biopsy instrument.	A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.
261.	Gastroenterology-urology evacuator.	A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, awhen manually powered
262.	Gastroenterology-urology fiberoptic retractor.	A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.
263.	Gastrointestinal tube and accessories.	A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray

S/No	Device Types with examples	Description/Intended Use
		(for gastrological use).for the dissolvable nasogastric feed tube guide for the nasogastric tube.
264.	Hernia support.	A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.
265.	Interlocking urethral sound.	An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.
266.	Manual gastroenterology-urology surgical instrument and accessories.	A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, non-self-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop. A manual surgical instrument that is intended specifically for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures

S/No	Device Types with examples	Description/Intended Use
267.	Ostomy pouch and accessories.	An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.
268.	Protective garment for incontinence.	A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.
269.	Rectal control system.	A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.
270.	Rectal dilator.	A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.
271.	Ribdam.	A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected
272.	Stomach pH electrode.	A stomach pH electrode is a device used to measure intragastric and intraesophageally pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

S/No	Device Types with examples	Description/Intended Use
273.	Tissue culture media for human ex vivo tissue and cell culture processing application	Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.
274.	Ureteral dilator.	A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.
275	Urethral dilator.	A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower. For the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound.
275.	Urine collector and accessories.	A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection the urine collector and accessories not intended to be connected to an indwelling catheter,
276.	Urological catheter and accessories.	These are flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract ureteral stylet (guidewire), stylet for gastrourological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph
277.	Urological clamp.	A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

S/No	Device Types with examples	Description/Intended Use
278.	Urological table and accessories.	A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually.
GENERAL HOSPITAL DEVICES		
279.	Cast cover.	A cast cover is a device intended for medical purposes that is made of waterproof material and placed over a cast to protect it from getting wet during a shower or a bath.
280.	Examination gown.	An examination gown is a device intended for medical purposes that is made of cloth, paper, or other material that is draped over or worn by a patient as a body covering during a medical examination.
281.	Neonatal eye pad.	A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.
282.	Absorbent tipped applicator	An absorbent tipped applicator is a device intended for medical purposes that consists of an absorbent swab on a wooden, paper, or plastic stick. The device is used to apply medications to, or to take specimens from, a patient.
283.	AC-powered adjustable hospital bed.	An AC-powered adjustable hospital bed is a device intended for medical purposes that consists of a bed with a built-in electric motor and remote controls that can be operated by the patient to adjust the height and surface contour of the bed. The device includes movable and latch able side rails.
284.	AC-powered medical examination light.	An AC-powered medical examination light is an AC-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.
285.	Apgar timer	The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.
286.	Battery-powered medical examination light.	A battery-powered medical examination light is a battery-powered device intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.
287.	Bed board.	A bed board is a device intended for medical purposes that consists of a stiff board used to increase the firmness of a bed.

S/No	Device Types with examples	Description/Intended Use
288.	Bed-patient monitor	A bed-patient monitor is a battery-powered device placed under a mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.
289.	Body waste receptacle.	A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient
290.	Burn sheet.	A burn sheet is a device made of a porous material that is wrapped around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants.
291.	Cardiopulmonary resuscitation board.	A cardiopulmonary resuscitation board is a device consisting of a rigid board which is placed under a patient to act as a support during cardiopulmonary resuscitation.
292.	Clinical color change thermometer	A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat causes a stable color change in the heat sensitive chemicals.
293.	Elastic bandage	An elastic bandage is a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient's body.
294.	General purpose disinfectants.	A general-purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general-purpose disinfectant can be used to preclean or decontaminate critical or semi critical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin.
295.	Hand-carried stretcher.	A hand-carried stretcher is a device consisting of a lightweight frame, or of two poles with a cloth or metal platform, on which a patient can be carried.
296.	Hot/cold water bottle.	A hot/cold water bottle is a device intended for medical purposes that is in the form of a container intended to be filled with hot or cold water to apply heat or cold to an area of the body.

S/No	Device Types with examples	Description/Intended Use
297.	Hydraulic adjustable hospital bed.	A hydraulic adjustable hospital bed is a device intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latch able side rails.
298.	Ice bag.	An ice bag is a device intended for medical purposes that is in the form of a container intended to be filled with ice that is used to apply dry cold therapy to an area of the body. The device may include a holder that keeps the bag in place against an external area of the patient.
299.	Infusion stand.	The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.
300.	Intravascular catheter securement device.	An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin.
301.	Irrigating syringe.	An irrigating syringe is a device intended for medical purposes that consists of a bulb or a piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.
302.	Lamb feeding nipple.	A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.
303.	Lice removal kit.	The lice removal kit is a comb or comb-like device intended to remove and/or kill lice and nits from head and body hair. It may or may not be battery operated
304.	Liquid bandage.	A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant.
305.	Liquid crystal vein locator.	A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).
306.	Liquid medication dispenser.	A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.

S/No	Device Types with examples	Description/Intended Use
307.	Liquid medication dispenser.	A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.
308.	Manual adjustable hospital bed.	A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latch able side rails.
309.	Manual patient transfer device.	A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.
310.	Mattress cover for medical purposes.	A mattress cover for medical purposes is a device intended for medical purposes that is used to protect a mattress. It may be electrically conductive or contain a germicide.
311.	Medical absorbent fiber.	A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient's body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.
312.	Medical adhesive tape and adhesive bandage.	A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin.
313.	Medical chair and table.	A medical chair or table is a device intended for medical purposes that consists of a chair or table without wheels and not electrically powered which, by reason of special shape or attachments, such as food trays or headrests, or special features such as a built-in raising and lowering mechanism or removable arms, is intended for use of blood donors, geriatric patients, or patients undergoing treatment or examination.

S/No	Device Types with examples	Description/Intended Use
314.	Medical device data system.	A medical device data system (MDDS) is a hardware device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
315.	Medical disposable bedding.	Medical disposable bedding is a device intended for medical purposes to be used by one patient for a period of time and then discarded. This generic type of device may include disposable bedsheets, bedpans, pillows and pillowcases, blankets, emergency rescue blankets, or waterproof sheets.
316.	Medical disposable scissors.	Medical disposable scissors are disposable type general cutting devices intended for medical purposes. This generic type of device does not include surgical scissors.
317.	Medical insole.	A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.
318.	Nipple shield.	A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.
319.	Non-AC-powered patient lift.	A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either fixed or mobile, used to lift and transport a patient in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and a sling to support the patient.
	Nonpowered flotation therapy mattress.	A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials that have the functionally equivalent effect of supporting a patient and avoiding excess pressure on local body areas. The device is intended to treat or prevent decubitus ulcers (bed sores).
320.	Patient lubricant.	A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device

S/No	Device Types with examples	Description/Intended Use
321.	Patient scale.	A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scale. This generic device includes devices placed under a bed or chair to weigh both the support and the patient, devices where the patient is lifted by a sling from a bed to be weighed, and devices where the patient is placed on the scale platform to be weighed. The device may be mechanical, battery powered, or AC-powered and may include transducers, electronic signal amplification, conditioning and display equipment.
322.	Pediatric position holder.	A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered
323.	Pressure infuser for an I.V. bag.	A pressure infuser for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.
324.	Protective restraint.	A protective restraint is a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap, that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others.
325.	Ring cutter.	A ring cutter is a device intended for medical purposes that is used to cut a ring on a patient's finger so that the ring can be removed. The device incorporates a guard to prevent injury to the patient's finger.
326.	Skin pressure protectors.	A skin pressure protector is a device intended for medical purposes that is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores).
327.	Stand-on patient scale.	A stand-on patient scale is a device intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.

S/No	Device Types with examples	Description/Intended Use
328.	Suction snakebite kit.	A suction snakebite kit is a device consisting of a knife, suction device, and tourniquet used for first-aid treatment of snakebites by removing venom from the wound.
329.	Surgical sponge scale.	A surgical sponge scale is a nonelectrically powered device used to weigh surgical sponges that have been used to absorb blood during surgery so that, by comparison with the known dry weight of the sponges, an estimate may be made of the blood lost by the patient during surgery.
	Temperature regulated water mattress.	A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.
330.	Therapeutic medical binder.	A therapeutic medical binder is a device, usually made of cloth, that is intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place. This generic type of device includes the abdominal binder, breast binder, and perineal binder.
331.	Therapeutic scrotal support.	A therapeutic scrotal support is a device intended for medical purposes that consist of a pouch attached to an elastic waistband and that is used to support the scrotum (the sac that contains the testicles).
332.	Tongue depressor.	A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.
333.	Ultrasonic cleaner for medical instruments.	An ultrasonic cleaner for medical instruments is a device intended for cleaning medical instruments by the emission of high frequency soundwaves.
334.	Umbilical occlusion device.	An umbilical occlusion device is a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.
335.	Vein stabilizer.	A vein stabilizer is a device consisting of a flat piece of plastic with two noninvasive prongs. The device is placed on the skin so that the prongs are on either side of a vein and hold it stable while a hypodermic needle is inserted into the vein.

S/No	Device Types with examples	Description/Intended Use
336.	Washers for body waste receptacles.	A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan. The device consists of a wall-mounted plumbing fixture with a door through which a body waste receptacle is inserted. When the door is closed the body waste receptacle is cleaned by hot water, steam, or germicide.
337.	Wheeled stretcher	A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps. The frame may be fixed or collapsible for use in an ambulance.
OBSTETRICAL AND GYNECOLOGICAL DEVICES		
	Liquid crystal thermographic system.	A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses -
338.	Amniotic fluid sampler (amniocentesis tray).	The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3-inch 20-gauge needle with stylet and a 30-cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16-18 weeks' gestation for antepartum diagnosis of certain congenital abnormalities or any time after 24 weeks gestation when used to assess fetal maturity.
339.	Fetal stethoscope.	A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction, but also through the user's head by tissue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.
340.	Fetal vacuum extractor	A fetal vacuum extractor is a device used to facilitate delivery. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an

S/No	Device Types with examples	Description/Intended Use
		external vacuum source. This generic type of device may include the cup, hosing, vacuum source, and vacuum control.
341.	Nonpowered breast pump.	A nonpowered breast pump is a manual suction device used to express milk from the breast.
342.	Obstetric fetal destructive instrument.	An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. This generic type of device includes the cleidoclast, cranioclast, craniotribe, and destructive hook.
343.	Obstetric forceps.	An obstetric forceps is a device consisting of two blades, with handles, designed to grasp and apply traction to the fetal head in the birth passage and facilitate delivery.
344.	Obstetric table and accessories.	An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.
345.	Obstetric-gynecologic general manual instrument.	An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following:
346.	Obstetrical and Gynecological Surgical Devices	Specialized surgical instrumentation for use with urogynecologic surgical mesh is a prescription device specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures. These procedures include transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of specialized surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors.
347.	Powered breast pump.	A powered breast pump in an electrically powered suction device used to express milk from the breast.

S/No	Device Types with examples	Description/Intended Use
348.	Scented or scented deodorized menstrual pad.	Scented or scented deodorized menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual pad) or for deodorizing purposes (scented deodorized menstrual pad). This generic type of device includes sterile scented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with added antimicrobial agents or other drugs.
349.	Unscented menstrual pad.	An unscented menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs
350.	Vaginal insufflator.	A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum
351.	Viscometer for cervical mucus	A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.
GROUP 4: SURGICAL AND INFECTION CONTROL DEVICES		
GENERAL AND PLASTIC SURGERY DEVICES		
352.	Air-handling apparatus accessory.	An air-handling apparatus accessory is a supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.
353.	Drape adhesive.	A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.

S/No	Device Types with examples	Description/Intended Use
354.	External facial fracture fixation appliance.	An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship
355.	Eye pad.	An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.
356.	Hydrogel wound dressing and burn dressing.	A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a non-resorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. This classification does not include a hydrogel wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources
357.	Hydrophilic wound dressing.	A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of non-resorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). This classification does not include a hydrophilic wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal source
358.	Introduction/drainage catheter and accessories.	An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.

S/No	Device Types with examples	Description/Intended Use
359.	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Special laser gas mixtures used as a lasing medium for this class of lasers for use in general surgery and in dermatology that is intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.
360.	Manual operating table and accessories and manual operating chair and accessories.	A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.
361.	Manual surgical instrument for general use.	A manual surgical instrument for general use is a non-powered, hand-held, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers.
362.	Needle-type epilator.	A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.
363.	Non-Powered suction apparatus device intended for negative pressure wound therapy.	A non-powered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

S/No	Device Types with examples	Description/Intended Use
364.	Non-absorbable gauze for internal use.	Non-absorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.
365.	Non-pneumatic tourniquet.	A non-pneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.
366.	Occlusive wound dressing.	An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.
367.	Operating tables and accessories and operating chairs and accessories.	Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.
368.	Organ bag.	An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.
369.	Pneumatic tourniquet.	A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.
370.	Removable skin clip.	A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable.

S/No	Device Types with examples	Description/Intended Use
371.	Removable skin staple.	A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.
372.	Silicone sheeting.	Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.
373.	Skin marker.	A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.
374.	Speculum and accessories.	A speculum is a device intended to be inserted into a body cavity to aid observation. It is either non-illuminated or illuminated and may have various accessories.
375.	Surgeon's gloving cream.	Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.
376.	Surgical apparel.	Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.
377.	Surgical camera and accessories.	A surgical camera and accessories is a device intended to be used to record operative procedures.
378.	Surgical drape and drape accessories.	A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy.

S/No	Device Types with examples	Description/Intended Use
379.	Surgical instrument motors and accessories/attachments.	Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.
380.	Surgical lamp.	A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.
381.	Surgical microscope and accessories.	A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.
382.	Surgical skin degreaser or adhesive tape solvent.	A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.
383.	Surgical stapler.	A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery.
384.	Suture retention device.	A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.
385.	Tweezer-type epilator	The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.
386.	Wound autofluorescence imaging device.	A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.
GROUP 5: IN VITRO DIAGNOSTICS, LABORATORY EQUIPMENT AND VETERINARY		
IN VITRO DIAGNOSTICS		
387.	Antimicrobial susceptibility test disc	An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or

S/No	Device Types with examples	Description/Intended Use
		a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.
388.	Antimicrobial susceptibility test powder	An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases
389.	Culture medium for antimicrobial susceptibility tests	A culture medium for antimicrobial susceptibility tests is a device intended for medical purposes that consists of any medium capable of supporting the growth of many of the bacterial pathogens that are subject to antimicrobial susceptibility tests. The medium should be free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.
390.	Anaerobic chamber	An anaerobic chamber is a device intended for medical purposes to maintain an anaerobic (oxygen free) environment. It is used to isolate and cultivate anaerobic microorganisms
391.	Coagulase plasma	Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is intended for medical purposes to perform coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an

S/No	Device Types with examples	Description/Intended Use
		aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus Staphylococcus and provide epidemiological information on disease caused by these microorganisms.
392.	Automated colony counter	An automated colony counter is a mechanical device intended for medical purposes to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.
393.	Manual colony counter	A manual colony counter is a device intended for medical purposes that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.
394.	Automated image assessment system for microbial colonies on solid culture media.	An automated image assessment system for microbial colonies on solid culture media is a system that is intended to assess the presence or absence of microbial colonies on solid microbiological culture medium, and to interpret their number, and phenotypic and morphologic characteristics through analysis of two dimensional digital images as an aid in diagnosis of infectious disease.
395.	Multipurpose culture medium	A multipurpose culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes for the cultivation and identification of several types of pathogenic microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.
396.	Differential culture medium	A differential culture medium is a device that consists primarily of liquid biological materials intended for medical purposes to cultivate and identify different types of pathogenic microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical

S/No	Device Types with examples	Description/Intended Use
		component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.
397.	Enriched culture medium	An enriched culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify fastidious microorganisms (those having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
398.	Microbiological assay culture medium	A microbiological assay culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate selected test microorganisms in order to measure by microbiological procedures the concentration in a patient's serum of certain substances, such as amino acids, antimicrobial agents, and vitamins. The concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the innoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Tests results may also be used to monitor the effects of the administration of certain antimicrobial drugs.
399.	Selective culture medium	A selective culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify certain pathogenic microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by

S/No	Device Types with examples	Description/Intended Use
		pathogenic microorganisms and also provides epidemiological information on these diseases.
400.	Transport culture medium.	A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
401.	Culture medium for pathogenic Neisseria spp	A culture medium for pathogenic Neisseria spp. is a device that consists primarily of liquid or solid biological materials used to cultivate and identify pathogenic Neisseria spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus Neisseria, such as epidemic cerebrospinal meningitis, other meningococcal disease, and gonorrhea, and also provides epidemiological information on these microorganisms.
402.	Automated medium dispensing and stacking device	An automated medium dispensing and stacking device is a device intended for medical purposes to dispense a microbiological culture medium into petri dishes and then mechanically stack the petri dishes.
403.	Supplement for culture media	A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is intended for medical purposes to enhance the growth of fastidious microorganisms (those having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.
404.	Quality control kit for culture media	A quality control kit for culture media is a device that consists of paper discs (or other suitable materials), each impregnated with a specified, freeze-dried, viable microorganism, intended for medical purposes to determine if a given culture medium is able to support the growth of that microorganism. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
405.	Microtiter diluting and dispensing device	A microtiter diluting and dispensing device is a mechanical device intended for medical purposes to

S/No	Device Types with examples	Description/Intended Use
		dispense or serially dilute very small quantities of biological or chemical reagents for use in various diagnostic procedures
406.	Microbiological incubator	A microbiological incubator is a device with various chambers or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained. It is intended for medical purposes to cultivate microorganisms and aid in the diagnosis of disease.
407.	Microbial growth monitor	A microbial growth monitor is a device intended for medical purposes that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease caused by pathogenic microorganisms.
408.	Gas-generating device	A gas-generating device is a device intended for medical purposes that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.
409.	Wood's fluorescent lamp	A Wood's fluorescent lamp is a device intended for medical purposes to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.
410.	Microorganism differentiation and identification device	A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more components, such as differential culture media, biochemical reagents, and paper discs or paper strips impregnated with test reagents, that are usually contained in individual compartments and used to differentiate and identify selected microorganisms. The device aids in the diagnosis of disease.
411.	Automated zone reader	An automated zone reader is a mechanical device intended for medical purposes to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain

S/No	Device Types with examples	Description/Intended Use
		culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in decisionmaking respecting the treatment of disease.
412.	Microbiological specimen collection and transport device	A microbiological specimen collection and transport device is a specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.
413.	Mass spectrometer system for clinical use for the identification of microorganisms	A mass spectrometer system for clinical use for the identification of microorganisms is a qualitative in vitro diagnostic device intended for the identification of microorganisms cultured from human specimens. The device is comprised of an ionization source, a mass analyzer, and a spectral database. The device is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections.
414.	Ouchterlony agar plate	An ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.
415.	Radial immunodiffusion plate	A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.
416.	Support gel	A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various immunochemical techniques,

S/No	Device Types with examples	Description/Intended Use
		such as immunoelectrophoresis, immunodiffusion, or chromatography.
GENERAL LABORATORY EQUIPMENT		
417.	Beaker	A beaker is a common container in most labs. It is used for mixing, stirring, and heating chemicals. Most beakers have spouts on their rims to aid in pouring. They also commonly have lips around their rims and markings to measure the volume they contain, although they are not a precise way to measure liquids. Beakers come in a wide range of sizes. Because of the lip that runs around the rim, a lid for a beaker does not exist. However, a watch glass can be used to cover the opening to prevent contamination or splashing.
418.	Erlenmeyer flasks, conical flasks	Also known as a conical flask, the Erlenmeyer flask was named after its inventor in 1861. It has a narrow neck and expands toward its base. This allows easy mixing and swirling of the flask without too much risk of spilling. The narrow opening also allows for the use of a rubber or glass stopper. It can easily be clamped to a ring stand as well as heated or shaken mechanically. Once again, the marks on the side are meant primarily for estimation rather than precision.
419.	Florence flasks, boiling flasks	Also known as a boiling flask, the Florence flask has a round bottom and a long neck. It is used to hold liquids and can be easily swirled and heated. It can also easily be capped by rubber or glass stoppers. Once again, safety dictates that this flask never be heated when capped. Pressure build-up and explosions can and do occur.
420.	Test tubes being lifted with tongs from a rack	A test tube is a glass tube with one end open and the other end closed. The closed end is rounded. Test tubes are used to hold small samples. They are primarily used for qualitative assessment and comparison. A common place to see these is the biochemistry lab. When a large number of samples need to be tested and compared, test tubes are used

S/No	Device Types with examples	Description/Intended Use
		to make this easier. They are also easily capped with a rubber or glass stopper. They are generally held in a test tube rack specifically designed for the purpose. If the test tubes become unsafe to touch with bare hands (whether due to heat or another reason), test-tube tongs can be used to move them.
421.	Watch glasses	A watch glass is just a round piece of glass that is slightly concave/convex (think of a lens). It can hold a small amount of liquid or solid. They can be used for evaporation purposes and also can function as a lid for a beaker.
422.	Crucibles	A crucible is a small clay cup made of a material that can withstand extreme temperatures. They are used for heating substances and come with lids.
423.	Funnels	A lab funnel is just like any other funnel except that it was designed to be used in a laboratory setting. They can be made of plastic or glass and can have either a short stem or a long stem, depending on what they are needed for. There are several sizes that can be chosen from based on the amount of liquid that needs to go through them quickly.
424.	Graduated cylinders	This is a primary measuring tool for the volume of a liquid. There are several markings up and down the length of the container with specific increments. Graduated cylinders come in many sizes. The smaller they are in diameter, the more specific the volume measurements will be. When reading the volume from a graduated cylinder, you will notice that the liquid seems to have an indentation. The liquid around the edges will be higher than the liquid in the center, sloping down like the sides of a trampoline when someone is standing in the middle. This is called the meniscus. Line the lowest point of the meniscus up with the nearest marking, keeping the cylinder level to properly read the volume
425.	Volumetric flasks	A volumetric flask is a round flask with a long neck and flat bottom. It is used to measure an exact volume of liquid. There is a small line on the neck that indicates how far to fill the bottle (use the bottom of the

S/No	Device Types with examples	Description/Intended Use
		meniscus). They come with special caps that will not let anything in or out. Remember that temperature affects volume; therefore avoid using liquids that will fluctuate in temperature (hot water that will cool, for example).
426.	Droppers	These are small glass tubes with narrow tips on one end and a rubber bulb on the other. They suck up liquid that can then be squeezed out in small drops. These can be used to add an indicator to a solution about to be titrated.
427.	Pipettes	There are a large variety of pipettes designed to accomplish specific goals. However, they are all for measuring an exact volume of liquid and placing it into another container.
428.	Burette	A burette is a glass tube that is open at the top and comes to a narrow pointed opening at the bottom. Right above the bottom opening is a stopcock that can be turned to control the amount of liquid being released. There are markings along the length of the tube that indicate the volume of liquid present. A burette is used for extremely accurate addition of liquid. By adjusting the stopcock, the amount of liquid that is released can be slowed to a drop every few seconds. Burets are one of the most accurate tools in the lab.
429.	Ring stands with rings attached	The ring stand is used to suspend burets, beakers, flasks, crucibles, etc. above other containers or, in some cases, a heat source. When using a ring on the stand, there are usually other pieces necessary to accomplish the goal. Wire mesh is laid across the ring to distribute evenly heat and support the beaker. A clay triangle with an open center is used to suspend crucibles.
430.	Two tongs and forceps below	Tongs and forceps are for grabbing things that should not be touched by hand. Some tongs are specially made to hold beakers, others to hold test tubes, and so on. There are also general tongs.

S/No	Device Types with examples	Description/Intended Use
		Forceps are used to grab small things like solid chemicals that are broken into chunks, so they can be safely handled and added to containers.
431.	Scoopulas and Spatulas	Spatulas and scoopulas are for scooping solid chemicals. They are typically used to scoop a chemical out of its original container onto a weigh boat so that it can be weighed on a balance.
432.	Laboratory Thermometers	A laboratory thermometer is used for measuring the temperature of liquids. It can be made of glass or it can be a thermocouple made of different metals
433.	Bunsen burner	A Bunsen burner is a mechanical apparatus that is connected to a flammable gas source. There is a knob to adjust the amount of gas flow and a rotating collar that controls airflow. These both must be adjusted to get an ideal flame for heating purposes. The burner is lit with a striker. Utmost safety is required when using a Bunsen burner.
434.	Balances	A balance is used to weigh chemicals. The chemicals are always in some form of container and never placed directly on the balance. It is important not to move a balance because they have been calibrated for the exact position they are in. Some balances have plastic housing with small doors to keep air currents from affecting the measurement. Close these doors whenever the balance is in use.
435.	Microscope	A microscope is a very basic and needed equipment in the biology laboratory. A simple light microscope (compound microscope) is the one, which is mostly used in schools and colleges and it uses natural or artificial light and a series of magnifying lenses to observe a tiny specimen
436.	Magnifying glass	A magnifying glass is one of the first introduced lab equipment among the students. As the name suggests, it is used to view enlarged or magnified images of objects or read the small calibrations marked on many equipment. It has a convex lens for object enlargement and usually has a wooden handle to hold it.
437.	Brushes	Brushes serve as the cleansing apparatus of the test tubes, as they are the only things that can get fit into

S/No	Device Types with examples	Description/Intended Use
		the narrow-mouthed test tubes and other cylindrical and narrow objects.
438.	Wash bottles	The wash bottles are laboratory consumables used for cleansing and sterilization purposes. These bottles are made up of plastic, which serves as a squeezy container with a long nozzle. They mostly contain distilled water, ethanol or deionized water.
439.	Spring balance	Spring balance also referred to as Newton meter, is another instrument helpful in measuring the weight of an object. This apparatus consists of a spring and a hook and it works on the principle of Hooke's law, according to which, the force applied to an object is directly proportional to the extension, provided that the elastic limit is not reached.
440.	Ammeter	Ammeter is important lab apparatus used to measure the amount of current flowing; very popular equipment presents in physics labs. It is also very handful during electrolysis reactions.
441.	Litmus and filter papers	The litmus paper serves to identify the pH of any solution by changing colors whereas, the filter paper serves in the filtration process.
442.	Wire Gauze	Wire screen with ceramic fibered center; used to spread the heat of a flame
443.	Well Plate	Small plate with several wells; used for reacting small amounts of chemicals
444.	Triple Beam Balance	Used for determining the mass, in grams, of a chemical or object
445.	Test Tube Rack	May be made of wood, metal, or plastic; used to hold test tubes in an upright position
VETERINARY USES MEDICAL DEVICES		
446.	All Medical devices Intended for veterinary uses only.	All medical devices intended to be used for Animal care, excluding devices which may be used for Human as well. These products should labeled "***for veterinary uses only***".
GROUP 6: MEDICAL GASSES *Medical devices already covered in other groups are not included.*		
447.	Locally manufactured gases for commercial use.	• Oxygen • Nitrous oxide • Nitrogen • Carbon dioxide

S/No	Device Types with examples	Description/Intended Use
		• Medical air
GROUP 7: BLOOD AND BLOOD PRODUCTS		
448.	Animal and human sera.	Animal and human sera are biological products, obtained from the blood of humans or other animals that provide the necessary growth-promoting nutrients in a cell culture system.
449.	Automated slide spinner	An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body's extremities, such as the arm).
450.	Automated slide Stainer.	An automated slide Stainer is a device used to stain histology, cytology, and hematology slides for diagnosis.
451.	Automated tissue processor.	An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.
452.	Blood bank centrifuge for in vitro diagnostic use.	A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.
453.	Blood bank supplies.	Blood bank supplies are general purpose devices intended for in vitro use in blood banking. This generic type of device includes products such as blood bank pipettes, blood grouping slides, blood typing tubes, blood typing racks, and cold packs for antisera reagents. The device does not include articles that are licensed by the Center for Biologics Evaluation and Research of the Food and Drug Administration
454.	Blood cell diluent.	A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.
455.	Blood grouping view box.	A blood grouping view box is a device with a glass or plastic viewing surface, which may be illuminated and heated, that is used to view cell reactions in antigen-antibody testing.
456.	Blood mixing devices and blood weighing devices.	A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.

S/No	Device Types with examples	Description/Intended Use
457.	Capillary blood collection tube.	A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.
458.	Cell And Tissue Culture Products	Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the survival and development of cell lines of humans and other animals. This does not include tissue culture media for human ex vivo tissue and cell culture processing applications
459.	Cell And Tissue Culture Products	A balanced salt solution or formulation is a defined mixture of salts and glucose in a simple medium. This device is included as a necessary component of most cell culture systems. This media component controls for pH, osmotic pressure, energy source, and inorganic ions.
460.	Cell-freezing apparatus and reagents for in vitro diagnostic use	Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.
461.	Cell And Tissue Culture Products	Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.
462.	Copper sulfate solution for specific gravity determinations.	A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men)
463.	Cytocentrifuge.	A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.
464.	Device for sealing microsections.	A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination
465.	Dye and chemical solution stains.	Dye and chemical solution stains for medical purposes are mixtures of synthetic or natural dyes or nondyed chemicals in solutions used in staining cells

S/No	Device Types with examples	Description/Intended Use
		and tissues for diagnostic histopathology, cytopathology, or hematology
466.	Enzyme preparations.	Enzyme preparations are products that are used in the histopathology laboratory for the following purposes:(1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin) ;(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).
467.	Erythrocyte sedimentation rate test.	An erythrocyte sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance or a device that measures the degree of sedimentation taking place in a given length of time. An increased rate indicates tissue damage or inflammation.
468.	General purpose reagent.	A general-purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labeled or otherwise intended for a specific diagnostic application. It may be either an individual substance, or multiple substances reformulated, which, when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general-purpose reagents, is part of a diagnostic test procedure or system constituting a finished in vitro diagnostic (IVDD) test.
469.	Heat-sealing device.	A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.
470.	Lymphocyte separation medium	A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.
471.	Manual blood cell counting device.	A manual blood cell counting device is a device used to count red blood cells, white blood cells, or blood platelets.
472.	Microscope Accessories	Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes. Variations of microscopes and accessories (through a change in the light source) used for medical purposes include the following:(1) Phase contrast microscopes, which permit visualization of unstained preparations by

S/No	Device Types with examples	Description/Intended Use
		altering the phase relationship of light that passes around the object and through the object. (2) Fluorescence microscopes, which permit examination of specimens stained with fluorochromes that fluoresce under ultraviolet light. (3) Inverted stage microscopes, which permit examination of tissue cultures or other biological specimens contained in bottles or tubes with the light source mounted above the specimen.
473.	Micro sedimentation centrifuge.	A micro sedimentation centrifuge is a device used to sediment red cells for the micro sedimentation rate test.
474.	Mycoplasma detection media and components.	Mycoplasma detection media and components are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures.
475.	Osmotic fragility test.	An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.
476.	OTC test sample collection systems for drugs of abuse testing.	An over-the-counter (OTC) test sample collection system for drugs of abuse testing is a device intended to: Collect biological specimens (such as hair, urine, sweat, or saliva), outside of a medical setting and not on order of a health care professional (e.g., in the home, insurance, sports, or workplace setting); maintain the integrity of such specimens during storage and transport in order that the matter contained therein can be tested in a laboratory for the presence of drugs of abuse or their metabolites; and provide access to test results and counseling.
477.	Red cell lysing reagent.	A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.
478.	Specimen transport and storage container.	A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general-

S/No	Device Types with examples	Description/Intended Use
		purpose reagent to preserve the condition of a biological specimen added to the container.
479.	Tissue processing equipment.	Tissue processing equipment consists of devices used to prepare human tissue specimens for diagnostic histological examination by processing specimens through the various stages of decalcifying, infiltrating, sectioning, and mounting on microscope
480.	Vacuum-assisted blood collection system.	A vacuum-assisted blood collection system is a device intended for medical purposes that uses a vacuum to draw blood for subsequent reinfusion

Note: *The list is not exhaustive all exempted product*

Bibliography

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3. Guidelines on Submission of Documentation for Registration of In Vitro Diagnostics Devices, 3rd Edition, April 2020
4. ISO 8601-The global standard for date and time formats.
5. ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.