TMDA/DMD/MDL/G/005
Rev.# 02

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR IMPORTATION AND EXPORTATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS, LABORATORY EQUIPMENT AND RAW MATERIALS

(Made under Section 73(1) of the Tanzania Medicines and Medical Devices Act, Cap 219)

Third Edition
May, 2024

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, Tel: +255 (26) 2961989/2061990/ +255(22) 2450512/2450751/2452108, Email: info@tmda.to.tz, Website: www.tmda.go.tz, Toll free: 08001100834

TABLE OF CONTENTS

ABBREVIATIONS

CoA	Certificate of Analysis
CoC	Certificate of Conformity
DoC	Declaration of Conformity
FoB	Free on Board
FoC	Free of Charge Goods
GCLA	Government Chemist Laboratory Authority
IMDRF	International Medical Device Regulators Forum
IRIMS	Integrated Regulatory Information Management System
LPO	Local Purchase Order
LTR	Local Technical Representative
NEMC	National Environment Management Council
NGOs	Non-Governmental Organizations
OGDs	Other Government Departments
PoE	Ports of Entry
TAEC	Tanzania Atomic Energy Commission
TBS	Tanzania Bureau of Standards
TMDA	Tanzania Medicines and Medical Devices Authority
TRA	Tanzania Revenue Authority
WHO	World Health Organization
PO-RALG	President's Office-Regional Administration and Local Government

ACKNOWLEDGEMENTS

This is the third edition of the Guidelines for Importation and Exportation of Medical Devices including In vitro Diagnostics, Laboratory Equipment and Raw Materials developed by Tanzania Medicines and Medical Devices Authority (TMDA). The edition supersedes the second edition which was developed in April, 2020 by experts from TMDA.

I would like to sincerely thank and appreciate the contribution of the following TMDA staff: Mr. Bryceson Kibassa, Mr. Felix Zelote, Mr. John Bugalama, Ms. Emmanuela Mkalawa, Mr. Yusto Patrick, Ms. Marina Sapali, Mr. Amani Molleli, Ms. Lineth Msele and Ms. Fatma Mafumbi who reviewed the second edition of the guidelines and crafted this third edition.

I also wish to extend my sincere gratitude to TMDA Management for providing the required resources in reviewing these guidelines. Dealers in medical devices who provided comments during stakeholder's consultative meetings are also acknowledged for their invaluable inputs. TMDA will continue to receive comments for improvement of these guidelines during its implementation.

Special gratitude is also owed to Health Canada, International Medical Devices Regulatory Forum (IMDRF) and World Health Organization (WHO) for making their guidelines available for reference.

The administrative and secretarial work offered by Ms. Irene Rubona for aligning and type-setting of the document is also highly appreciated.

Kissa W. Mwamwitwa
Director, Medical Devices and Diagnostics Control

FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act, Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of medicines, medical devices and diagnostics.

In view of complexity of the medical devices and the accompanied risk in various ways of utilization, the Control of Medical Devices Regulations, 2015 has laid down the rules pertaining to importation and exportation of medical devices including in vitro diagnostics, laboratory equipment and their accompanying spare parts and accessories. The rules require any person dealing with importation of these products to have valid permit issued by the Authority for that purpose. The regulations further set the requirements for application of the permits, issuance of the permits, conditions for importation of medical devices for personal use, exhibitions, use during emergence situations such as outbreak, designating the ports of entry, conditions for importation of donated medical devices and other related aspects of this important regulatory interventions.

The goal of these guidelines is to help manufacturers, importers, distributors and exporters comprehend the requirements to obtain approval to import and export medical devices in Tanzania. The guidelines provide information and documentation required for application submitted to TMDA by the importer or exporter of medical devices. The guidelines also outline appeal procedures in the event an applicant is aggrieved by decision of the Authority.

All dealers involved in importing and exporting medical devices are encouraged to familiarize with these guidelines and follow them strictly when preparing and submitting applications. Adherence to these guidelines will ensure that all relevant information and documentation are submitted and therefore avoid unnecessary delays in approval process and hence expedite provision of quality services to clients.

The Authority would like to emphasize that the requirements in these guidelines have been provided to ensure that only medical devices, including In vitro diagnostics and laboratory equipment of acceptable quality, safety and performance are imported into or exported out of the country. It is therefore expected that all concerned parties will adhere to the specified requirements in these guidelines.

Dr. Adam M. Fimbo
Director General

DEFINITION OF TERMS

For the purpose of these guidelines the following terms shall be defined as follows:

Act

Means the Tanzania Medicines and Medical Devices Act, Cap 219.

Authority

Means the Tanzania Medicines and Medical Devices Authority, or its acronym "TMDA" established under section 4 (1) of the Tanzania Medicines and Medical Devices Act, Cap 219.

Applicant

Means a person or company who submits an application for marketing authorization of a new medical product, an update to an existing marketing authorization or a variation to an existing marketing authorization.

Application

Means the information provided by the applicant to the Authority for evidence-based evaluation and marketing authorization decision.

Consignment

Means a quantity of goods that are sent to a person or place to be sold.

Donation

Means an act or instance of presenting medical devices to recipients in emergency or as part of development aid in non-emergency situations.

Donor

Means a governmental or nongovernmental organization or individual who voluntarily donates medical devices as a donation.

Exhibitor

Means a person or a company that shows their work or products to the public.

Exporter

Means a person or institution licensed and/or authorized to export medical devices outside the country.

Export Permit

Means a permit issued to exporter by the Authority, authorizing him to export medical devices from the country.

Inspector
Means TMDA inspector appointed, authorized or recognized under Section 105 of the Act.

Importer
Means a person or institution authorized to import medical devices and in vitro diagnostics or raw materials into the country.

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.

Large medical equipment
Means large-scale medical devices with complex technology used for the specific purposes of diagnosis and treatment of diseases or rehabilitation, significant capital investment, high operating costs, and a substantial impact on medical expenses. These devices are typically included in catalogue management systems; they exclude implantable, disposable, or single-use medical devices.

Portable medical devices
Means medical devices that play a crucial role in healthcare, encompassing a wide range of technologies used for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliation. They are mostly disposable, one-time in use, sterile, and can be discarded after a single patient encounter. They are also designed to be placed inside the body and used to replace damaged or missing body parts, support bodily functions, or deliver treatments.

Import permit
Means a permit issued to importer by the Authority, authorizing him to import medical devices into the country.

Identifier
Means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.

Label
Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any medical devices including in-vitro diagnostics.

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.

Laboratory equipment
Means tools and equipment used by scientists to perform experiment and take measurement in laboratory.

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

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

a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;

b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;

c) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

Packaging material
Means any material, including printed material, employed in the packaging of medical devices including in vitro diagnostics and laboratory equipment, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Permit
Means certificate of approval to import and export medical devices.

Raw materials
Means any substance of a defined quality used in the production of medical devices and diagnostics, including packaging materials.

Recipient
Means a person, governmental, non-governmental or private health institution that voluntarily receives medical devices as a donation.

Shelf life
Means the period of time, from the date of manufacture, that a product is expected to remain within its approved product specification while handled and stored under defined conditions.

Online Trader Portal
Means customer online self-service portal available on TMDA website.

INTRODUCTION

These revised guidelines offer comprehensive guidance for importers and exporters of medical devices, including in vitro diagnostics, laboratory equipment, and raw materials as mandated by Regulation 45 of the Tanzania Medicines and Medical Devices (Control of Medical Devices) Regulations, 2015.

This document applies to any individual, institution, or organization involved in importing or exporting medical devices for sale, research, exhibition, training, hospital use, laboratory use, donation or personal use within Tanzania mainland. The primary objective is to equip importers and exporters with the necessary information to comply with the laws and regulations governing the circulation of medical devices into and out of the country. Additional objectives include; controlling the importation of unwanted medical devices, minimizing the accumulation of non-functional devices and encourage best practices for donating safe and functional medical devices.

The document outlines the requirements and procedures for importing medical devices, the procedures for donating medical devices, details the requirements and procedures for exporting medical devices. It also explains the review and appeal processes for applicants aggrieved by TMDA decisions.

It's crucial to understand that approval for importing, exporting, and donating medical devices hinges on adhering to the requirements stipulated in the Act, regulations, these guidelines, and any relevant guidelines published by the Ministry of Health (MoH). Applicants are strongly advised to thoroughly read and understand these requirements before initiating any import or export activities.

1.0 IMPORTATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS LABORATORY EQUIPMENT AND RAW MATERIALS

1.1 Categories of importers of medical devices, in vitro diagnostics and laboratory equipment:

1.1.1 Importers of medical devices, in vitro diagnostics, laboratory equipment and raw materials shall fall under the following categories:

a) Government and Non-Governmental Institutions;

b) Medical devices and In vitro diagnostics wholesalers;

c) Medical devices and In vitro diagnostics Manufacturers;

d) Clinical Trial Sponsor, Principal Investigators and Researchers; and

e) Recipients of Donations.

1.1.2 Notwithstanding with 1.1.1 above, the following may be authorized to import medical devices and In vitro diagnostics on special circumstances for public interest: -

a) Persons importing medical devices and In vitro diagnostics for personal use;

b) Hospitals importing medical devices, In vitro diagnostics and laboratory equipment for hospital use;

c) Institutions importing medical devices and In vitro diagnostics for laboratory use and training purpose;

d) Exhibitors and

e) Importing wholesalers

1.2 General requirements for importers

1.2.1 All medical devices, In vitro diagnostics and laboratory equipment for human use to be imported must have marketing authorization (registration or notification) by TMDA unless given special approval by the Authority.

1.2.2 All Medical devices including In vitro diagnostics for veterinary use are exempted from registration and therefore they should only be notified to TMDA unless given special approval by the Authority.

1.2.3 All importation of medical devices including In vitro diagnostics, laboratory equipment and raw materials must be done by importers whose premises are dully registered or authorized by TMDA or relevant Government institutions.

1.2.4 All importers must import medical devices including In vitro diagnostics, laboratory equipment and raw materials through the authorized ports of entry (PoE) as outlined under section 1.9 of these guidelines.

1.2.5 A person shall not import any device with shelf life of more than twenty-four months whose remaining shelf life is less than 60% or a device with shelf life of less or equal to twenty-four months whose remaining shelf life is less than 80%. (Where applicable).

1.2.6 In case of donations refer to section 2.0 of these guidelines.

1.2.7 All imported medical devices including In vitro diagnostics, laboratory equipment should be labelled in the manner consistent with labelling information approved during marketing authorization application. Particularly, the following minimum information should be contained on the label: -

a) Name of the device (common name and brand name where applicable)

b) Name and address of the manufacturer

c) Batch, lot or serial number

d) 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

e) The words “sterile” if the manufacturer intends to sale the device in a sterile condition

f) The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device family or medical devices group family

g) The words “for single use only” if the device is intended for that purpose

h) The manufacturing and expiry date of the device expressed in month and year (*where applicable)*

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

j) The directions for use, unless directions are not required for the device to be used safely and effectively and any special storage conditions applicable to the device

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

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

1.2.8 In case of imported raw materials the following labeling requirements should be adhered to: -

a) Information printed on labels must be visible and indelible;

b) Immediate outer packaging of the raw material must be labeled in English and/or Kiswahili
c) Product name and description of raw materials including dimensions/ size and uses
d) Name and address of manufacturer should be stated;
e) Date of manufacture and expiry should be stated (where applicable);
f) Batch or Lot number should be stated;
g) Storage conditions should be stated;
h) Weight and or volume should be stated

1.3 Procedure for importation of medical devices including In vitro diagnostics, laboratory equipment and raw materials

1.3.1 Authorized importers shall have an account in RIMS Customer Self Service Portal issued by TMDA upon filling in customer online access registration form through TMDA website www.tmda.go.tz

1.3.2 All applications shall be made online (RIMS Customer Self Service Portal) accompanied with uploaded scanned copies of the proforma invoice and valid TMDA business permit.

1.3.3 The proforma/commercial invoice shall state for each medical device to be imported, the following: -

a) Proforma invoice number and date;
b) Name and address of the supplier;
c) Name and address of the importer;
d) Name and address of the manufacturer;
e) Country of origin;
f) Clear description of item including brand and common names and in case of kit, system or group of medical devices should list the content/name of each item present
g) The quantity, pack size of device, unit value, total value in convertible currency;
h) Batch, lot or serial number;
i) Manufacturing and expiry date (where applicable);
j) Mode of shipment (sea, air, road);
k) Destination port of entry;
l) Signature and stamp of the supplier and/or manufacturer;
m) Name, signature and stamp of importer

1.3.4 For large medical equipment the applicant shall declare in the application details the premises where the equipment is to be installed.

1.3.5 Applications must be submitted at least 14 days before the arrival of the consignment to avoid delays in processing import applications.

1.4 Processing of applications for importation of medical devices including in vitro diagnostics, laboratory equipment and raw materials

1.4.1 Upon receiving the application as specified above, TMDA will scrutinize to verify whether the requirements have been fulfilled.

1.4.2 If the application meets the prescribed requirements, the applicant will be required to pay import fees as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an import permit as set out in the **Annex I** of these guidelines.

1.4.3 In case of an application not complying with the prescribed requirements, the Authority shall issue online query(s) to the applicant for rectification before further processing or reject right away.

1.4.4 Upon receiving query response, the Authority shall reprocess application and if satisfied, the applicant will be required to pay import fees as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an import permit as set out in the **Annex I** of these guidelines. In case of dissatisfaction, the Authority shall reject the application and communicate with applicant by letter or online clearly stating reason(s) for rejection.

1.4.5 Applicant will receive online notification for queried, rejected and approved applications. In case of approved application, the applicant shall be accountable to print the import permit online and proceed with clearance of consignment at port of entry.

1.4.6 All applications will be processed within one day (24 hours) with exception of special requests which shall be processed within seven (7) working days.

1.4.7 Import permit shall be valid for six (6) months from date of TMDA granting the importation of the devices.

1.4.8 Import permit issued shall not be transferable and shall cover only one shipment. However, in case of partial shipments, only three shipments may be allowed based on the initial import permit within validity of the initial permit.

1.4.9 The Authority upon request from the applicant may extend not more than one time the validity of the issued import permit if satisfied with reasons given by the applicant.

1.4.10 Application for extension of the permits shall be made prior to its expiry and the maximum period for extension given shall not exceed three (3) months.

1.4.11 Importers will be required to hold a valid importation permit issued by the Authority prior to shipping of the consignment.

1.5 Requirements for special importation of medical devices including in vitro diagnostics and laboratory equipment

The same application requirements and procedures as prescribed under Sections 1.3 and 1.4 respectively shall apply. However, in some special circumstances the following requirements will be applicable.

1.5.1 Importation of unregistered / unnotified medical devices including in vitro diagnostics and laboratory equipment

Permit for importation of unregistered/ unnotified medical devices including in vitro diagnostics and laboratory equipment may be issued if the following requirements have been complied: -

a) The applicant has uploaded covering letter stating reasons for importing such devices

b) The applicant has uploaded Certificate of Analysis - CoA (where applicable)

c) The applicant has uploaded Certificate of Conformity (CoC)/Declaration of Conformity (DoC) from manufacturer

d) The applicant has uploaded Certificate of compliance of the manufacturer to ISO 13485 or other relevant standards

e) Medical device or in vitro diagnostic has been approved by IMDRF founding member countries (Japan, Australia, Canada, Europe and United States of America) or prequalified by WHO;

f) In case of request to import Devices for health facilities the applicant in addition is required to upload supporting letter and Local Purchase Order (LPO) /Requisition form from the respective facility

g) The device under request is not available from local suppliers

1.5.2 Importation of medical devices for personal use

Importation of medical devices including in vitro diagnostics for personal use shall be approved at Port of Entry if the following requirements have been complied: -

a) The device does not require special settings such as hospitals and not intended for professional use only

b) The device does not emit radiations

c) The quantity does not exceed more than three (3) unit of a commercial pack unless justified otherwise

d) Applicant have a letter addressed to TMDA stating reasons for importation and any supporting documents of the stated reason as may be applicable

e) Prescription or evidence from qualified medical practitioner, dentist, or any other authorized practitioner which confirm the devices are for personal use (where applicable)

f) Medical report/History

g) Airway bill/ Bill of lading

Importation of medical devices including In vitro diagnostics for personal use which does not meet the above criteria should be subjected to online application procedures and the permit may be issued if the following requirements have been complied: -

a) Applicant have a letter addressed to TMDA stating reasons for importation and any supporting documents of the stated reason as may be applicable

b) Prescription or evidence from qualified medical practitioner, dentist, or any other authorized practitioner which conform the devices are for personal use (where applicable)

c) Medical report/History

1.5.3 Importation of medical devices including in vitro diagnostics, Human specimens and laboratory equipment for clinical trial purposes/research

a) Application for importation of medical devices including laboratory equipment should be accompanied by the valid ethical clearance certificate issued by the recognized institution and certificate of analysis/certificate of conformity where applicable

b) Application for clinical trial devices should be made by a clinical trial sponsor or Principal Investigator for a study approved to be conducted in Tanzania Mainland. Such applications should be accompanied by clinical trial ethics approval letter, copy of certificate of clinical trial issued by TMDA and certificate of analysis/certificate of conformity.

1.5.4 Importation of exhibition of medical devices including in vitro diagnostics and laboratory equipment

All devices to be imported for exhibition shall have a TMDA Trade fair permit where it will be charged as per fees and charges regulation enforce, all application for such permit shall be submitted through a letter accompanied with the following documents: -

a) Invitation letter to participate in exhibition

b) A list of such devices that stipulate name and quantity of the devices,

c) Device shall bear a label printed “for exhibition only – sample not for sale”.

d) Quantity of the device should not exceed ten (10) commercial unit pack

1.5.5 Importation of sample for registration of medical devices including in vitro diagnostics and laboratory equipment

Importation of samples for registration shall meet the following criteria: -

a) The proforma invoice meets the requirements indicated in 1.3.3 and clearly state “samples for registration purposes only”.

b) The quantity should not exceed two (2) units of a commercial pack for medical devices and one (1) for in vitro diagnostics, unless approved by the Authority.

1.5.6 Importation of promotion materials for medical devices including in vitro diagnostics and laboratory equipment

a) Permits for importation of medical devices including in vitro diagnostics and laboratory equipment promotional materials such as calendars, diaries, t-shirts, fliers, pens, caps, key holders, cups shall be issued if the applicant has attached TMDA approval letter for the promotional materials.

b) For the case where medical devices such as stethoscope, thermometers, and blood pressure machine are used as promotion material such medical devices should be registered or notified accordingly

1.5.7 Importation of Free of Charge (FoC) medical devices including in vitro diagnostics and laboratory equipment

a) The devices should be registered/Notified by TMDA

b) All free of charge goods shall be charged as per Fees and Charges Regulations in force.

c) The proforma invoice of free of charge goods shall meet the requirements indicated at 1.3.3 above.

1.5.8 Importation of spare parts, accessories and consumables of medical devices including laboratory equipment

Application for importation of spare parts of medical devices including laboratory equipment shall be accompanied by the letter stating reasons for importation and the following;

a) A contract of preventive and corrective maintenance between the supplier and the facility (where applicable).

b) Valid TMDA registration certificate of the medical device.

c) In case of request to import spare parts of medical devices for health facilities the applicant in addition shall be required to upload a supporting letter which states the device name and its model number/ serial number and Local Purchase Order (LPO) /Requisition form from the respective facility.

1.5.9 Importation of medical devices including in vitro diagnostics during emergencies such as out break

Applicant should submit a letter to TMDA to justify the need of such devices in addition to requirements stipulated in section 1.3 and 1.4 of these guidelines.

1.5.10 Importation of laboratory equipment including glass wares for laboratory use

a) The applicant has uploaded covering letter stating reasons for importing such laboratory equipment

b) Material safety data sheet or certificate of analysis (where applicable)

c) For laboratory equipment for use within laboratory schools, the applicant is required to include supporting letter and Local Purchase Order (LPO) /Requisition form from such schools or PO-RALG.

1.6 Inspection of imported consignments at ports of entry

1.6.1 On arrival at the ports of entry, medical devices and in vitro diagnostics will be inspected by TMDA Inspector to ensure that they comply with the approved specifications and regulations before they are released.

1.6.2 Each consignment must be accompanied by an import permit, proforma invoice, commercial invoice, airway bill or bill of lading certificate of conformity/certificate of analysis where relevant.

1.6.3 Other Government Departments (OGDs) such as Tanzania Revenue Authority (TRA), Tanzania Bureau of Standards (TBS), Government Chemist Laboratory Authority (GCLA) may also inspect these consignments as per their rules and regulations.

1.6.4 Inspectors shall be duty bound to ensure that records of inspection for all imported medical devices including in vitro diagnostics, laboratory equipment and raw materials are timely maintained in Regulatory Integrated Management Information System (RIMS).

1.6.5 At the time of importation, the device with shelf life of more than twenty-four months should have a remaining shelf life of more than 60% and for a device with shelf life of less or equal to twenty-four months should have a remaining shelf life of more than 80% (where applicable).

1.7 Sampling of imported products

1.7.1 Sampling of portable medical devices

i) TMDA will sample imported medical devices for further investigation when deemed necessary. The sample collection form **Annex II** will be used during sampling which will be signed in duplicate by TMDA inspector and the consignee and one copy will be issued to the later.

ii) Investigation or consultation may take some time before they are concluded, especially where it involves laboratory analysis of the consignment. Where such cases arise, a conditional release will be given to the importer with instructions to store the consignment in approved premises until results of the investigations are out.

iii) It is important to note that laboratory analysis normally takes a period of twenty-one (21) days from the time a consignment is sampled to when the results are released. The time mentioned above applies only if the laboratory analysis is to be done at TMDA Laboratory. Where analysis is to be carried out outside TMDA, a longer period may be required.

iv) Sampling for high-risk medical devices such as Condoms and in vitro diagnostics will be carried out on every lot of the consignment. TMDA shall from time to time prescribed the list of items to which this pre-distribution requirement is mandatory.

1.7.2 Sampling of Large Medical Equipment

i) Sampling of large medical equipment will not be done at PoE but will be inspected at the owner's premises after installation. All equipment qualification documents (Installation, Operational and Performance) should be available at the owner's premises.

ii) At the PoE, TMDA shall document all necessary information for tracing the equipment for inspection at the owner's premises.

1.8 Action to be taken on Inspected Consignment

The following actions may be taken by inspector after conducting inspection: -

a) An approval for release or entry into the country; for large medical equipment importer will be required to notify the Authority after installation to inspect the equipment as per checklist of inspection of equipment after installation Annex III in order to verify its performance.

b) A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation;

c) An outright rejection of the consignment pending re-exportation or destruction at owner's expenses.

1.9 AUTHORIZED PORTS OF ENTRY

All medical devices including in vitro diagnostics, laboratory equipment and raw materials imported into Tanzania shall be allowed to enter through the following authorized ports of entry (PoE):

a) Julius Nyerere International Airport,

b) Dar es salaam Sea Port,

c) Kilimanjaro International Airport,

d) Horohoro dry port,

e) Holili dry port,

f) Namanga dry port,

g) Tarakea dry port,

h) Sirari dry port,

i) Mwanza Lake Port,

j) Mwanza Airport,

k) Tanga Sea Port,

l) Tunduma dry port,

m) Mutukula dry port,

n) Rusumo Fall dry port,

o) Manyovu dry port,

p) Kasumulu dry port,

q) Kabanga dry port.

The Authority reserves the final decision in authorizing importation of medical devices and in vitro diagnostics through any other PoE other than those indicated above.

1.10 RELEASE OR REJECTION OF A CONSIGNMENT

1.10.1 Conditions for release of a consignment:

a) All approved consignments will be released by TMDA Inspector once satisfied that all importation conditions have been fulfilled.

b) An Inspector will stamp all the supporting documents with an official stamp marked **"APPROVED FOR RELEASE"**.

c) In case of partial shipment, a consignment will be issued with one import permit which can be used in three divided shipments and an inspector will clearly mark in the Importation permit that it is "**PARTIAL SHIPMENT**" and the quantity imported and remaining will be indicated in the importation permit.

1.10.2 Conditions for not releasing the consignment

1.10.2.1 Consignments which do not meet importation requirements will be rejected by TMDA and the accompanied documents shall be stamped with an official stamp marked **"STOP RELEASE"**

1.10.2.2 Medical devices including in vitro diagnostics laboratory equipment and raw materials rejected for quality reasons will be CONDEMNED and the authority shall order destruction or re-exportation of such medical devices at owner's cost.

1.10.2.3 Destruction of rejected consignments will be done as per the TMDA regulations and guidelines of Handling of unfit medical devices and Diagnostics. However, Customs department, NEMC and other law enforcing agencies shall be involved.

1.10.2.4 Consignments rejected for being unregistered in Tanzania or inadequate labeling may be re-exported to the country of origin, or re–exported to a third-part country on special request and special clearance from the National Regulatory Authority (NRA) of the country where the consignment is being re-exported.

1.10.2.5 TMDA shall officially inform the Customs departments for re-exportation of the consignment.

1.10.2.6 A re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before re-export permit is issued by TMDA.

1.10.2.7 Re-loading for re-export should be witnessed by Customs officials and Inspector(s) from TMDA.

1.10.2.8 Copies of re-export documents stamped at the exit port shall be submitted to TMDA as evidence of completion of re-exportation exercise.

1.10.2.9 Destruction of rejected medical devices and diagnostics shall be done as per the Customs requirements and TMDA will provide technical advice on mode of destruction according to the guidelines for Handling of unfit medical devices and diagnostics.

1.10.2.10 TMDA will issue a Destruction Certificate after completion of the destruction exercise.

1.10.2.11 Where the consignment is rejected/detained, TMDA Inspector will issue a Rejection/Detain Form of medical device consignment(s) as specified under **Annex IV** of these guidelines.

2.0 IMPORTATION OF DONATED MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS AND LABORATORY EQUIPMENT

2.1 Scope of Application

The procedures outlined below will be applicable to all donated medical devices, in vitro diagnostics and laboratory equipment.

2.2 Principle

2.2.1 All donations will be in accordance with the recipient's need and should comply with the existing government policies, laws, guidelines and administrative arrangements.

2.2.2 Donation should comply with applicable standards and there will not be double standards regarding quality of donated items. Unacceptable medical devices, in vitro diagnostics and laboratory equipment in the donor country shall not be allowed into the recipient's country.

2.3 Requirements for Donation

General Requirements

2.3.1 Any person, institution and organization intending to donate medical devices will be required to apply for import permit through TMDA Online portal (tmda.go.tz/portal) as prescribed under Section 1.3.1 of these guidelines prior to shipment of the donated consignment.

2.3.2 Application for donated medical devices should be accompanied by the following documents: -

a) A support letter from recipients to justify needs of such donation

b) A support letter from the importer importing on behalf of the end user of such donation

c) Donation certificate/letter which include a declaration that such donated devices are in use or not in the donor country

d) Proforma invoice;

e) Declaration of Conformity of donated medical devices or diagnostics from manufacturer or relevant Authority (applicable for new devices)

f) Letter/ certificate from biomedical engineer or relevant technicians approved by a relevant board to verify quality and performance evaluation of donated devices (applicable for used devices)

g) Certificate/report of refurbishment for refurbished medical devices (issued by manufacturer/ certified company)

h) Certificate of analysis (CoA) for sterile medical devices including in vitro diagnostics

i) Certificates from Tanzania Atomic Energy Commission (TAEC) for device emitting radiations

2.3.3 Medical devices, in vitro diagnostics and laboratory equipment intended to be donated must be collected as much as possible from known sources for ease of traceability.

2.3.4 If the medical device, in vitro diagnostic and laboratory equipment is used, it must be reconditioned, tested and all essential parts, accessories and working materials included during shipment together with the relevant supporting documents to indicate that the device is in good order.

2.3.5 Donated medical devices, in vitro diagnostics and laboratory equipment shall Meet existing safety and performance specifications provided by the manufacturer, international or appropriate national standards

2.3.6 Donated medical devices, in vitro diagnostics and laboratory equipment shall be fully operational as a full system or as a separate subsystem;

2.3.7 Donated medical devices, in vitro diagnostics and laboratory equipment shall have its label, user manual and other documents written in English or Swahili;

2.3.8 Donated medical devices, in vitro diagnostics and laboratory equipment shall be packed in the manner that is suitable for road, air or sea transport under tropical conditions.

2.3.9 For software operated medical devices and diagnostics, the software shall be either preloaded and/or accompanied by the software package.

2.3.10 Damaged, outmoded, and redundant medical devices and diagnostics for which spare parts and consumables are no longer available shall not be accepted.

2.3.11 Each donated medical device, in vitro diagnostic or laboratory equipment shall have accompanied user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.

2.3.12 Donated medical devices, in vitro diagnostics or laboratory equipment shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.

2.3.13 The Authority will assess if the medical device, in vitro diagnostic and laboratory equipment is compatible with the recipient also the application will be processed as per section 1.4 and inspected at PoE as per section 1.6 of these guidelines.

2.4 Label of the donated medical device, in vitro diagnostic and laboratory equipment

2.4.1 Labeling information of the medical device, in vitro diagnostic and laboratory equipment can be provided on the device itself, packaging used for the device, on an Insert supplied with the device or in a printed document or using other appropriate media.

2.4.2 Depending on its nature and type, the label of donated medical device, in vitro diagnostic or laboratory equipment should have the following minimum information:

a) The name of the medical device, in vitro diagnostic or laboratory equipment;

b) Model number or serial number;

c) Manufacturing and expiry dates; (where applicable)

d) Life span or expectancy;

e) Name and address of the manufacturer;

f) Handling and storage requirement(s)

g) Technical direction for use;

h) An indication, if applicable, that the medical device, in vitro diagnostic or laboratory equipment is intended to be used

i) The words “used only for clinical or performance investigations” before being supplied;

j) For a sterile medical device, the word “Sterile” and where appropriate, description of methods of re-sterilization;

k) If it is a refurbished device or laboratory equipment, an indication that the device or laboratory equipment is refurbished;

l) If the device is intended for presentation or demonstration purposes only, it must be labeled as “for presentation or demonstration purposes only, not for use on human”;

m) If the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of the respective radiation;

n) If the device is to be installed with or connected to other medical device, in vitro diagnostic or laboratory equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use in order to obtain a safe combination;

o) If the device is an in vitro diagnostic device, it must be labeled as “in vitro diagnostic” or “IVD”;

p) The intended purpose of the medical device, in vitro diagnostic or laboratory equipment, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious);

q) Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.

2.5 Reporting

The recipient will be required to report relevant information to the Authority including defects, adverse effects, problems related to quality and safety and other reportable cases related to the donated equipment prior to the use or as soon as the same is discovered.

2.6 Disposal

If donated medical device, in vitro diagnostic and laboratory equipment are found to be unfit, the recipient shall be required to dispose or return the product to the country of origin at his/her own cost.

3.0 EXPORTATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS, HUMAN SPECIMEN FOR RESEARCH PURPOSE AND LABORATORY EQUIPMENT

3.1 Categories of exporters of medical devices including in vitro diagnostics and laboratory equipment

Exporters of medical devices, in vitro diagnostics and laboratory equipment fall under the following categories:

a) Registered local devices manufacturers;

b) Registered wholesalers;

c) Government and non-Government Institutions

d) Clinical trial sponsors and investigators;

e) Research institutions and researchers

f) Persons authorized by TMDA.

3.2 General requirements for exporters

a) No person shall export devices out of the country without a valid export permit issued by the Authority.

b) All devices to be exported must originate from a registered manufacturer or wholesaler in Tanzania Mainland.

c) All exporters must export devices through authorized PoE or other PoE as may be determined by TMDA.

d) Devices intended to be exported should either be registered or authorized by TMDA.

3.3 Procedure for exportation of medical devices, in vitro diagnostics and laboratory equipment

3.3.1 Authorized exporter intending to export devices should apply through TMDA online portal (tmda.go.tz/portal). The application shall be accompanied by one proforma invoice.

3.3.2 The proforma/commercial invoice shall state each of the following; -

a) Invoice Number and date;

b) Name and address of the supplier;

c) Name and address of the importer;

d) Name and address of the manufacturer;

e) Country of origin;

f) Country of destination;

g) Clear description of item including brand and common names and in case of kit, system or group of medical devices should list the content/name of each item present

h) The quantity to be exported for each device, pack size, its unit value and total value in convertible currency;

i) Batch, Lot number or serial number;

j) Mode of shipment (sea, air, road);

k) Port of exit;

l) Signature and stamp of the supplier and/or manufacturer.

3.3.3 Export permit shall not be transferable and shall be issued to cover only one shipment.

3.3.4 Application for export permit shall be accompanied by a processing fee as prescribed in TMDA Fees and Charges Regulations enforce.

3.3.5 After being satisfied by the information submitted, an *Export Permit* will be issued as prescribed under Annex V of these guidelines. The permit will be valid for 3 months from the date of issue.

3.3.6 Exporting wholesalers will be required to provide evidence of source of the exported products.

3.3.7 All applications for export will be processed within one working day (24hrs).

3.3.8 Applications for export permit must be submitted and approval obtained before shipment of the consignment.

3.3.9 An application will be rejected if it does not meet any of the exportation requirements and it will be communicated to the applicant by letter or online clearly stating reason(s) for rejection.

4.0 REVIEW AND APPEAL PROCEDURE

4.1 Any person aggrieved by the decision of the Authority in relation to any application for importation or exportation of devices may appeal for review of the decision to the Director General within a period of 14 days from the date of receipt of the decision.

4.2 The Authority may review its decision, reject or vary the condition of approval.

4.3 After reconsideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to the Minister responsible for Health.

4.4 The decision of Minister responsible for Health shall be final and conclusive.

5.0 ANNEXES

ANNEX I: Permission to import registered product(s)

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA/DMD/MDL/P/001

Rev #:00

PERMISSION TO IMPORT REGISTERED MEDICAL DEVICES/ DIAGNOSTICS/LABORATORY EQUIPMENT

(Made under Section 73(1) of Tanzania Medicines and Medical Devices Act 2003)
Permit No: ……

PART A: PARTICULAR OF IMPORTER

Name of registered importer.....Postal address .....Tel. No..... Exporting Country.....Invoice No……Date.....

Exporter/Sender..... Postal address.....

Arrival expected by ship/air/motor vehicle, via ..... Port of entry.

Sn	Name of Product		Product	Quantity to be Imported	Value of product (s)
	Brand name	Common name	Registration No		
TOTAL (FOB Value)					

Fees Receipt No …… Dated…….

PART B: GRANTING PERMISSION

Permission is hereby granted to import the above-mentioned product(s). The importer has to contact the Port TMDA Inspector to examine the approved product(s) before entry into Tanzania Mainland.

Prepared By: ……

FOR: DIRECTOR GENERAL

PART C: DECLARATION BY TMDA INSPECTOR

I _____ being TMDA Inspector at _____ port Office has examined the above-listed product(s) and I therefore grant/not grant entry into Tanzania Mainland.

_____ _____

Date SIGNATURE OF TMDA PORT OFFICER AND STAMP

This permit is valid from dd/mm/yyyy to dd/mm/yyyy

Note:

The inspector has to return immediately a completed copy of this permit bearing import stamp to TMDA zone office.

ANNEX II: Sample Collection form

MEDICAL DEVICES AND IN VITRO DIAGNOSTICS SAMPLE COLLECTION FORM

TMDA/DMD/MDV/F/007
Rev #:00
Page 1 of 1

(*Made under section 101(1) of Tanzania Medicine and Medical Devices Act Cap 219*)

Name of the/Institution/Company/PoE…….
Address: ……
Date of collecting sample: …….
Reason for collecting (Indicate laboratory analysis needed where possible)
……..
……

S/No	Product Name and Size	Common /Generic Name of Device	Batch/ Lot Number	Manufacturing Date	Expiry Date	Name and Address of Manufacturer	Quantity Sampled

Name of Representative(s) of the company/Consignment — Telephone number — Signature — Date

1. …… ……..... ……. ……

Name of TMDA Inspector(s) (Sampling Officer) — Signature — Date

1……..... …… ……
2. ……..... …….. …….

NB: Distribution of the sampled batch/lot will not be permitted until laboratory analysis is completed and the result are officially communicated to you.

Effective Date:17/05/2024

ANNEX III: Checklist for inspection of large medical equipment

Indicate the criteria (s) to classify the inspected device as Large Medical device/Equipment by Putting a tick (√) mark in the check box beside criteria listed below

- ☐ Device require Installation and qualification
- ☐ Device have Maintenance schedule
- ☐ Operator of the device Need of training
- ☐ Device has Detailed user manual/service manual
- ☐ Device require Daily verification prior to operation

A. LARGE MEDICAL DEVICE INFORMATION REVIEW

1. Device Name……
2. Brand Name……
3. Serial No..... Model No……
4. Year of Manufacturing……
5. Name and physical address of the manufacturer……
……
……
……
6. Quantity imported……
7. Import permit number……
8. TANSAD number ……
9. Equipment status at the time of Importation (New/Second hand/unknown) ……
10. Name & address of the facility where the device is to be installed
……
……
……
……
……

B. ***PHYSICAL VERIFICATION***

Sno.	Document Name	Available Yes/No/NA	Remarks
General condition of the device			
1.	Is the device complete with accessories?		
2.	Are there any extra accessories accompanied with equipment?		
3.	Is the packaging material for the device intact?		
4.	Does the device appear clean?		
5.	Is there any visual damage noted on the device?		
6.	Presence of label containing all particulars as per labelling requirements (where applicable)?		
Documentation			
7.	Is the user manual and service manual accompanied with the equipment?		
8.	Is there a certificate of conformity/certificate of analysis/Inspection report and certificate of refurbishment for refurbished devices?		
9.	Radiation Safety Report for Equipment that Emits Radiations from manufacturer?		

C. OVERALL CONCLUSION ON MEDICAL EQUIPMENT INSPECTION

……
……
……
……
……

D. Name and signature of the inspectee

Name.....Signature.....Date.....

Name of Inspector(s)

S/N	Name	Organization	Signature	Date
1.				
2.				
3.				
4.				

Effective Date:17/05/2024

ANNEX IV: Detention/Rejection Form

DETENTION/REJECTION FORM FOR PRODUCTS CONSIGNMENT AT PORT OF ENTRY

(Made under Section 106(1)(d)(e) of the Tanzania Medicines and Medical Devices Act, Cap 219)

1. Importer/Exporter: ……
2. The inspected consignment(s) as per Proforma Invoice No.: ……
3. Airway Bill No.: ……/Bill of Lading No ……
4. R. Number: …… Dated: ……
5. TANSAD Number: …… Dated: ……

6. Has been detained/rejected for the following reasons: - *(Tick whichever applicable)*

a) TMDA Importation permit is not present ☐

b) The product(s) is/are not registered by TMDA (where applicable) ☐

c) Consignee is unauthorized dealer of the product(s) being imported ☐

d) Manufacturer of the product(s) is not indicated ☐

e) Description of the items is not clear ☐

f) Manufacturing and/ expiring date of product (s) not indicated ☐

g) The product (s) shelf life is too short/expired ☐

h) Physical quality of the product is poor ☐

i) Packaging inserts not included ☐

j) Certificate of Analysis (CoA) not present and/or results of the tests on CoA do not comply with specifications ☐

k) Batch/ Lot number (s) not indicated ☐

l) Any other (Specify) ……

7. Consignee is required to resolve the above issue(s) within 30 days after which the consignment shall be forfeited or disposed of. The Consignee may write to Director General to request an extension after expiry of the detention period.

8. Inspector's comments if any
……...……...…….
……..……
……
……

9. List of Detained/Rejected Items

……..	……
……..	……
……..	……
……..	……
……..	……
……..	……
……..	……
……..	……

…….	…….....	……
Name of TMDA Inspector	Signature	Date
…….	…….	……
Name of Consignee/Clearing Agent	Signature	Date

Effective Date:17/05/2024

ANNEX V: Permission to export product(s)

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA/DMD/MDL/P/002

Rev #: 00

PERMISSION TO EXPORT REGISTERED MEDICAL DEVICES/ DIAGNOSTICS/LABORATORY EQUIPMENT

(Made under Section 73(1) of Tanzania Medicines and Medical Devices Act 2003)
Permit No: ……

PART A: PARTICULAR OF EXPORTER

Name of registered exporter**.....**Postal address **.....**Tel. No**.....** importing Country**.....**Invoice No**.……**Date**.....**

Sender/Receiver **.....** Postal address.....