

TANZANIA FOOD AND DRUGS AUTHORITY



**GUIDELINES FOR IMPORTATION AND EXPORTATION OF MEDICAL DEVICES
INCLUDING IN VITRO DIAGNOSTICS**

(Made under Section 73 of the Tanzania Food, Drugs and Cosmetics Act, 2003)

FIRST EDITION

May, 2015

P. O. Box 77150, EPI Mabibo, Off Mandela Road, Dar es Salaam, Tanzania
Tel: +255-22-2450512/2450751/ 2452108; Fax: +255-22-2450793
Email: info@tfda.go.tz; Website: www.tfda.go.tz

Contents

ACKNOWLEDGEMENTS	II
INTRODUCTION	1
DEFINITIONS	2
CHAPTER ONE	5
1. IMPORTATION OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS	5
1.1 CATEGORIES OF IMPORTERS OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS:	5
1.2 REQUIREMENTS FOR IMPORTERS	5
1.3 PROCEDURE FOR IMPORTATION OF MEDICAL DEVICES	6
1.4 PROCESSING OF APPLICATIONS	7
1.5 SPECIAL IMPORTATION REQUIREMENTS	7
1.5.1 Importation of Syringes	7
1.5.2 Importation of unregistered medical devices including in vitro diagnostics	8
1.5.3 Importation of medical devices for personal use	8
1.5.4 Importation of investigational medical devices	9
1.6 INSPECTION OF IMPORTED CONSIGNMENTS AT PORTS OF ENTRY	9
1.6.1 Sampling of imported products	9
1.6.2. During inspection of the consignment the following actions may be taken:	9
1.6.3 Authorized Ports of Entry (PoE)	10
1.6.4 Release or rejection of a consignment	10
CHAPTER TWO	12
IMPORTATION OF DONATED MEDICAL DEVICES	12
2.1 SCOPE OF APPLICATION	12
2.2 REQUIREMENTS FOR DONATION	12
2.2.1 General Requirements	12
2.2.2 Requirements at the Port of Entry	13
2.2.3 Label of the donated medical device	14
2.2.4 Reporting	15
2.2.5 Disposal	15
CHAPTER THREE	16
3.1 EXPORTERS OF MEDICAL DEVICES	16
3.2 REQUIREMENTS FOR EXPORTERS	16
3.3 PROCEDURE FOR EXPORTATION OF MEDICAL DEVICES	16
3.4 REVIEW AND APPEAL PROCEDURES	17
ANNEX I	18
ANNEX II	20
ANNEX III	22
ANNEX IV	23
ANNEX V	24
ANNEX VI	26
ANNEX VII	28

ACKNOWLEDGEMENTS

The process for developing these guidelines started in April 2015 and concluded in August 2015. I would like to sincerely thank TFDA staff namely; Mrs. A. Kijo, Mr. A. Bitegeko, Mr. E. Alphonse, Ms J. Jasson and Ms. R. Mariki who developed these guidelines.

Special gratitude is also owed to the Ethiopian Food, Medicine and Healthcare Administration and Control (FMHACA) and Health Science Authority (HSA) of Singapore for making their guidelines available for reference.

Dealers in medical devices including Medical Stores Department (MSD) who provided comments during stakeholder's consultative meetings are also acknowledged for their valuable inputs.

The TFDA will welcome comments for improvement of the guidelines during implementation.

M. A. Fimbo
Director, Medicines and Complementary Products
Tanzania Food and Drugs Authority

FOREWORD

In view of complexity of the medical devices and the accompanied risk in various ways of utilization, the Tanzania Food, Drugs and Cosmetics Act, Cap 219 has provided for control of importation and exportation of medical devices including in vitro diagnostics. The law requires that any person dealing with importation of these products must be registered by TFDA and the imported medical devices must also be registered or approved by the Authority. These are principal requirements for authorizing importation of medical devices into Tanzania.

This is the first guidelines for importation and exportation of medical devices including in vitro diagnostics to be developed by TFDA. 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 in an application submitted to TFDA by an importer or exporter of medical devices including in vitro diagnostics.

All applicants are encouraged to familiarize with the 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 safe, effective medical devices of acceptable quality including in vitro diagnostics and spare parts 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.

Hiiti B. Sillo
Director General
Tanzania Food & Drugs Authority

INTRODUCTION

These guidelines have been developed to provide guidance for importers and exporters of general medical devices and in vitro diagnostics pursuant to legal requirements prescribed under section 21(1)(d) of the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

The document applies to any person, institution and organization that intends to export or import for the purpose of selling, research or donation of medical devices in Tanzania mainland. The main objective of these guidelines is to provide importers and exporters of medical devices with the necessary information to enable them comply with the law and regulations governing importation and exportation of medical devices into and outside the country respectively. Other objectives include control of unwanted medical devices as well as minimizing the accumulation of non-functional medical devices but also to alleviate problems associated with donation by promoting good medical devices donation practice.

The document has been organized into three main chapters. The first chapter provides for the requirements and procedures to be followed up during importation of medical devices, the second chapter outlines the requirements and procedures for the exportation of medical devices and third chapter describes procedures for donation of medical devices. Formats of application forms and certificates have been appended for easy referencing.

Approval for importation, exportation and donation of medical devices will be based on fulfillment of the requirements prescribed in these guidelines and Guidelines published by the Ministry of Health and Social Welfare therefore applicants are advised to read and understand the guidelines before applying for importation or exportation of devices.

DEFINITIONS

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

Authority

Means the Tanzania Food and Drugs Authority, or its acronym “TFDA” established under section 4 (1) of the Tanzania Food, Drugs and Cosmetics Act (TFDCA), Cap 219.

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 a 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;

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.

In Vitro Diagnostic Medical Device

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

Importer

Means a person or institution licensed and/or authorized to import medical devices into the country.

Import permit

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

Label

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

Labeling / information supplied by the manufacturer

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

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;

Medical Device or Devices

Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is –

- (a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
- (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;

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

Permit

Means certificate of approval to import and export medical devices

Recipient”

Means a governmental, non-governmental or private health Institution that voluntarily receives medical devices as a donation;

CHAPTER ONE

1. IMPORTATION OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS

1.1 Categories of importers of medical devices including in vitro diagnostics:

Importers of medical devices including in vitro diagnostics shall fall under the following categories:

- a) Authorized Government and Non- Governmental institutions
- b) Medical Devices and In Vitro Diagnostics wholesalers
- c) Clinical Trial Investigators
- d) Recipients of donations
- e) Persons importing medical devices for medical purposes
- f) Exhibitors

1.2 Requirements for importers

- 1.2.1 All medical devices including diagnostics to be imported must be registered by TFDA unless given special approval by the Authority.
- 1.2.2 All importation of medical devices including diagnostics must be done by importers whose premises are dully registered by TFDA
- 1.2.3 All importers must import medical devices including diagnostics through the authorized ports of entry (POE).
- 1.2.4 In case of donations please refer **chapter two** of these guidelines.
- 1.2.5 All imported medical devices including in vitro diagnostics should bear the following minimum information on the label:
 - a. Name of the device
 - b. Name and address of the manufacturer
 - c. The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device
 - d. Family or medical device group family (*where applicable*)
 - e. Batch or lot number
 - f. If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units
 - g. The words “sterile” if the manufacturer intends to sale the device in a sterile condition
 - h. The words “for single use only” if the device is intended for that purpose
 - i. the manufacturing and expiry date of the device expressed in month and year (*where applicable*)

- j. 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
- k. the directions for use, unless directions are not required for the device to be used safely and effectively and
- l. any special storage conditions applicable to the device
- m. 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.

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.

1.3 Procedure for importation of medical devices

- 1.3.1 Authorized importers intending to import medical devices shall apply to the Director General, TFDA by filling in the application form as prescribed in **Annex I** of these guidelines.
- 1.3.2 All applications may be submitted to TFDA head quarter offices or zone offices located in Arusha, Mwanza, Mbeya, Dar Es Salaam, Mtwara and Dodoma regions.
- 1.3.3 The application form shall be accompanied by one original proforma invoice and two (2) copies of original from the marketing authorization holder of the product(s) or authorized supplier(s), subject to provision of the original proforma at the time of importation.
- 1.3.4 The proforma invoices shall state for each medical device to be imported, the following (s);
 - 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 items including brand and common names as declared in information of medical devices including in vitro diagnostics submitted to TFDA;
 - g. The quantity, pack size, unit value, total value in convertible currency;
 - h. Batch or Lot number;
 - i. Manufacturing and expiring date;
 - j. Mode of shipment (sea, air, road);
 - k. Port of entry;
 - l. Signature and stamp of the supplier and/or manufacturer.

- 1.3.5 Application form shall be stamped and signed by the importer or in-charge of the importing company before submission to TFDA.
- 1.3.6 In a situation where section 1.3.5 does not apply, the application form shall be signed by the applicant.
- 1.3.7 Import permit shall be valid for six (6) months and shall not be transferable and will be issued to cover only one shipment.
- 1.3.8 Once the authorization has expired or cancelled, no further importation and supply of medical device at any quantity shall be permitted.

1.4 Processing of applications

- 1.4.1 Upon receiving the application as specified above, TFDA 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 Free on Board (FoB) 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 II** of these guidelines.
- 1.4.3 An application will be rejected if it does not meet any of the importation requirements. An applicant will be given a rejection form (**Annex III**) stating clearly reason(s) for rejection.
- 1.4.4 All applications will be processed after twenty four hours (24) during working days with exception of special requests which may take longer period.
- 1.4.5 All importers will be required to hold a valid importation permit issued by the Authority prior to shipping of the consignment.

1.5 Special importation requirements

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

1.5.1 Importation of Syringes

- a. Application for importation permit shall consists either of auto disabled (AD) syringes only or AD and standard disposable syringes and/or type II re-use prevention syringes in a ratio of 90%:10%. The 10% of standard disposable syringes and type II re-use prevention syringes is to cater for specific procedures like naso-gastric feeding; blood drawing and delicate aspirations.

- b. Applications for importation permit consisting of standard disposable syringes and/or type II re-use prevention syringes of nominal capacity of 10ml and below only will not be honoured.
- c. Application for importation of standard disposable syringes and type II re-use prevention syringes of nominal capacity of more than 10ml will be honored without any restriction till further notice.
- d. All types of syringes sterilized by Ethylene Oxide (EO) gas must be packed either in blister pack or ribbon pouch. Syringes packed in polybags are completely not acceptable. It should be noted that polybags are considered not appropriate for (EO) sterilization and therefore sterility of syringes packed in poly-bags is not assured.

1.5.2 Importation of unregistered medical devices including in vitro diagnostics

An application for importation of unregistered medical devices should be accompanied by a letter stating reasons for importation. An import permit will be issued if the following criteria are complied with:-

- a. Medical device is in the TFDA notification list;
- b. Medical device has been approved by IMDRF member countries or prequalified by WHO;
- c. Evidence that a medical device is in circulation in the manufacturer's country of origin (Free Sales Certificate);
- d. Declaration of Conformity;
- e. CE Certificate except for medical devices of "class A";
- f. Evidence of insurance against consequences of the use of a class D medical device (policy insurance);

Failure to submit any of the above documents shall render the application invalid and shall be rejected.

1.5.3 Importation of medical devices for personal use

- a. Applications for importation of class B, C and D medical devices for personal or animal use, should be accompanied by a written recommendation from a registered medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.
- b. Applications for importation of medical devices for personal use should also be submitted along with a letter giving reasons for importation from applicant or qualified medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.

1.5.4 Importation of investigational medical devices

Applications for importation of investigational medical device 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 approval letter and copy of certificate of clinical trial issued by TFDA.

1.6 Inspection of imported consignments at ports of entry

- a. On arrival at the ports of entry, medical devices will be inspected by a TFDA Inspector to ensure that they comply with the approved specifications and regulations before they are released.
- b. Each consignment must be accompanied by an import permit, an original proforma invoice, a corresponding certificate of analysis for each batch and airway bill or bill of lading.
- c. Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Tanzania Revenue Authority (TRA) or other authorized agents.
- d. At the time of importation, medical devices must have a valid shelf life not less than 60 % of the original shelf life.

1.6.1 Sampling of imported products

- a. TFDA will sample imported medical devices for further investigation when deemed necessary. The sample collection form **Annex IV** will be used during sampling which will be signed in duplicate by TFDA inspector and the consignee and one copy will be issued to the later.
- b. 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.
- c. 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 TFDA Laboratory. Where analysis is to be carried out outside TFDA Laboratory, a longer period may be required.

1.6.2. During inspection of the consignment the following actions may be taken:

- a. An approval for release.
- 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.

1.6.3 Authorized Ports of Entry (PoE)

Class B, C and D medical devices as well as in vitro diagnostics imported into Tanzania would be allowed to enter through the following official POEs:

- (i) Dar-es-salaam International Airport,
- (ii) Dar es salaam Sea Port,
- (iii) Kilimanjaro International Airport,
- (iv) Horohoro
- (v) Holili,
- (vi) Namanga,
- (vii) Sirari,
- (viii) Mwanza Lake Port,
- (ix) Mwanza Airport,
- (x) Tanga Sea Port,
- (xi) Tunduma
- (xii) Mtukula

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

1.6.4 Release or rejection of a consignment

(i) Conditions for release of a consignment:

- a. All approved consignments will be released by TFDA 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 two divided shipments and an inspector will clearly mark in the original permit and profoma invoice that it is "**PARTIAL SHIPMENT**" and the quantity imported and remaining will be indicated in the profoma invoice and permit.

(ii) Conditions for not releasing the consignment

- a. Consignments which do not meet importation requirements will be rejected by TFDA and the accompanied documents shall be stamped with an official stamp marked "**STOP RELEASE**".
- b. Medical devices rejected for quality reasons will be **CONDEMNED**;
- c. Medical devices rejected because of being unregistered in Tanzania or with neutral labeling, upon application *may* be re-exported to a third country *on special request* and *with special clearance from*

the Regulatory Authority of the country where the consignment is being exported to;

- d. 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 TFDA;
- e. Re-loading for re-export should be witnessed by Customs officials and Inspector(s) from TFDA;
- f. Copies of re-export documents stamped at the exit port shall be submitted to TFDA as evidence of completion of re-exportation exercise;
- g. Destruction of rejected medical devices will be done as per the Customs requirements and TFDA will provide technical advice on mode of destruction according to the guidelines for disposal of unfit medical devices.
- h. TFDA will issue a Destruction Certificate after completion of the destruction exercise.
- i. Where the consignment is rejected/ detained an inspector will issue a Rejection/Detain Form of medical device consignment(s) as specified under **Annex V** of these guidelines.

CHAPTER TWO

IMPORTATION OF DONATED MEDICAL DEVICES

2.1 Scope of Application

The procedures outlined below will be applicable to all donated medical devices.

Principle

1. *All Donations will be in accordance with the recipient's need and should comply with the existing government health policies, laws, guidelines and administrative arrangements.*
2. *Donation should comply with applicable standards and there will not be double standards regarding quality of donated items. Medical devices unacceptable in the donor country shall not be accepted.*

2.2 Requirements for Donation

2.2.1 General Requirements

1. Any person, institution and organization intending to donate medical devices will be required to apply for import permit at TFDA by filling in application form prescribed under section 1.3.1 of these guidelines PRIOR TO SHIPMENT of the donated consignment.
2. Application form should be accompanied by the following documents:
 - a. A support letter from the relevant authority which supports such donation (where applicable).
 - b. A support letter from the importer.
 - c. Donation certificate
 - d. One original proforma invoice and two copies of the original
3. The Authority will assess if the medical device is compatible with the recipient.
4. Medical devices intended to be donated must be collected as much as possible from known sources for ease of traceability.
5. Donated medical devices should have a shelf life of not less than twelve months (where applicable).
6. If the medical device is used it must be reconditioned, tested and all essential parts, accessories and working materials included before shipment together with the relevant supporting documents to indicate that the device is in good order and must not be in use for more than five years.
7. Donated medical devices shall:

- a. be robust and fully operational as a full system or as a separate subsystem;
 - b. meet or exceed existing safety and performance specifications provided by the manufacturer, international or appropriate national standards;
 - c. include all essential parts, accessories and working materials;
 - d. have its label, user manual and other documents written in English or Swahili;
 - e. be packed suitable for road, air or sea transport under tropical conditions.
8. For software operated medical devices, the software shall be either preloaded and/or accompanied by the software package.
 9. For electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz to 240V/50Hz and for X-ray emitting equipment that it shall be calibrated and inspected by a qualified Medical Physicist
 10. Damaged, outmoded, and redundant medical devices for which spare parts and consumables are no longer available and/or equipment which is no longer supported by the manufacturer shall not be accepted.
 11. The Authority will issue Donation import permit when satisfied that all conditions of application have been fulfilled; otherwise the application will be rejected in writing by stating the reason for rejection.
 12. The permit issued for importation of donated medical devices will be valid for six months.

2.2.2 Requirements at the Port of Entry

Donated medical devices shall have port clearance from the Authority and shall be accompanied by the following documentary evidences:

- a. valid import permit;
- b. packing list;
- c. proforma invoice,
- d. airway bill or bill of lading;
- e. certificate of refurbishment for used medical devices (issued by manufacturer of certified company)
- f. certificate of analysis for sterile medical devices;
- g. In case the device emits radiation, a permit or certificate from Tanzania Atomic Energy Commission will be required.
- h. The certificate of refurbishment mentioned under (g) must state the following:
 - (i) tested, labeled and packed; and
 - (ii) replaced or repaired and the repair service that were performed on the medical device and the source of the repair parts and provide an acceptance report for these parts;
 - (iii) calibrated it shall state and verify the operation of the medical device.

- i. performance standard used to calibrate it; and
- j. disinfected or decontaminated.

2.2.3 Label of the donated medical device

- a. Depending on its nature and type, the label of donated medical device should have the following minimum information:
 - i. the name of the medical device;
 - ii. model number or serial number;
 - iii. manufacturing and expiry date;(where applicable)
 - iv. life span or expectancy;
 - v. name and address of the manufacturer;
 - vi. handling and storage requirement (s);
 - vii. technical direction for use;
 - viii. an indication, if applicable, that the medical device is intended to be
 - ix. The words “used only for clinical or performance investigations” before being supplied;
 - x. for a sterile medical device, the word “Sterile” and where appropriate, description of methods of re-sterilization;
 - xi. if the device is a refurbished, an indication of the device as refurbished device;
 - xii. 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”;
 - xiii. if the device emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of this radiation
 - xiv. if the device is to be installed with or connected to other medical device or 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;
 - xv. if the device is an in vitro diagnostic medical device it must be labeled as “ in vitro diagnostic” or “IVD”;
 - xvi. the intended purpose of the medical device, the intended user of the medical device, and the kind of patient on whom the medical device is intended to be used (if this information is not obvious).
 - xvii. Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.
- b. Each donated medical device shall have accompanying user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.
- c. Donated medical devices shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.
- d. Labeling information of the medical device can be provided on the medical device itself, packaging used for the medical device, on an

insert supplied with the medical device or in a printed document or using other appropriate media.

- e. At the time of importation, medical devices must have a valid shelf life not less than 60 % of the original shelf life.

2.2.4 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.

2.2.5 Disposal

If donated medical equipment are found to be violative, the recipient shall dispose or return the product to the country of origin on its own expense.

CHAPTER THREE

EXPORTATION OF MEDICAL DEVICES

3.1 Exporters of medical devices

Exporters of medical devices fall under the following categories:

- a. Registered local medical devices manufacturers
- b. Registered wholesalers
- c. Clinical trial sponsors and investigators
- d. Persons authorized by TFDA

3.2 Requirements for exporters

- 3.2.1 No person shall export medical devices out of the country without having a valid export permit issued by the Authority.
- 3.2.2 All medical devices to be exported must originate from a registered manufacturer or wholesaler in Tanzania Mainland.
- 3.2.3 All exporters must export medical devices through authorized PoEs or as determined by TFDA.
- 3.2.4 Medical devices intended to be exported should either be registered or authorized by TFDA.

3.3 Procedure for exportation of medical devices

- 3.3.1 Authorized exporter intending to export medical devices should apply to the Director General, TFDA by filling in application form as prescribed under **Annex VI** of these guidelines.
- 3.3.2 All applications may be submitted to TFDA head quarter offices or TFDA zone offices located in Dar es Salaam, Arusha, Mtwara, Mwanza, Mbeya and Dodoma regions.
- 3.3.3 The application form shall be accompanied by one original proforma invoice.
- 3.3.4 Proforma invoices shall state for each medical device to be exported, the following(s);
 - a) 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 items including brand and common names as declared in information of medical devices including in vitro diagnostics submitted to TFDA;
- h) The quantity to be exported for each medical device, its unit value, total value in convertible currency,
- i) The product registration number issued by the Authority;
- j) Batch or Lot number;
- k) Manufacturing and expiring date;
- l) Mode of shipment (sea, air, road);
- m) Port of exit;
- n) Signature and stamp of the supplier and/or manufacturer.

3.3.5 In a situation where section 1.3.4 (l) does not apply, the application form shall be signed by the applicant.

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

3.3.7 Application for export permit shall be accompanied by a processing fee as prescribed in TFDA Fees and Charges Regulations in force.

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

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

3.3.10 All applications for export will be processed within two working days.

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

3.3.12 An application will be rejected if it does not meet any of the exportation requirements by stating clearly reason(s) thereof.

3.4 Review and Appeal procedures

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

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

3.4.3 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.

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FOR IMPORTATION OF MEDICAL DEVICES

To: **Director General**
Tanzania Food and Drugs Authority
P.O Box 77150
Dar-es-salaam

I/We.....
.....
of (postal address).....undertaking the business of Wholesale/
manufacturing/Other Specify).....
hereby apply for importation permit for Medical Devices into the United Republic of
Tanzania.
License Number.....issued on.....
Location of Business.....
Name of the Owner of the business.....

Purpose of importation permit, for: **(Tick** whichever is applicable)

- Spare parts for Medical Devices for human/veterinary use;
- Finished Medical Devices for human/veterinary use;
- Clinical Trial of a specified product (only one product per application)

Donation

Reasons for donation

- Emergency
- Development aid program
- Other.....

Checklist for completeness of proforma invoice **(Tick** as appropriate)

- Name and address of the supplier
- Name and address of the importer
- Name and country of the manufacturer
- Invoice number
- Invoice date
- Unit price of each item
- Quantity of each item
- Mode of transport
- Clear description of items including brand names and common names as declared in information of medical devices submitted to TFDA
- Stamp and/or signature of supplier
- Stamp and/or signature of importer
- Certificate of donation (for donated medical devices)
- FoB and CIF value of the items
- Port of discharge of goods

Attached herewith the Proforma Invoice No..... of
(date).....

Declaration:

I certify that the information provided in the application form and proforma invoice is true and correct.

Date of application..... Signature of Applicant.....

Stamp.....

For official use only:

.....
.....
.....
.....
.....

Name of Officer : Signature.....

Stamp.....

TANZANIA FOOD AND DRUGS AUTHORITY



PERMISSION TO IMPORT MEDICAL DEVICES

Permit No: TFDA...../...../.../.....

PART A:

Name of registered importer.....Postal addressTel No.....
Exporting Country.....Invoice No.....
Date.....Time.....
Exporter/Sender..... Postal address
Arrival expected by ship/air/motor vehicle, via Port of entry
Application for permission to import the following product (s) in accordance with the above mentioned Act and Regulations made

Table with 6 columns: Sno, Generic name, Brand name, Batch No., Product (Registration/Notification number), Permit Quantity, Value of the products.

TOTAL:

Fees Receipt No Dated

PART B:

Permission is hereby granted to import the mentioned medical devices. The importer has to inform the Port TFDA Inspector to examine the approved medical devices for fitness of the intended use before being allowed entry into Tanzania.

Date

FOR: Director General and stamp

PART C:

I _____ being TFDA inspector at TFDA port office has examined the above listed medical devices and have found them fit/unfit for the intended use hence allowed/not allowed entry into Tanzania.

Date

Signature of TFDA port officer and stamp

(The inspector has to return immediately a completed copy of this permit together with a copy of a release certificate to the Director General)

N.B: This permit is for *single consignment* only and shall be valid for *6 Months* from the date of approval.

TANZANIA FOOD AND DRUGS AUTHORITY



IMPORT PERMIT REJECTION FORM FOR MEDICAL DEVICES

TFDA Serial Number _____ **of**

Proforma Invoice Number _____ **Dated**

A. Reasons for rejection (Tick as appropriate)

- Product is not registered/notified
- Importer/Consignee is not registered
- Manufacturer(s) of the product is not indicated
- Number of Proforma Invoice is not shown
- Name and/or identity of items is not clear
- The product (s) is/are not regulated by the Authority
- The Proforma Invoice is not signed and/or stamped by supplier
- The Proforma Invoice is not counter signed and or stamped by Importer
- Certificate of Donation is not attached
- Product(s) registration number is not shown
- Proforma Invoice is not original

- Others.....

B. Conditions for approval

In case item(s) listed under A above have been fulfilled/submitted, the proforma invoice will be approved.

..... Name of officer rejecting Signature Date
..... Name of Person collecting Signature Date

TANZANIA FOOD AND DRUGS AUTHORITY



MEDICAL DEVICES POST MARKETING SURVEILLANCE

SAMPLING FORM

1. Sample code:.....
(Region/product/sequence number/sampling date (ddmmyy))
2. Name of Premises where sample was taken:.....
3. Physical Address.....Postal address.....
Telephone No..... Fax No.....
Email address..... (if applicable)
4. Product name of the sample:
5. Strength (if applicable):.....
6. Device type:
7. Pack size:
8. Batch/lot number:.....Date of manufacture:
- Expiry date:
9. Name and physical address of the manufacturer:
.....
.....
10. Number of units collected.....
11. Comment on storage condition of device at the premises:.....
.....
.....
12. Name and signature of the Representative of the premise where sample was collected:

Name.....Signature.....Date.....
13. Name of Inspector (s)/Sampling officer

S.No	Name	Organization	Signature	Date

Note: Samples should be collected in their original containers.

TANZANIA FOOD AND DRUGS AUTHORITY



REJECTION/RETENTION OF MEDICAL DEVICE CONSIGNMENT(S)

(Made under section 99 (4) of Tanzania Food, Drugs and Cosmetics Act Cap 219)

Exporter /Consigner

Importer/Consignee.....

...

The inspected consignment (s) as per Proforma Invoice No.....Airway Bill No...../Bill of Lading

No...../R.Number.....dated.....and the single Bill of Entry Number.....dated.....has been

Rejected/Retained for the following reasons:- (Tick whichever applicable)

- 1. Proforma Invoice is not approved by TFDA
- 2. 1% FOB is not paid to TFDA
- 3. The products (s) is/are not registered by TFDA
- 4. consignee is unauthorized dealer of pharmaceuticals
- 5. Manufacturer of product is not indicated
- 6. Description of the items is not clear
- 7. Manufacturing and/expiring date of products (s) not indicated
- 8. The products (s) shelf life is too short/expired
- 9. Physical quality of the product is poor
- 10.Packaging Insert not included
- 11.Certificate of analysis not present
- 12. Batch number not indicated
- 13. Any other.....(Specify)

Comments from the inspector if any.....
.....

.....
Name of Inspector

.....
Signature

.....
Date

.....
Full name of consignee/
Clearing agent

.....
Signature

.....
Date

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FOR EXPORTATION OF MEDICAL DEVICES

To: Director General
Tanzania Food and Drugs Authority
P.O Box 77150, Dar-es-salaam

I/We.....
of (postal address)..... undertaking the business of Wholesale/Medical Devices
manufacturing/Other (Specify).....
Permit number.....issued on.....
Location of Business.....
Name of Person in charge of the business.....Registration Number.....
Hereby apply for export permit of medical devices to:
Consignee.....Physical address/Location of
business... ..Postal address.....
Country name.....

Purpose of export permit, for:

- Medical devices for human use;
- Medical devices for veterinary use;
- Clinical Trial of a specified product (only one product per application)
- Any other
(Specify).....

(Tick whichever is applicable)

Attached herewith the Proforma Invoice No.....of (date).....

Declaration:

I certify that the information provided in the application form and proforma invoice are true and correct.

Date of application.....Signature of Applicant

Stamp.....

For official use only:

Received by:

Signature.....

Stamp.....

.../DMC/.../SOP/...

TANZANIA FOOD AND DRUGS AUTHORITY



Permit No.

DATE:

Exporter name

P.O. Box.....

Region.....

RE: PERMIT TO EXPORT MEDICAL DEVICES FROM(Company name).....(Exporting country) TO, (Company name).....(Country name)

Reference is made to your application letter received on attached with a proforma invoice number..... dated.....

Subject to compliance with other laws regulating the export trade, permission is hereby granted to, under section 73(1) of the Tanzania Food, Drugs and Cosmetics Act, 2003 to export the following medical devices to
COUNTRY NAME.....;

S/no	Item	Unit price	Quantity	Value of the products

TOTAL:

Permission is hereby granted to export the mentioned medical devices. This permit is valid from Date to Date.....

Date

FOR: DIRECTOR GENERAL