



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

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*Rwanda FDA, P.O.Box:1948 Kigali-Rwanda, Email: [info@rwandafda.gov.rw](mailto:info@rwandafda.gov.rw)*

*Website: [www.rwandafda.gov.rw](http://www.rwandafda.gov.rw), Toll Free:9707*

## **FOREWORD**

Rwanda Food and Drugs Authority is a regulatory body established by Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drug Authority and determining its mission. One of the functions of the Rwanda FDA as per the law is to regulate the import and export of Medical Devices including in-vitro diagnostics (IVDs), especially in articles 3, 8, and 9.

Reference to the provisions of the technical regulations No FDISM/FDIEC/TRG/001 governing the control of importation and exportation of pharmaceutical products and medical devices.

These guidelines provide the information and documentation required in any application submitted to Rwanda FDA by an importer or exporter of Medical Devices including IVDs, and their respective raw materials as set in these guidelines. Adherence to the set requirements will speed up the provision of quality services to clients and ensure the quality and safety of Medical Devices or IVDs.

These guidelines also provide guidance to Rwanda FDA Staff to minimize risks of trading sub-standard and falsified products among nations and therefore prevent dumping these products in our country.

These guidelines will be reviewed from time to time as the need arises.

Rwanda FDA acknowledges all the efforts of stakeholders who participated in the development and validation of these guidelines.

**Prof. Emile BIENVENU**  
**Director General**

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13/07/2021	1	First issue
17/10/2022	2	<ol style="list-style-type: none"> <li>1. Requirements for import visa of registered products: certificates of compliance to international standards such as GMP, ISO, IEC, CE, etc. are not required;</li> <li>2. Requirements for import visa and license for non-registered products: COAs is no longer required if the manufacturer is located in a country with stringent regulatory authority and GDP or Operational license of the supplier can replace certificates of compliance to international standards such as GMP, ISO, IEC, CE, etc;</li> <li>3. The application processing time has been updated;</li> <li>4. The validity for import/export license has been updated</li> <li>5. The validity for official certificate of importation of controlled substances has been updated;</li> <li>6. The conditions for re-exportation of rejected consignment have been added.</li> <li>7. The application processing chart/diagram was added.</li> </ol>
Refer to the approval date	2	<ol style="list-style-type: none"> <li>1. Import VISA has been removed;</li> <li>2. Certificate of conformity requirement have been improved based on product risks;</li> <li>3. Inclusion of key considerations for importation of products of shelf life below 2/3 of its total shelf life.</li> <li>4. Update on eligibility criteria;</li> <li>5. Update on requirement on donation used medical equipment.</li> </ol>

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**ACRONYMS AND ABBREVIATIONS**

<b>CE</b>	Conformité Européenne
<b>COA</b>	Certificate of Analysis
<b>GDL</b>	Guideline
<b>GDP</b>	Good Distribution Practices
<b>GMP</b>	Good Manufacturing practices
<b>IEC</b>	International Electrotechnical Commission
<b>ISO</b>	International Organization for Standardization
<b>IVDs</b>	In-Vitro Diagnostics
<b>MEE</b>	Medical Electrical Equipment
<b>MoU</b>	Memorandum of Understanding
<b>NGOs</b>	Non-Government Organizations
<b>PoE</b>	Point of Entry
<b>RFID</b>	Radio Frequency Identification
<b>SRA</b>	Strength Regulatory Authority
<b>WLA</b>	WHO Listed Authority
<b>SaMD</b>	Software as Medical Device

## **GLOSSARY / DEFINITIONS**

In these guidelines, unless the context otherwise states:

**Authorization** means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization, and functioning; it includes import visas, import/export licenses, permits, certificates, and other types of approval as may be issued by Rwanda FDA.

**Consignment** means a number of goods that are sent to a person or place to be sold;

**Donation** means an act or instance of presenting medical products, processed foods, and others; Products regulated to recipients in an emergency or as a part of development aid in non-emergency situations;

**Label (human readable):** Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

**Exporter** means a person, country, or organization that sends goods or services to another country;

**Export License** means an authorization/permit issued to an eligible exporter by Authority, authorizing him/her to export pharmaceuticals or medical devices or their respective raw materials from the country;

**Importer** means a person or organization that brings goods or services into a country from abroad;

**Import License** means an authorization/permit issued to the importer by Rwanda FDA, authorizing him/her to import Medical Devices or In-Vitro Diagnostics devices or their respective raw materials into the country after complying with the importation requirements;

**Manufacturer** means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making it available for use, under their name; whether the medical device is designed and/or manufactured by that person or on their behalf by another person.

**Medical device** is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- a. diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- c. investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- d. supporting or sustaining life,
- e. control of conception,
- f. cleaning, disinfection, or sterilization of medical devices,
- g. providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

**In Vitro Diagnostic (IVD) Medical Device:** means a medical 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. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

**Model:** The name and/or number used to represent one medical device, or a family of medical devices to group many variations that have shared characteristics.

**Refurbishment:** A refurbishment of a medical device is to restore a used medical device or system to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use.

**Raw material** means any substance of a defined quality used in the production of a pharmaceutical product and medical devices or in-Vitro Diagnostics devices, but excluding packaging materials;

**Special import authorization** refers to an import authorization issued for unregistered Medical Devices or in-Vitro Diagnostics devices.

**Serial Number:** A unique sequence of numbers or letters in a series used to identify an individual unit of a medical device.

**Shelf-Life:** Period of time until the expiry date during which a medical device or IVD medical device in its original packaging maintains its stability under the storage conditions specified by the manufacturer.

**Research use only:** A device that has been made available to institutions/laboratories solely for their use in studies involving the collation of data. The device is not intended for any medical purpose or objective.

## **INTRODUCTION**

The safety, efficacy/performance, and quality of Medical Devices or IVDs can be highly affected by the lack of adequate control on importation and exportation. It is therefore imperative that the manufacture, importation, and exportation of Medical Devices or IVDs, both nationally and internationally conform to certain set standards.

Rwanda FDA has developed these guidelines to strengthen the control of the importation and exportation of these products and to assist stakeholders to adhere to the legal framework during importation and exportation activities.

The main objective of these guidelines is to provide importers and exporters of Medical Devices or IVDs with the necessary information to enable them to comply with the law and regulations governing the control of the importation and exportation of these products.

These guidelines are organized into three chapters, the first chapter provides the requirements and conditions to fulfil during the importation of Medical Devices including IVDs, the second chapter outlines the requirements and conditions for the exportation of these products while the third chapter describes the application process flow chart and timelines .

## **SCOPE**

These guidelines apply to importation and exportation of Medical Devices including IVDs, and their respective raw materials as specified in the law NO 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products.

These guidelines outline requirements for the importation and exportation of Medical Devices including IVDs for human beings or animals, raw materials and equipment used in manufacturing of medical devices /IVDs and pharmaceutical products.

## **CHAPTER I. IMPORTATION OF MEDICAL DEVICES INCLUDING IVDs**

### **1.1. Requirements**

#### **1.1.1. General requirements**

- a. All medical devices including IVDs to be imported must be either registered, notified or granted special approval by Rwanda FDA;
- b. The importation process of medical devices including IVDs shall pass through two mandatory phases: import license application and physical inspection;
- c. The importation/ exportation of medical devices including IVDs for personal use is guided by relevant guidelines ~~for importation~~ and Exportation of regulated products declared as personal effects;
- d. All imported medical devices including IVDs (where applicable) must have at least two-thirds of their shelf life remaining when they arrive at the Point of Entry;

*Guidelines for Importation and Exportation of Medical Devices Including In-Vitro Diagnostics*

- e. The importer is only eligible to import medical devices including in vitro Diagnostics falling under its scope of licensed activities;
- f. The importation of Medical Devices including IVDs labelled for sale in a specified country is prohibited in Rwanda except where Rwanda is one of the specified countries;
- g. All applications for import authorization shall be submitted using **an online** platform defined by Rwanda FDA;
- h. Rwanda FDA advises importers to finalize product orders with their suppliers only after obtaining the required import license from Rwanda FDA. This practice will help to prevent delays or losses that may arise at the Point of Entry due to regulatory non-compliance;
- i. All consignments of medical devices including IVDs shall pass through the approved Points of Entry;
- j. All imported consignments of medical devices including IVDs shall be subjected to physical inspection at the Point of Entry or at the importer's premises (for the consignments released under seal) before being used, to ensure that they comply with claimed specifications;
- k. The importer shall notify to Rwanda FDA the arrival of the consignment through the defined **online** platform;
- l. Any medical devices or IVDs shall be clearly labelled in one of the official languages in Rwanda. The label should have the following minimum information:
  - i. The trade or brand name;
  - ii. The generic name of Medical Devices or IVDs if applicable
  - iii. The dates of manufacture and expiry where applicable;
  - iv. Batch number or Serial/model number where applicable;
  - v. Storage conditions and handling requirements where applicable;
  - vi. The name and address of the manufacturer where applicable;
  - vii. Any other safety information, depending on the nature of the product.

The labelling information may be provided in a human-readable code or through automatic identification technology such as barcodes or Radio Frequency Identification (RFID).

Labels should be durable and legible for at least the lifetime of the medical device or IVD medical device.

Apart from the specific requirements for importation/exportation, Rwanda FDA reserves the right, when deemed necessary and for justified reasons, to request the importer to provide any other document/information for further analysis.

**1.1.2. Eligibility for Import Authorization**

All medical devices including IVDs must be imported by importers whose premises are licensed by Rwanda FDA or who fall within the eligible importers category. Only the following shall be allowed to import medical devices including IVDs:

- a. Licensed manufacturers and wholesale companies of pharmaceutical and medical devices including IVDs;
- b. Licensed retail pharmacies in case the product is not available on the market with justified reason;
- c. Licensed Hospital pharmacies (in line with Public-Private-Partnership);
- d. Licensed optical wholesale/retail shop;
- e. Licensed medical devices/IVDs repair;
- f. Public and authorized private health facilities;
- g. Authorized hatcheries;
- h. Non-governmental organizations (NGOs) with a Memorandum of Understanding (MoU) with the Ministry of Health or Government of Rwanda;
- i. Government institutions and Embassies;
- j. UN organizations intervening in the Health sector;
- k. Research institutions/researchers with clinical trial or research approval/certificate issued by competent authority in the country;
- l. Educational institutions with scope covering regulated products;
- m. A tourist, a visitor, a company or any other person, with justified reasons.

**1.1.3. Specific requirements**

**1.1.3.1. Import license requirements**

The following requirements are mandatory to apply for an import license

- a. The invoice that has the following information:
  - i. Invoice number and date;
  - ii. The address of exporter and importer;
  - iii. Manufacturer name and country of origin of the manufacturing site for each product;
  - iv. A clear description of each product including brand and common names;
  - v. Quantity and value for each product.
- b. Proof of compliance (ISO, CE, USFDA 510(k),...) to the international standards issued by an accredited certifying/notified body or Valid Good Manufacturing Practices certificate (GMP) if the manufacturer is not located in a country with Stringent regulatory authority(SRA)/WHO Listed Authority (WLA) or Valid Good Distribution Practices certificate (GDP) or Operational License of the supplier if the manufacturer is located in a country with SRA/WLA. The following are examples of proof of compliance for specific categories of medical devices/IVDs:

#	Compliance Certificate	Category
1	ISO13485(Quality Management System for	High risk (Class C and D) devices.

	Medical Devices), CE mark (Product Certification), or equivalent	
2	Declaration of conformity to IEC60601 Series (General Safety, Essential Performance, environment, usability, EMC, alarms)	Class C and D Medical Electrical Equipment (MEE)/Device
3	Certificate of refurbishment issued by the manufacturer or certified refurbishment company	Only for used donated equipment
4	ISO9001 or equivalent	Class A, B, raw materials, spare parts, accessories of medical devices or IVDs, hospital utility/support equipment (non-medical, non-diagnostic, non-therapeutic equipment used in healthcare settings), equipment used in manufacturing process of regulated products.
5	Proof of WHO prequalification of the manufacturer and the proof of registration on national testing algorithm (where applicable)	Rapid Test Device (RTD) for HIV/AIDS, Hep B, Hep C, HPV, Malaria, G6PD, Cholera, Syphilis other IVDs Devices
6	Proof of WHO prequalification of the manufacturer or ISO 4074	Latex condoms
7	Proof of compliance to ISO13485 & IEC62304,	Software as Medical Devices (SaMD) Class III & IV
8	ISO 9001 or equivalent; A formal declaration/commitment limiting use to teaching/demonstration/research.	Devices used for training/research use only.

*Table 1: Compliance certificate vs product category*

- c. The license to operate of the importer (if applicable);
- d. The MoU with the Ministry of Health (MoH) or government of Rwanda (if applicable);
- e. A Packing list (where applicable) detailing imported quantities, batch/lot or model numbers, and expiry dates, as applicable;
- f. Certificate(s) of Analysis or equivalent quality control documentation, where applicable, for medical devices, including IVDs;
- g. Payment of verification fees as specified in the Regulations governing tariff/fees and charges on services rendered by Rwanda FDA , where applicable.

### **1.1.3.2. Requirement for importation of donated medical Devices/IVDs.**

In addition to the above-mentioned requirements to apply for an import license, the following conditions shall be fulfilled for the importation of donated medical devices including IVDs:

- a. All donations will be in accordance with the recipient’s need and should comply with the existing government policies, laws, guidelines, and administrative arrangements;
- b. Donations should comply with applicable standards and there will not be double standards regarding the quality of donated items. Unacceptable medical devices including IVDs in the donor country shall not be allowed into the recipient’s country;
- c. Any person, institution, or organization intending to import donated medical devices or IVDs will be required to apply for import license;

- d. Donated medical devices including IVDs, should have a shelf life of not less than 2/3 of the original shelf life or 80% for products with a shelf life of less than 24 months;
- e. If the medical equipment/instrument is used, it must be reconditioned and 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 state;
- f. For software-operated medical devices including IVDs, the software shall be either preloaded and/or accompanied by the software package;
- g. For medical electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz, and for X-ray emitting equipment shall be calibrated and inspected and the corresponding report shall be submitted;
- h. Damaged, outmoded, and redundant medical devices or IVDs for which spare parts and consumables are no longer available will not be accepted.
- i. Donated medical devices or IVDs must meet the labelling requirements.
- j. The application for an import license should be accompanied also by the following documents:
  - i. A supporting document from the relevant institution which supports such donation (if applicable).
  - ii. A donation letter from the donor to the beneficiary.
  - iii. Signed & stamped donated product information Form
  - iv. Certificate of refurbishment (for used medical devices including IVDs) issued by the manufacturer or certified company, where applicable.
- k. For more information about donation best practices, kindly refer to Guidelines for Donation of Medical Products, DD/HMDR/GDL/008 Version 2

#### **1.1.3.3. Requirement for importation of products for clinical trial or research purposes**

In addition to the above-mentioned requirements to apply for an import license (**Section 1.1.3.1**), the following conditions shall be fulfilled to import products used for clinical trial or research purposes:

- a. Clinical trial approval certificate (issued by Rwanda FDA) or any other research approval;
- b. Clinical trial approval certificate or ethical committee approval/certificate or approval from government institutions (for human/veterinary research) in case of investigational products and related trial products, a corresponding form shall be filled and submitted during application, if applicable.

#### **1.1.3.4. Inspection of imported consignments**

- a. Each consignment of Medical Devices or IVDs shall be inspected by Rwanda FDA to ensure that it complies with the approved requirements and applicable regulations;

- b. The importer must notify ( through the online platform) Rwanda FDA the arrival of the consignment and the proposed date for physical inspection;
- c. Rwanda FDA reserves the right, when deemed necessary and for justified reasons, to request the importer to provide any other document/information for further analysis;
- d. The imported medical devices or IVDs must have at least 2/3 (where applicable) of their shelf life remaining on arrival at the point of entry. However, products with less than two-thirds (2/3) of the remaining shelf life may be authorized for importation on an exceptional, case-by-case basis, subject to an adequate justification, such as public health emergencies, identified risk of shortage, raw materials or documented consumption and distribution rates demonstrating that the products will be used before expiry;
- e. Rwanda FDA may take samples of medical devices or IVDS for further investigation in case of suspected poor-quality products or in case of routine sampling. Suspicious consignment in which a sample was taken for analysis, shall not be used until a final decision is made based on the laboratory results;
- f. Rwanda FDA shall release the consignment if it meets the quality, documentary, and physical verification requirements for the importation of Medical Devices or IVDs.
- g. In case the physical inspection cannot be conducted at the Point of Entry for example: for intra-region consignments, consignments that require special storage conditions, or consignments that cannot be offloaded at the Point of Entry, the consignment shall be released under-seal for further inspection at the importer's premises;
- h. The imported Medical Device or IVD shall be rejected if it doesn't meet the labelling specifications , not allowed or withdrawn from the Rwanda market. In this case, the rejected product shall be re-exported within a period not exceeding 90 days or disposed-off following the procedure for disposal of unfit products;
- i. The instruction for use (IFU)/manual shall be in one of the official language and shall indicate the name and address of the manufacture;
- j. If a Medical Device or IVD is rejected due to quality and/or safety reasons, the applicant will proceed for safe disposal. The Rejected product will get a full release in the Rwanda electronic single window (Resw) after the submission of the destruction/disposal certificate;
- k. In cases where a consignment or product has been rejected and designated for re-export, a follow-up inspection will be conducted at the owner's premises after the expiry of the predefined period allowed for re-export. The purpose of this inspection is to verify the status of the rejected consignment or product(s) and to ensure compliance with the resolution from the initial inspection. If it is determined that the required actions have not been implemented as directed, the inspector shall recommend administrative sanctions in accordance with the applicable regulations. These sanctions will be applied to uphold regulatory compliance and public health safety.

## **CHAPTER II. EXPORTATION OF MEDICAL DEVICES INCLUDING IVDs**

### **2.1. General requirements**

Exporters of medical devices including IVDs should have a valid export authorization issued by Rwanda FDA.

All consignments of medical devices including IVDs to be exported must go through the authorized point of entry (PoE)/Exit.

### **2.2. Eligibility for Export Authorization**

Eligible applicants to export medical devices including IVDs include:

- a. A manufacturer of medical devices or IVDs;
- b. A wholesaler of medical devices or IVDs;
- c. A donor of medical devices or IVDs;
- d. Referral hospitals, Government institutions;
- e. Private health facilities with justified reasons;
- f. Research institutions/researchers with clinical trial or research approval in the country;
- g. Non-governmental organizations (NGOs) with MoU with the Ministry of Health (MoH) or Government of Rwanda;
- h. UN organizations and other international organizations intervening in the health sector;
- i. A tourist, a visitor, a company or any other person, with justified reasons.

### **2.3. Requirements for exportation of medical devices including IVDs**

All applications for an export license shall be accompanied by the following documents:

- a. Invoice of the product to be exported including the following information:
  - i. Name and address of the exporting and address of importing companies,
  - ii. Invoice number and date,
  - iii. A clear description of items with the quantity and values of the product to be exported.
- b. Certificate of analysis for every batch with details of tested parameters, if applicable.
- c. Packing list with the following details: *Batch Number or model number for medical equipment and Manufacturing & Expiry dates, quantity, and value of the category item to be exported.* where applicable,
- d. Operational license of the exporter, where applicable.
- e. Evidence of the source of the products to be exported, if applicable.

An export license shall not be transferable and shall be issued to cover only one shipment and the license will be valid for six (6) months from the date of issuance.

NB: All applications for export License shall be submitted using an online platform and will be processed within 3 working days.

### **2.3.1. Inspection of consignments to be exported**

- a. Each consignment of medical devices including IVDs shall be inspected by Rwanda FDA at the point of exit to ensure that it complies with claimed and approved specifications;
- b. The exporter shall notify (through the online platform) Rwanda FDA the proposed date for physical inspection

## **CHAPTER III. APPLICATION FLOWCHART AND TIMELINES**

### **3.1. Application processing flow chart**

Upon submission of the application via the online portal, Rwanda FDA will verify the eligibility and completeness of the application dossier. The application screening is done as indicated in the diagram of **Figure 1**.

In case the application does not comply with guidelines and regulations, a query will be submitted back to the applicant. A regulatory decision is made based on the outcome of the assessment of the submitted application. Based on the type of application, a processing period has been allocated. However, the stop-clock starts whenever a query is raised and ends when a satisfactory response is received from the applicant.

Applicants are required to ensure that their applications fulfil **ALL** eligibility criteria and that all required information is provided correctly and accurately. Any application that fails to meet eligibility criteria specified in these guidelines shall be queried.

### **3.2. Timelines**

The application for import/export license will be processed within 3 working days. Any application that does not meet the importation requirements will be queried, the review timeline (stop-clock) shall be paused until satisfactory response is received from the applicant, after which, the processing time shall resume.

The import/export license is granted for a single consignment, valid for six (6) months from the date of issue.

The import license may be renewed once, for a period of six months, provided it has not been utilized.

## REFERENCES

1. Law NO 47/2012 of 14/01/2013 relates to the regulation and inspection of food and pharmaceutical products.
2. Ministerial instructions No 20/12 of 18/02/06 determine the guideline for donated drugs in Rwanda.
3. The regulation governing control of importation and exportation of pharmaceuticals and devices.
4. Guidelines for Importation and Exportation of Medical Devices Including In Vitro Diagnostics and Laboratory Equipment, Second Edition, April 2020. Tanzania Medicines and Medical Devices Authority.
5. International Electro-Technical Commission, IEC 60601-1 Edition 3.1 2012-08
6. Stringent Regulatory Authority: <https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs#>
7. Medical device donations: considerations for solicitation and provision Second edition: WHO Medical device technical series

## ENDORSEMENT OF THE GUIDELINES

	<b>Prepared by</b>	<b>Checked by</b>		<b>Approved by</b>
<b>Title</b>	<b>Division Manager for Drugs Imports &amp; Exports Control</b>	<b>Head of Drug Department</b>	<b>Division Manager for Quality Management System</b>	<b>Director General</b>
<b>Names</b>	Theobald HABIYAREMYE	Dr. Vedaste HABAYARIMANA	Marie Ange UWASE	Prof. Emile BIENVENU
<b>Date &amp; Signature</b>				

**APPENDICES**

**1. Donated product information Form**

<b>Item under consideration</b>	<b>YES / NO</b>
Is this donation compatible with your healthcare settings?	
Are donated medical equipment easy to use and maintain?	
Do you have trained technicians for equipment to be donated?	
The equipment to be donated is/are still supported by the manufacturer?	
Have you been involved during the selection/identification of products to be donated?	
The equipment to be donated will come with all required spare parts/reagent, and/or accessories?	
If 6. is <i>NO</i> , spare parts and consumables are affordable vis a-vis the available budget?	
The equipment to be donated have their user and/or service manuals?	
The power supply system of equipment to be donated meet with our local requirements?	
Reagents or sterile supplies have an adequate expiry date ?	
Are products to be donated acceptable in the donor country?	

Biomedical Engineer/Technician	Names	.....
	Contact	.....
	e-mail	.....
Signed By:		Stamp and Signature of the head of recipient's health facility

## 2. Application processing chart

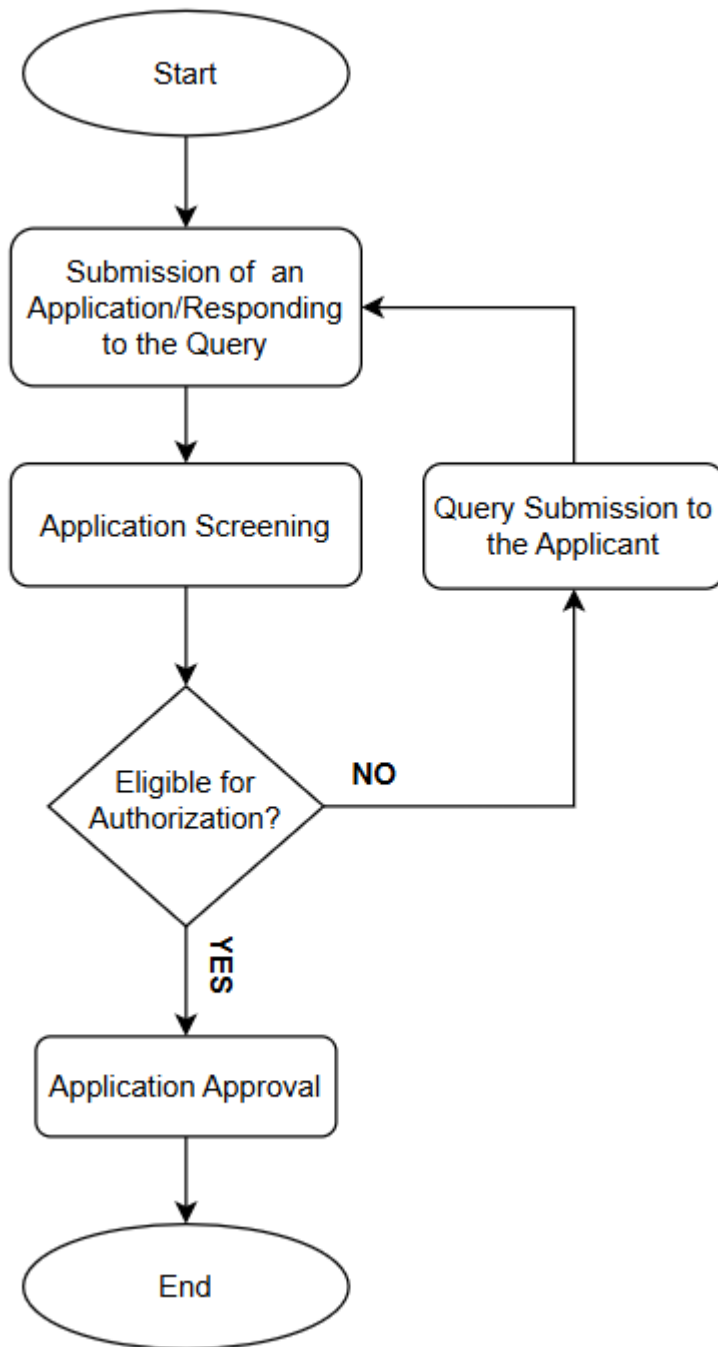


Figure 1: Application processing chart