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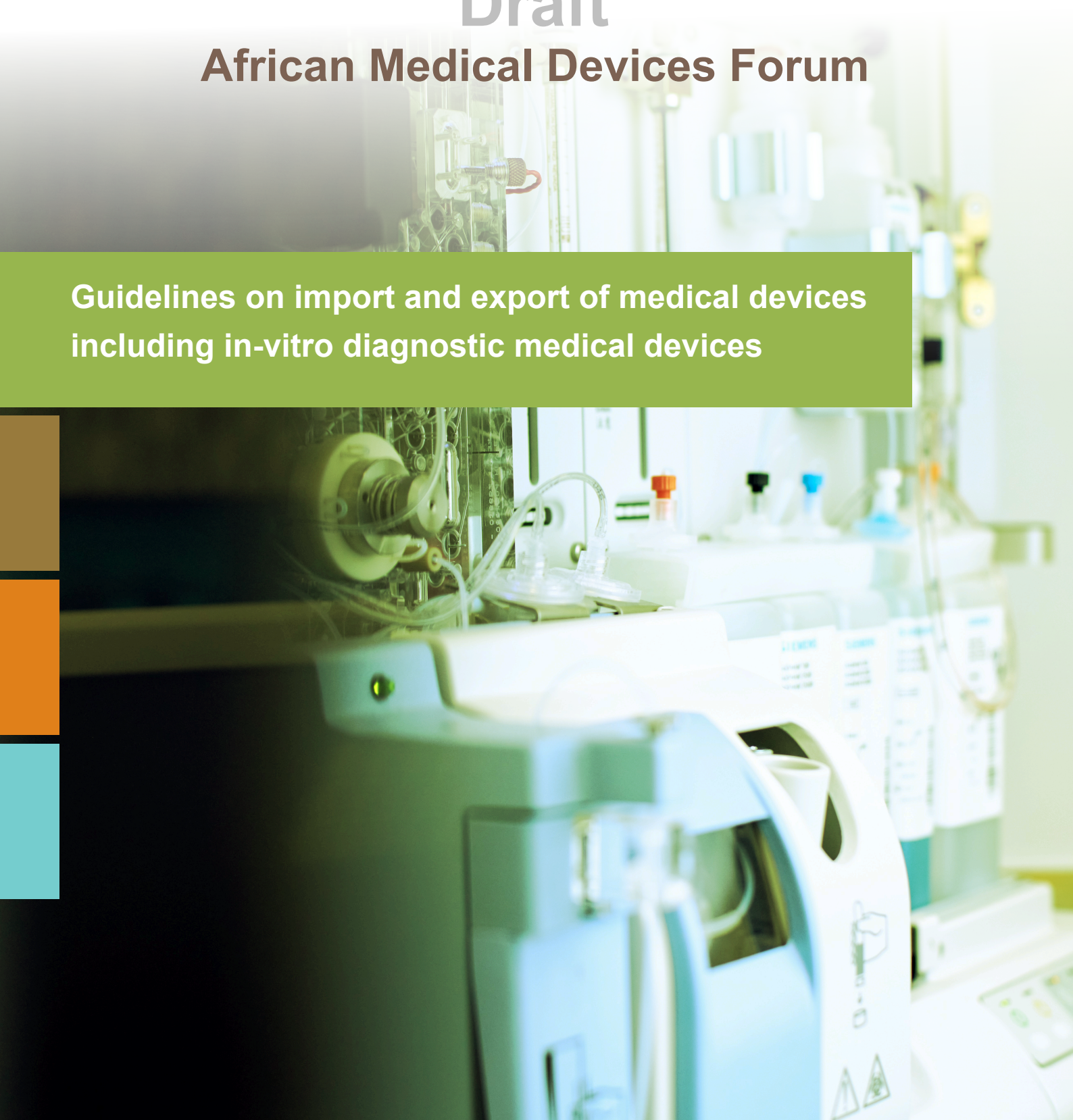
African Medical Devices Forum

Guidelines on import and export of medical devices including in-vitro diagnostic medical devices



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ABBREVIATIONS

CE:	**Conformité Européene (European conformity)**
EO:	**ethylene oxide**
GHTF:	**Global Harmonization Task Force**
ISO:	**International Organization for Standardization**
IVD:	**in-vitro diagnostic device**
NRA:	**national regulatory authority**

DEFINITIONS

For the purposes of the present guidelines, the following terms shall be defined as follows.

Act: the <Relevant NRA> Act, CAP XXX.

Applicant: any person, institution or company that applies formally to get market authorization for a medical device in partner States.

Authority: the <Name of NRA>, or its acronym, <AAA>, established under section <xxx> of the <Name of NRA> Act.

Authorized representative/local responsible person: a natural person residing in the country or a corporate body registered in the country that has received a legal mandate from the Applicant to act on the Applicant's behalf in matters pertaining to registration of devices in in the country (1).

Certified copy: a true copy of an original document certified by a person registered to practise law in the manufacturer's country of origin and endorsed with the registered person's official stamp and signature.

Consignment: a quantity of goods sent to a person or place to be sold.

Donation: the act or an instance of presenting medical devices to recipients in an emergency or as development aid in non-emergency situations.

Donor: a governmental or nongovernmental organization or individual that voluntarily supplies medical devices as a donation.

Exporter: a person or institution licensed and/or authorized to export medical devices outside the country of manufacture.

[1] Note: terms in red and in angle brackets should be replaced by the relevant name, acronym, legislative provision, etc. for the country concerned.

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

Importer: a person or institution licensed and/or authorized to import medical devices into the country ( ).

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

Intended use: the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer (, , , ,).

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. It includes reagents, calibrators, control materials, specimen receptacles, software and related instruments, apparatus or other articles ( ).
LABEL: any written, printed or graphic representation that appears on, or is attached to, the medical device or active ingredient or any part of its packaging; it includes any informational sheet or leaflet that accompanies the medical device or active ingredient when it is being supplied ( ).

Labelling/information supplied by the manufacturer: written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description and use of the medical device, but excluding shipping documents (8).

Manufacturer: any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under the manufacturer's name, whether or not such a medical device is designed and/or manufactured by that natural/legal person or by another person(s) on the manufacturer's behalf (1).

Marketing authorization: a legal document issued by a national regulatory authority (NRA), authorizing the sale of a drug or a device based on the health and safety requirements of established national regulations.

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

a) diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury;
b) investigation, replacement, modification or support of the anatomy or of a physiological process;
c) supporting or sustaining life;
d) control of conception;
e) disinfection of medical devices;
f) providing information for medical or diagnostic purposes by means of in-vitro examination or speci mens derived from the human body or other animal; and which
g) does not achieve its primary intended action in or on the human body by pharmacological, immuno logical or metabolic means, but which may be assisted in its intended function by such means.
Source: adapted from (7).

Medical device establishment certificate: a certificate giving businesses the right to conduct work in a particular State and to open a current business bank account.

Medical device licence: a licence issued to manufacturers authorizing them to import or sell their Class II, III or IV medical devices.

National regulatory authority:
A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements (20). national regulatory agency responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines) are evaluated properly and meet international standards of quality and safety ( ).

Quality management system: the set of business processes that aim to direct and control an organization with regard to quality, including establishing quality policy and quality objectives and implementing and maintaining a quality system ( ).

Recipient: a governmental, nongovernmental or private health institution that voluntarily receives medical devices as a donation.

Registrant: the person who applied for and obtained registration of medical devices, including in-vitro diagnostic devices (IVDs) under the medical device regulations.

Risk: Combination of the probability of occurrence of harm and the severity of that harm (2, 3, 5, ,).

[1]For examples of the various classes of device, see Table 1 below.

1 INTRODUCTION

Around the world, medical devices have become an integral part of modern health care and even of daily life. These advances are largely due to an influx of innovative, digital technology that has changed the medical device environment. More importantly, medical devices are steadily becoming easier to use, allowing untrained individuals, not just health care professionals, to use medical technology and interpret the results effectively. Accordingly, regulatory agencies around the globe are faced with the challenge of determining whether their existing regulatory frameworks for medical devices are effective enough to ensure device performance, quality and safety, even in the hands of untrained users.

Globally, medical device regulations should be improved to provide a better safeguard for public health and to ensure that high-quality and effective devices reach patients and consumers. This is even more important in African countries, where regulation of medical devices is still in its infancy. It is therefore crucial for medical device economic operators to understand fully the applicable local regulations.

The main requirements globally for import control of medical devices are usually identification of a local representative, a certificate of free sale from the country of origin, an import licence from the competent Authority in the import country and registration of the company and the product. To accomplish this, it is necessary to fulfil the essential principles, classify the product, implement good manufacturing practice and risk management, follow the labelling requirements and establish a documented post-marketing and market surveillance system.

Objectively, medical device import requirements should be risk-based and will therefore vary depending on the classification of the device, as elaborated in the International Organization for Standardization standard ISO 14971 (Medical devices — Application of risk management to medical devices). Clinical trials are required for more high-risk devices. All health products commercially imported into <Name of Country> must meet all applicable requirements of the act and regulations issued by the Authority, including, but not limited to:

a) labelling, marketing authorization requirements and establishment licence, site licence; or
b) establishment of registration requirements or authorization to conduct a clinical trial, good manufacturing practice requirements.

Most countries consider that commercial importation activities include, but are not limited to, the following imports.

a) A shipment destined for a retailer, distributor or commercial establishment. This would include shipments being sent to independent sales contractors/distributors, or to practitioners for use in their practice.
b) A shipment from a single foreign supplier consisting of individually addressed parcels, where the importer of record, as indicated on a separate invoice for each parcel, is not unique for each parcel.
c) A shipment that contains more than a 90-day supply of a drug, judging by its directions for use or a reasonable intake.
d) A shipment that is part of a pattern of repeat personal importations of the same drug by the same individual at the same address within a 90-day period, with the total quantity imported in all shipments totalling more than a 90-day supply, judging by its directions for use or a reasonable intake.
e) A shipment that is accompanied by or associated with materials to be used for ad

vertising or promotion.

f) A shipment destined for export.

g) A shipment of a health product intended for a practitioner or qualified investigator of a clinical trial that is to be given to or used to treat a patient or a subject in a clinical trial. In the case of an animal practitioner, this includes importation and administration to animals they do not own.

It is important to note that risk classification of medical devices, especially IVDs, varies greatly between developing and developed countries, mainly because of differences in the specific disease prevalence and level of health care provision. Consequently, the requirements and processes guiding importation, exportation and donation of medical devices should be risk-based. Table 1 below is an example of risk-based national requirements for importation of medical devices based on risk classes.

Table 1. Risk-based national requirements for importation of medical devices based on risk classes (2,5)

Commercial imports	National requirements
Class I devices (examples: bandages, wheelchairs, bed scales, hospital beds/stretchers and crutches)	Device licence not required; importer must have a medical device establishment certificate
Class II, III and IV medical devices (examples: gauze pads, electronic stethoscopes, electrodes, hearing aids, medical examination gloves, scalpels, electrocardiographs, blood pressure cuffs, latex condoms, pregnancy tests, defibrillators, infusion pumps, bacteria and drug test kits, hyperbaric oxygen therapy chambers, implants, insulin pumps and cardiac pacemakers, glucose testing systems, embolectomy and occlusion catheters, balloon thermodilution catheters, blood catheters, central venous catheter kits, aneurysm clips, excimer lasers and intraocular lenses)	Medical device licence required for each device; importers must have a medical device establishment certificate

The present guidelines have been developed to provide guidance for importers and exporters of general medical devices including in-vitro diagnostics, pursuant to legal requirements prescribed under the relevant section of the < NRA Act>, CAP XXX.

The present guidelines apply to any person, institution and organization that intends to export or import medical device(s) for the purpose of selling, research or donation of medical devices in <Name of Country>. The main objective of the present guidelines is to provide importers and exporters of medical devices with the information they need to comply with the law and regulations governing importation and exportation of medical devices into and out of the country. Other objectives include control of unwanted medical devices and reduction of the accumulation of non-functional medical devices, as well as mitigation of problems associated with donation by promoting good practice in medical devices donation.

The guidelines have been organized in three main chapters. The first chapter provides for the requirements and procedures to be followed during importation of medical devices; the second chapter outlines the requirements and procedures for the exportation of medical devices; and the third describes procedures for donation of medical devices. Model formats for application forms and certificates are annexed to the document for easy reference (Annexes 1–7). Approval for importation, exportation and donation of medical devices will be based on fulfilment of the requirements prescribed in the present guidelines and any other guidelines published by the ministry of health and relevant authorities. Applicants are therefore advised to ensure that they read and understand the present guidelines before applying to import or export medical devices.

2 IMPORTATION OF MEDICAL DEVICES, INCLUDING IN-VITRO DIAGNOSTICS

2.1 Importers of medical devices, including in-vitro diagnostics

Importers of medical devices, including in-vitro diagnostics, may be:

a) manufacturers
b) authorized representatives
c) distributors/wholesalers
d) clinical trial investigators
e) individuals (for medical purposes only)
f) government and nongovernmental institutions as authorized by the NRA.

2.2 Minimum requirements for importation of medical devices, including in-vitro diagnostics.

a) All medical devices, including diagnostics, intended to be imported, must be registered with or authorized by the Authority.
b) Importers mentioned under section 4.1 must be registered or otherwise authorized by the Authority.
c) Medical devices, including diagnostics, shall be imported through authorized, designated or official points of entry.

All imported medical devices, including in-vitro diagnostics, should bear the following minimum information on their 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) an indication of what the package contains if the contents are not readily apparent, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units;
g) the word “sterile” if the manufacturer intends to sell the device in a sterile condition;
h) the words “for single use only” if the device is intended to be used once only;
i) the manufacturing and expiry date of the device, expressed in months/years (where applicable);
j) the medical conditions, purposes and uses for which the device is manufactured, sold or represented, unless these are self-evident to the intended user, 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 any special storage conditions applicable to the device;
l) where a package that contains a device is too small to display all the information listed in subparagraphs (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 sale.

Labelling information shall be written in a language understood by the users. It may be in English and/or <local language> and shall be expressed in a legible, permanent and prominent manner that can easily be understood by the intended user.

2.3 Application to import medical devices, including in-vitro diagnostics (Applicant).

a) The application shall be submitted to the Authority using the application form reproduced in Annex 1.
b) Applications may also be submitted through other designated offices located at <Address of Authority>.
c) The application form shall be accompanied by <one (1)> original and <two (2)> copies of the

proforma invoice 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.

The proforma invoices shall state the following information for each medical device to be imported:

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 the information on the medical devices, including in-vitro diagnostics, submitted to the Authority;
g) the quantity, pack size, unit value and total value in convertible currency;
h) batch or lot number;
i) manufacturing and expiry date;
j) mode of shipment (sea, air, road);
k) point of entry;
l) signature and stamp of the supplier and/or manufacturer responsible for exporting the products; and
m) application form signed by the importer.

2.4 Processing of importation applications (Authority).

a) Upon receiving the application as specified above, all documents will be checked by the designated officer to verify whether all documentation requirements have been fulfilled.
b) The applicant will be required to pay relevant fees as specified by the Authority.
c) Importation permit, as shown in Annex 2, will then be issued.
d) An application will not be approved if it does not meet the importation requirements stated above. A form indicating the reason(s) for not authorizing importation will be given to the Applicant (format as shown in Annex 3).
e) All applications will be processed in <24 hours> on working days, with the exception of applications for the importation of products which have not been registered and applications for donations, which may take longer to process.
f) All importers will be required to apply for and obtain a valid importation certificate or document issued by the Authority before the consignment is shipped.
g) The Authority shall indicate validity of the importation certificate (a minimum validityof six (6) months is recommended). The certificate shall not be transferable and shall be issued to cover only a single shipment for ease of traceability.

2.5 Special importation requirements (emergencies)

All application requirements and procedures shall apply, as prescribed under sections 4.3 and 4.4, respectively. However, in some special circumstances, the following requirements will be applicable.

2.5.1 Importation of syringes.

a) Applications for an importation permit shall be either for auto-disable syringes only, or for auto-disable syringes (90% of order) and standard disposable syringes and/or type II reuse prevention syringes (10% of order). The 10% quota of standard disposable syringes and/or type II reuse prevention syringes is intended to cater for specific procedures such as nasogastric feeding, blood-drawing and delicate aspirations.
b) Applications for an importation permit consisting of standard disposable syringes and/or type II reuse prevention syringes with a nominal capacity of 10 ml and below only will not be accepted.
c) Applications for importation of standard disposable syringes and type II reuse prevention syringes with a nominal capacity of more than 10 ml will be honoured without any restriction.
d) All types of syringes sterilized by ethylene oxide (EO) gas must be packed in either

blister packs or ribbon pouches. Syringes packed in polybags are completely unacceptable, since polybags are considered inappropriate for EO sterilization and therefore the sterility of syringes packed in polybags is not guaranteed.

2.5.2 Importation of medical devices, including in-vitro diagnostics, which have not been granted market authorization.

An application for importation of such medical devices should be accompanied by a letter stating the reasons for the importation. An importation permit will be issued if the following criteria are fulfilled:

a) the medical device has been approved by the member countries of the International Medical Devices Regulator's Forum, pre qualified by WHO or listed in the WHO Emergency Use Listing;
b) evidence is provided that a medical device is in circulation in the manufacturer's coun try of origin (certificate of free sale);
c) a declaration of conformity with essential principles of safety and performance is pro vided, issued by the manufacturer;
d) A Conformité Européene (CE) certificate is provided, except for class A medical devices; and
e) evidence of insurance against the conse quences of the use of a class D medical device (country policy insurance) is provided.

2.5.3 Importation of medical devices for personal use.

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 other authorized practitioner.

2.5.4 Importation of investigational medical devices.

Applications for importation of investigational medical devices should be made by a clinical trial sponsor or principal investigator for a study approved to be conducted in <Name of Country>. Such applications should be accompanied by a clinical trial approval letter, ethical board clearance and copy of the clinical trial certificate issued by the Authority.

2.5.5 Importation of medical and in-vitro devices for demonstration/sample/training purposes.

The requirements for importation of medical devices/IVDs for demonstration/sample/training purposes are based on the NRA regulations, which govern all aspects related to placing medical devices on the market. However, specific rules and requirements to be applied to medical devices intended for demonstration or training purposes include the following.

a) Such devices are exempt from mandatory registration.
b) However, these devices cannot be imported without the appropriate importation licence.
c) In order to apply for the appropriate impor tation licence, any interested entity shall submit the application form for medical de vices intended for demonstration or training purposes only, in electronic form.

Documents required: besides the general requirements, the following documents shall be submitted by the entity applying for an importation licence for medical devices intended for demonstration or training purposes only. They include the following:

a) classification certificate, proof of marketing in other countries, declaration of conformity or other document confirming that the prod uct in question is classified as a medical device;
b) instructions for use/user manual – if neces sary because of the type of the device;
c) sample of the labelling, containing an in dication that the medical device is intended for demonstration or training purposes only (e.g. "for demo only", "for training only" or "not for sale");
d) copy of the appropriate commercial invoice;
e) copy of the bill of lading or air waybill (if ap plicable);
f) attestation, printed and signed by the au thorized persons of the importer;
g) the set of documents required for shipment clearance, which includes the following:

i. a copy of the commercial invoice containing the invoice number, manufacturer`s name and address, product name, quantity, unit price, model/part numbers and lot/serial numbers (these two numbers could be indicated either in the invoice itself or in the packaging list), and the beneficiary name;

ii. bill of lading or air waybill;

iii. copy of customs declaration; and

iv. copy of the appropriate importation licence.

2.6 Inspection of imported consignments at ports of entry.

On arrival at the port of entry, medical devices will be inspected by an Authority inspector to ensure that they comply with the approved specifications and regulations before they are released. Each consignment must be accompanied by an importation permit, an original proforma invoice, a corresponding certificate of analysis for each batch and an airway bill or bill of lading. Other government agencies may also conduct inspections in accordance with the prevailing rules and regulations. At the time of importation, medical devices must have a valid shelf life that is no less than 60% of the original shelf life (if applicable).

2.6.1 Sampling of imported products.

The NRA officer may decide to sample imported medical devices for further investigation when deemed necessary. The medical devices sampling form (Annex 4) will be signed in duplicate by the NRA officer and the consignee. Original document will remain with the NRA officer and a copy will be issued to the consignee.

Investigations or consultations may take some time to conclude, especially where they involve laboratory testing. In this case, a conditional release will be given to the importer with instructions to store the consignment in approved premises until the results of the investigations become available.

2.6.2 Verification of the consignment.

During the verification exercise, the NRA officer may take either of the following actions:

a) authorize release of the consignment; or

b) detain the consignment at either the customs warehouse or the owner's premises, pending further investigation.

2.6.3 Release or rejection of a consignment at the point of entry.

2.6.3.1 Release of a consignment.

Imported consignments will be released by the NRA officer when the latter is satisfied that all importation requirements have been fulfilled.

2.6.3.2 Rejection/retention of unauthorized consignments at the point of entry.

a) Consignments which do not meet importation requirements will not be allowed to enter the country.

b) Medical devices rejected because they are unregistered in <Name of Country> or have neutral labelling may be re-exported to a third country by special request and with special clearance from the Authority of the country to which the consignment is being exported.

c) Before such a consignment is re-exported, it should be reverified to confirm that it is still intact before the Authority issues a re-export permit.

d) Reloading for re-export should be witnessed by customs and NRA officials.

e) Copies of re-export documents signed by all parties involved at the exit port shall be submitted to the Authority as evidence of successful re-exportation.

f) Rejected medical devices will be disposed of in accordance with customs requirements (point of entry policies and procedures); the Authority will provide technical advice on the method of disposal following internationally accepted standards and guidelines.

g) The Authority will issue a disposal certificate when destruction is complete.

h) Where the consignment is not authorized, or is detained at the point of entry, the appropriate form (Annex 5) will be issued by the NRA officer.

3 DONATED MEDICAL DEVICES

3.1 Principles of donation

It is important that Applicants should adhere to the following key principles for donations:

a) all donations should correspond to the recipient's needs and should comply with the existing government health policies, laws, guidelines and administrative arrangements;

b) donations should confer the maximum benefit on the recipient;

c) donations should comply with applicable standards; there should be no double standards regarding the safety and performance of donated items; and

d) there should be prior and effective communication between donor and recipient before products are donated.

3.2 Application to import donated medical devices

Any person, institution or organization intending to import donated medical devices will be required to apply for a certificate to import the products from the Authority prior to shipment of the donated consignment. The following documents shall accompany the application:

a) letter of support from the relevant Authority in the exporting country which supports such donations (where applicable);

b) letter of support from the importer;

c) donation certificate from the donor (affidavit showing the safety and performance of the donated medical device(s)); and

d) one original proforma invoice and two copies of the original (as specified in section 4.3 below).

The Authority will assess whether the medical device is compatible with the recipient's request.

Medical devices intended to be donated must be collected from known sources, as far as possible, for ease of traceability in case of field safety corrective action by the manufacturer.

Donated medical devices should have a shelf life of no less than <twelve (12)> months (where applicable).

If the medical device has previously been 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 working condition.

3.3 Requirements for donated medical devices

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 defined by the manufacturer and by international or appropriate national standards;

c) include all essential parts, accessories and working materials;

d) have their label, user manual and other documents written in English or <local language>; and

e) be packed appropriately for road, air or sea transport under tropical conditions.

For software-operated medical devices, the software shall be preloaded and/or the device shall be accompanied by the relevant software package.

Electrical equipment shall be set to the standard voltage of 220 v/50 Hz–240 v/50 Hz.

X-ray emitting equipment shall be calibrated and inspected by a qualified medical physicist or certified by an approved radiation body.

Damaged, outmoded or redundant medical device(s) 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.

The Authority will issue a donation importation

certificate when it is satisfied that all conditions of the application have been fulfilled; otherwise, the application will be rejected in writing, stating the reason(s) for rejection. The permit issued for importation of donated medical devices will be valid for <six (6)> months.

3.4 Verification at the port of entry

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

a) valid importation certificate;
b) packing list;
c) proforma invoice;
d) airway bill or bill of lading;
e) certificate of refurbishment for used medical devices (issued by the manufac turer or a certified company);
f) certificate of analysis for sterile medical devices;
g) if the device emits radiation, a permit or certificate from a relevant body, e.g. <National Atomic Energy Commission>;

The certificate of refurbishment mentioned above must state the following:

a) that the device has been tested, labelled and packed after it was replaced or re paired, specifying the repair(s) performed and the source of the repair parts and pro viding an acceptance report for these parts; and
b) if the device has been calibrated, the certificate shall state and verify the opera tion of the medical device performance standard used for calibration and confirm that the device has been disinfected or de contaminated as appropriate.

3.5 Labelling of donated medical devices.

Depending on the nature and type of the donated medical device(s), the label should include the following minimum information:

a) name of the medical device;
b) model number or serial number;
c) manufacturing and expiry date (where applicable);
d) name and address of the manufacturer;
e) handling and storage requirement(s);
f) technical directions for use;
g) intended use
h) statement that the device was previously “used only for clinical or performance investigations”;
i) for a sterile medical device, the word “Sterile” and, where appropriate, a description of the method of resterilization used;
j) for a refurbished device, a statement to that effect;
k) if the device is intended for presentation or demonstration purposes only, the label “for presentation or demonstration purposes only, not for use with humans”;
l) if the device emits radiation for medical purposes, details of its nature, type and, where appropriate, the intensity and distri bution of the radiation;
m) if the device is to be installed with or con nected to other medical devices or equip ment or used 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 ensure a safe connection;
n) if the device is an in-vitro diagnostic medical device, the label “in-vitro diagnostic” or “IVD”; and
o) the intended purpose and 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).

Any number, letter or symbol, and any letter or number in a symbol used on the label, shall be legible. Each donated medical device shall have an accompanying user manual giving detailed information on handling, installation, operation, maintenance, troubleshooting, precautions and other important information.

Donated medical devices shall be transported, stored and handled in accordance with relevant transportation, storage and handling requirements.

Labelling information for the medical device may be provided on the medical device itself, packaging used for the medical device, on an insert supplied with the medical device, in a printed document or via other appropriate media.

At the time of importation, medical devices must have a valid shelf life of no less than <60%> of the original shelf life (where applicable); exceptions may be considered during emergencies and when it is evident that the product will be fully consumed within a specific period of time.

3.6 Reporting.

The recipient shall be required to report relevant information to the Authority, including defects, adverse events, problems related to quality and safety and other reportable issues with the donated equipment.

3.7 Disposal.

Donated medical devices shall be disposed of in accordance with the manufacturer`s instructions.

4 EXPORTATION OF MEDICAL DEVICES

4.1 Exporters of medical devices.

Exporters of medical devices include manufacturers, distributors /wholesalers, clinical trial sponsors and investigators and governmental and nongovernmental institutions authorized by the Authority to export such devices.

4.2 Requirements for exporters

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

b) All medical devices to be exported must originate from a registered manufacturer or wholesaler in <Name of Country>.

c) All exporters must export medical devices to authorized points of entry, or as deter mined by the Authority.

d) Medical devices intended to be exported should be either registered or authorized by the Authority.

4.3 Procedure for exporting medical devices

The following procedure should be observed.

a) Authorized exporter intending to export medical devices must apply to the Authority by filling in the application form as pre scribed in Annex 6 of these guidelines.

b) All applications may be submitted to the Authority offices located at <Address of Authority>.

c) The application form shall be accompanied by one original proforma invoice.

d) Proforma invoices shall state the following for each medical device to be exported:

i. number and date;
ii. name and address of the supplier;
iii. name and address of the importer;
iv. name and address of the manufacturer;
v. country of origin;
vi. country of destination;
vii. clear description of items including brand and common names as declared in the information of medical devices, including in-vitro diagnostics, submitted to the Authority;
viii. the quantity to be exported for each medical device, its unit value and total value in convertible currency;
ix. product registration number issued by the Authority;
x. batch or lot number;
xi. manufacturing and expiry date;
xii. mode of shipment (sea, air, road);
xiii. port of exit; and
xiv. signature and stamp of the supplier and/or manufacturer.

e) In a situation where the item “signature and stamp of the supplier and/or manufac

turer" does not apply, the application form shall be signed by the Applicant.

f) The export permit shall not be transferable and shall be issued to cover one shipment only.

g) Application for export permit shall be ac companied by a processing fee, as pre scribed in the Authority's fees and charges regulations in force.

h) When the Authority is satisfied with the information submitted, an export permit will be issued, as prescribed in Annex 7 of the present guidelines. The permit will be valid for <three (3)> months from the date of issue.

i) Exporting wholesalers will be required to provide evidence of source of the export ed products.

j) All applications for export will be processed within <two (2)> working days.

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

l) An application will be rejected if it does not meet the export requirements, with a clear statement of the reasons for the decision.

5 Review and appeal procedures

a) Any Applicant that is not satisfied by the de cision of the Authority in relation to any ap plication to import or export medical devic es may submit an appeal for a review of the decision to the Head of the Authority within a period of <fourteen (14)> days from the date of receipt of the decision.

b) The Authority may review its decision, reject the decision or vary the conditions for approval.

c) After reconsideration of the application, if the Applicant is not satisfied by the decision of the review, the Applicant may appeal to higher authorities (depending on individual countries' appeal policies and procedures).

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8. Unique device identification (UDI) system for medical devices (document GHTF/AHWG-UDI/N2R3:2011). Global Harmonization Task Force Unique Device Identifiers (UDI) Ad Hoc Working Group; 2011 (*www.imdrf.org/docs/ghtf/final/steering-committee/technical-docs/ghtf-sc-n2r3-2011-unique-device-identification-system-110916.pdf*, accessed 23 May 2021).

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ANNEX 1. APPLICATION FOR A CERTIFICATE TO IMPORT MEDICAL DEVICES, INCLUDING IN-VITRO DIAGNOSTICS

< NAME OF AUTHORITY>

APPLICATION FOR PERMIT FOR IMPORTATION OF MEDICAL DEVICES

To:

<Address of Authority>

I/We..... ..... of (postal address),..... undertaking the business of Wholesale/Manufacturing/Other – specify),..... hereby apply for an importation permit for medical devices into <Name of Country>.

Licence number.....issued on.....

Location of business.....

Name of owner of the business.....

Purpose of importation: (tick as applicable):

- ☐ Spare parts for medical devices
- ☐ Medical devices
- ☐ In-vitro diagnostics
- ☐ Clinical trial of a specified product (only one product per application)

Donation

Reasons for donation

- ☐ Emergency
- ☐ Development aid programme
- ☐ Other.....

Checklist for completeness of proforma invoice (tick as appropriate)

- ☐ Name and address of supplier
- ☐ Name and address of importer
- ☐ Name and country of 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 on medical devices submitted to the Authority
- ☐ Stamp and/or signature of supplier
- ☐ Stamp and/or signature of importer
- ☐ Certificate of donation (for donated medical devices)
- ☐ Free on board (FoB) and cost, insurance and freight (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.....

ANNEX 2. CERTIFICATE TO IMPORT MEDICAL DEVICES, INCLUDING IN VITRO DIAGNOSTICS

< NAME OF THE AUTHORITY>

CERTIFICATE TO IMPORT MEDICAL DEVICES, INCLUDING IN-VITRO DIAGNOSTICS

(*Made under section XXXX) of <Name of Authority> Act (Chapter YYYY*)

Certificate No. …….

Part A

Name of registered importer**……**Postal address**……**Tel 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

Serial No.	Generic name	Brand name	Batch No.	Product registration /notification number	Permit quantity	Value of the products
					TOTAL:	

Fees Receipt No. …….

Date……

PART B:

Permission is hereby granted to import the mentioned medical devices. The importer must inform the port Authority inspector and the latter must examine the approved medical devices for fitness for the intended use before the devices are allowed entry into <Name of Country>.

…… **……**

Date **For: Head of Authority**……..

..

PART C:

I, …….. , being the Authority inspector at**……** (Authority port office) have examined the above-listed medical device(s) and have found it/them fit/unfit for the intended use, hence it is/they are **allowed/not allowed** entry into <Name of Country> ……

Date

……

Signature of the Authority port officer and stamp

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

NB This permit is for a single consignment only and shall be valid for six (6) months from the date of approval.

ANNEX 3. FORM FOR NON-AUTHORIZATION OF IMPORTATION OF MEDICAL DEVICES, INCLUDING IN-VITRO DIAGNOSTICS

<NAME OF COUNTRY AUTHORITY>

FORM FOR NON-AUTHORIZATION OF IMPORTATION OF MEDICAL DEVICES, INCLUDING IN-VITRO DIAGNOSTICS

The Authority Serial Number …… of ……
Proforma Invoice No. …….. Date ……

A. Reasons for rejection (Tick as appropriate)

- ☐ Product not registered/notified
- ☐ Importer/consignee not registered
- ☐ Manufacturer(s) of the product not indicated
- ☐ Number of proforma invoice not shown
- ☐ Name and/or identity of items not clear
- ☐ Product not regulated by the Authority
- ☐ The proforma invoice not signed and/or stamped by supplier
- ☐ The proforma invoice not countersigned and/or stamped by importer,
- ☐ Certificate of donation not attached
- ☐ Product registration number not shown
- ☐ Proforma invoice not original
- ☐ Other. (Specify)……

B Conditions for approval

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

…… …… ……

Name of NRA officer Signature Date

…… …… ……

Name of Applicant Signature Date

ANNEX 4. MEDICAL DEVICES SAMPLING FORM

<NAME OF COUNTRY AUTHORITY>

MEDICAL DEVICES SAMPLING FORM

1. Sample code.....
   Region/product/sequence number/sampling date (dd/mm/yy)
2. Where the sample was taken.....
3. Reason for sampling .....
4. Physical address.....Postal address.....
   Telephone No.....
   Email address..... (if applicable)
5. Product name of the sample.....
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(s) at the premises.....
    .....
12. Name and signature of the representative of the premises where sample was collected:
    Name ..... Signature ..... Date .....
13. Name of NRA officer(s)

Sample No.	Name	Organization	Signature	Date

Note: samples should be collected in their original containers.

ANNEX 5. REJECTION/RETENTION OF MEDICAL DEVICE CONSIGNMENT(S)

<NAME OF AUTHORITY>

REJECTION/RETENTION OF MEDICAL DEVICE CONSIGNMENT(S)

(*Made under section XXXX) of <Name of Authority> Act (Chapter YYYY*)

Exporter /consigner.....

Importer/consignee.....

The inspected consignment (s) as per proforma invoice No.....

Airway bill No...../Bill of lading No...../Reg. No.....

dated..... and the single Bill of entry No..... dated..... has been rejected/retained for the following reasons:-

(Tick as applicable)

- ☐ Proforma invoice not approved by the Authority
- ☐ Fee not paid to the Authority
- ☐ Product(s) not registered by the Authority
- ☐ Consignee is unauthorized dealer for the medical device(s)
- ☐ Manufacturer of product not indicated
- ☐ Description of the items not clear
- ☐ Manufacturing and/expiry date of product(s) not indicated
- ☐ Shelf life of the product(s) too short/expired
- ☐ Physical quality of the product poor
- ☐ Packaging insert not included
- ☐ Certificate of analysis not present
- ☐ Batch number not indicated
- ☐ Other..... (Specify)

Comments from the inspector (if any): .....

.....

Name of inspector	Signature	Date
.....	.....	.....
Full name of consignee	Signature	Date
.....	.....	.....

ANNEX 6. APPLICATION FOR EXPORTATION OF MEDICAL DEVICES

<NAME OF COUNTRY AUTHORITY>

APPLICATION FOR EXPORTATION OF MEDICAL DEVICES

To: Director General
<Name of Authority>
<Address>

I/We..... (Name), of..... (postal address), undertaking the business of Wholesale/Medical devices manufacturing/Other (Specify),..... (Permit No.), issued on.....(Date), **.....** (Location of business),..... (Name of person in charge of the business),..... (Registration No.),..... hereby apply for a permit for export of medical devices to: **.....** (Consignee),..... (Physical address/location of business), **.....** (Postal address),..... (Country name).

Purpose for which export certificate is requested:

(Tick as applicable)

- ☐ Medical devices for human use
- ☐ Medical devices for veterinary use
- ☐ Clinical trial of a specified product (only one product per application)
- ☐ Other (Specify).....

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:

Received by.....
Signature.....
Stamp.....

ANNEX 7. LETTER

<NAME OF AUTHORITY>

Certificate No..... **Date: .....**

Exporter name.....

P.O. Box.....

Region.....

Re: Certificate to export medical devices, including in-vitro diagnostics, ...(Company name) (Exporting country), to..... (Company name) (Importing country)

Reference is made to your application letter received on..... attached with a proforma invoice No..... dated.....

Subject to compliance with other laws regulating the export trade, permission is hereby granted to....., under section 73(1) of the <Name of Country NRA> Act, <Cap XXXX> 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 above-mentioned medical devices. This permit is valid from..... (Date) to..... (Date).

....

Date <Title of Head of NRA>