ETHIOPIAN FOOD and DRUG AUTHORITY (EFDA)

GUIDELINE ON REQUIREMENTS OF MEDICAL DEVICES CLEARANCE AT PORTS OF ENTRY

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Abbreviations

AWB	Airway Bill
EFDA	Ethiopian food and drug authority
COA	Certificate of Analysis
COC	Certificate of Conformance
COO	Certificate of Origin
IMDRF	International Medical Device
IU	International Unit
IVD	In Vitro Diagnostic
PIP	Pre-Import Permit
PO	Purchase Order
USFDA	U.S. Food and Drug Authority
WHO	World Health Organization

1. Introduction

The Ethiopian Food and Drug Authority (EFDA) established to safeguard the health and safety of patients, users, and other persons by ensuring that manufacturers of medical devices follow specified procedures during the design, manufacture, and marketing as described in Proclamation No. 1112/2019 for the regulation of medicines and healthcare products. Under this proclamation the basic responsibilities of the Authority is to evaluate the quality, safety, and effectiveness of imported medical device at port of entry by ensuring the labeling, packaging, product and storage conditions and document requirements for each medical device which are imported to the country.

Generally, this guideline categorized medical devices in to two main categories i.e. IVD medical devices and other than IVD medical devices. The IVD medical devices are sub-classified in to four classes in alphabet (A, B, C, and D) and medical devices other than IVD medical devices also sub-classified into four classes in roman number (I, II, III, and IV). The class to which the device assigned determines, among other things, labeling requirements, inspection practice at port of entry and document requirements during importation. So based on these classification, risk based inspection may be practiced at entry port for imported medical devices.

This Guideline have been developed based on the Authority ‘s day-to-day experience as well as recommendations on the regulation of medical devices by other international organizations, such as the European Commission, Global Harmonization Task Force (GHTF), United States Food and Drug Administration (USFDA) and World Health Organization (WHO) guidelines.

The guideline describe the general requirements of importation of medical devices which include labeling requirements, procedure for importation of medical devices, and the required documents (administrative and technical documents) in support of the port clearance of medical devices. Furthermore, the inspection and port clearance procedures are also described in the respective section of the guideline. Applicants are advised to follow the requirements of this guidelines while importing of the medical device either for sale, donation, Investigation, personal use and exhibition.

2. Objective

The objective of this guideline is:

1. To provide guidance for medical device manufacturers, suppliers, donors, importers and recipients on the regulatory requirements for port clearance.
2. To assist EFDA experts on requirements that need to be fulfilled while clearing medical devices at port of entry.
3. To control importation of medical device that does not fulfill regulatory requirements as well as minimize the accumulation of non-functional, and non-effective medical device.

3. Scope

This guideline is applicable to all imported medical devices.

4. Definition

Accessory - A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices. Accessories are designed specifically for a device, and may include consumables, parts, add-ons, and other components for use in conjunction with, or for upgrade, replacement and repair of parts of a medical device.

Authority - is the Ethiopian Food and Drug Authority

Consignment – is a quantity of goods that are sent to a person or place to be sold.

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

Import permit – is a permit issued to importer/institution/receipient by the Authority, authorizing him to import medical devices into the country.

Port clearance – is official permission to bring medical devices into the country (Ethiopia) for sales or distribution for use.

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

Spare part - Is a part for replacement of existing components of a device, the conformity of which has already been established

5. Medical devices Importation

The medical device may be imported through the following institutions:

a) Medical Devices Importers
b) Government and Non- Governmental Health institutions
c) Clinical Trial Investigators
d) Health Research Institutions
e) Recipients of donations
f) Persons importing medical devices for medical purposes
g) Exhibitors

6. Requirements for importation of medical devices

6.1. General Requirements

1. The medical devices (including IVD medical devices, accessories, spare parts) to be imported should be registered by EFDA unless given special approval by the Authority.
2. All importation of medical devices through importers should be done by licensed importers whose premises are dully registered by the Authority.
3. All institutions participated in importation of medical devices need to have pre-approved purchase order (PO) or pre-import permit and imported through the authorized ports of entry (POE).
4. In case of donations, applicant should have pre-import permit from Authority after fulfilling the requirements indicated in donation directive of the authority.
5. Importation of medical devices for clinical trial investigation should be done only after approval of the aclinal trial authorization application by responsible directorate of the Authority.
6. Recipient should not receive and import medical device donation without the prior approval of the Authority.
7. Medical device should not be donated if it was collected from unknown source. It should not be sent without prior communication between the recipients and donors or given to health professionals as free samples.
8. If the donated device is used, it should be reconditioned, tested and all essential parts, accessories and working materials included before shipment.

9. Medical device should not be donated if the equipment has been in used for more than five years.

6.2. Packaging of medical device

Container packaging of medical devices should be suitable for the proposed transportation of medical devices. The packaging of medical device should protect the product from temperature, moisture and humidity, exposure to light and physical damage (during storage, transport, loading and unloading).

The packaging of medical device should also indicate the direction the package and the maximum number of packages stacked above each other.

6.3. Labeling Requirements at port of Entry

All medical device labelling information should be in English and/or Amharic language and shall be as per the requirements in the authority's Guideline on Labelling Requirements of Medical Device Labelling. Furthermore such labels should be expressed in a legible and indelible manner (not easily detachable) that can easily be understood by the intended user. Any information appearing in the product information should be based on scientific justification. All imported medical devices should bear the following minimum information on the label:

a. Name of the device: Product name, brand name (optional)
b. Model, Serial or Batch number: As applicable based on the type of medical device to be imported
c. Name and full address of the manufacturer (and license holder, as applicable)
d. If the device imported as a part of a system, test kit, medical device group and families, the list of individual components should be mentioned.
e. Family or medical device group (where applicable)
f. 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 should be indicated.
g. The words "sterile" if the manufacturer intends to sale the device in a sterile condition, and sterility method.
h. The words "for single use only" if the device is intended for that purpose
i. The manufacturing and expiry date or use-by-date of the device expressed in month and year (where applicable)

j. If the device to be used for clinical trial (investigation), the label should bear “the device is used only for clinical trial(investigation)”
k. Any special storage conditions applicable to the device
l. For hazardous medical devices, statement and/or symbol indicating the devices is hazardous should be indicated.
m. For IVD medical devices, a statement of warnings or precautions for users and any other warnings appropriate to user hazards, and a statement "For In Vitro Diagnostic Use;"
n. For reagents:
    - Quantity, proportion, or concentration of all active ingredients: e.g. percentage, ml & mg, weight per unit volume, mg./dl etc., and for reagents derived from biological materials the source and measure of its activity, e.g., bovine, I.U., etc.;
    - The net quantity of contents.
    - Manufacturing date and expiry date or retest date
o. In addition to the labeling requirements indicated above the following labels required for refurbished medical device:
    - ✓ Refurbished by (company name, full address, country)
    - ✓ Refurbished date/month/year (DD/MM/YYYY)
    - ✓ Validity date the service or refurbishment and the period for the next service

The labelling requirements for active and implantable medical device should follow the requirements indicated in the authority’s Guideline on Labelling Requirements of Medical Device Labelling. For specific product like sunlamp products and ultraviolet lamps should have label(s) with the warning statement: "DANGER-Ultraviolet radiation, Avoid overexposure.”

In addition to the above labelling requirements, user/operational manual, service manual, instruction for use, insert labelling should included depending on the medical device types and availability of space on immediate and outer carton labels.

Use of internationally accepted symbols as indicated Annex 4 of this guideline can used by the product license holder. The medical device storage condition of imported product should also be as per the requirements indicated in Annex 5 of this guideline.

6.4. Exemptions from labelling requirement for IVD medical device

A product in the laboratory research phase not represented as an IVD that is prominently labeled: "For Research Use Only. Not for use in diagnostic procedures;" and A product that is being shipped or delivered for product testing prior to full commercial marketing that is prominently labeled: "For investigational Use Only"

7. Procedure for importation of medical devices

The importers and/or the institutions intending to import medical devices should apply online a purchase order or pre-import permit through eRIS system. Related documents should be uploaded in the system including proforma invoice, supporting letter as applicable, GMP certificate, donation certificate (for donation) and others.

Import permit(i.e. purchase order and/or pre import permit) should be valid for twelve (12) months and should not be transferable and will be issued to cover one or more shipments. Partial shipment may be possible as applicable.

Once the authorization of import permit has expired or cancelled, no further importation and supply of medical device at any quantity should be permitted.

Applications for importation of investigational medical device should be made by a clinical trial sponsor or principal investigator for a clinical trial study authorized to be conducted in Ethiopia. Such applications should be accompanied by clinical trial approval letter and pre-import permit from responsible directorate of EFDA indicating the importation of such investigational products.

Applications for importation of class II, III and IV medical devices other than IVD (or B, C and D IVD medical devices) for personal use, should be accompanied by a written prescription paper from a registered medical practitioner, dentist, or any other authorized practitioner.

For class I medical devices other than IVD (or Class A IVD medical devices) for personal use, should be accompanied by a written prescription paper or medical certificate from a registered medical practitioner, dentist, or any other authorized practitioner. The quantity of the devices to be imported without prescription paper shall be limited to the quantity sufficient for his/her medical purpose only.

8. Document Requirements

The documents required for port clearance of medical device can be classified into two. These are administrative and technical documents.

8.1. Administrative documents

The following administrative documents are required at port of entry for all imported medical devices

1. **Valid purchase order (PO) or pre-import permit (PIP).** It may generated through eRIS or hard copy authorized by responsible directorate of EFDA.
2. **Valid registration certificate**
3. **Certificate of competency (COC)**
4. **Certificate of Origin (COO):** Certificate of origin may be a printed or electronic document. It should contain the following:-
    - Completed and signed by the exporter
    - Countersigned by the local commerce
    - Origin name
    - Destination name
    - Medical device name with its model and is quantity
5. **Clinical trial authorization (approval) letter from responsible directorate of EFDA**.
6. **Written prescription paper:** For importation of class II, III and IV medical devices other than IVD (or class B, C and D IVD medical devices) for personal use, written prescription paper from a registered medical practitioner, dentist, or any other authorized practitioner.
7. **Prescription paper or medical certificate**: Written prescription paper or medical certificate for class I or class A medical device other than IVD and IVD medical device respectively
8. **Donation certificate:** The Donation certificate for donated medical device should contains:
    - Donor company name with address
    - Company authorized person name, signature, and stump
    - Recipient name with address

- Product description with specification
- Product status (new, used, refurbished)

8.2. Technical documents

1. **Packing list.** It contains:
    - Exporter /Consigner
    - Consignee/Buyer
    - description, quantity and weight of medical device, if applicable batch number.
2. **Commercial invoice.** The document title should clearly state “Commercial Invoice”. The invoice should contains:
    - The name of the exporter (referred to as the shipper) and their contact details(tel, fax, cell, e-mail), including physical (not postal) address;
    - The name of the importer (referred to as the consignee, meaning the person or firm o whom the goods are to be sent) and their contact details (tel, fax, cell, e- mail), including physical (not postal) address (In the case of transshipment, there may be an intermediate consignee and their contact details and addresses should then also be included on the invoice.);
    - The name of the person and company to notify once shipment has taken place and their contact details and physical address (here the contact details tel, fax and cell number and e-mail address are more important than the physical address);
    - A commercial invoice reference number;
    - A purchase order or similar reference for correspondence between the supplier and importer;
    - The date of issue of the commercial invoice;
    - A complete, detailed and clear description of medical device
    - The quantity of devices in question, including the number of units/items;
    - Unit and grand total price of the product
    - The currency in which the goods will be sold (e.g. US dollars);
    - And other information‘s
3. **Airway bill (AWB) or bill of loading.** It should be:
    - Legally binding document issued by a carrier or agent that provide details about goods being shipped.
    - The document title is “Airway Bill” or “Bill of Loading”

- Three parties the sender, airline (sea logistics) and recipient are involved
- Before goods are shipped , the Airway Bill (AWB) or Bill of Loading (BL) must be filled out
- Contains the evidence of goods or descriptions of goods , addresses and contact information for sender and recipient
- Tracking of shipment
- Fright bill number
- Mode of transport (sea or air)
- Date that the good or shipment is arrived

4. **Certificate of analysis (COA) for sterile medical devices (sterility certificate). It should indicates:**
    - Title ―Certificate of Analysis
    - Name/address/phone number of supplier and manufacturer
    - Name of raw material/finished product
    - Category: (component, ingredient, in-process, finished product)
    - Lot/Batch number
    - Product Code or Number, if applicable
    - Re-evaluation date (if applicable)
    - Stability statement (if required), e.g. Store at -80°K
    - Test parameters
    - Test reference(s), e.g. USP 28/NF 34
    - Test results actual values and acceptance criteria usually something along the lines of not less than x, or not more than y. It should also indicate the pass/fail designation.
    - Certification of compliance something like this material complies with the specifications set forth in XXXX (e.g. USP 34/NF 28, In-House Specification) for the manufacture of Finished Product ‘QQQQ‘ as described in Master Batch Record _‘VVVV’
    - Printed name(s) and signature(s) of analysts
    - Printed name and signature of Approver
    - Page number and total pages, e.g. page 1 of 5
    - Date of manufacture of the material being certified

- Expiration date (if applicable)
- Analysis date(s)
- Batch release date for the certified material

5. **Certificate of refurbishment (for used medical device)**
   - Refurbishment certificate should be issued by the manufacturer or certified company that refurbished it. It should indicate refurbished date and should state if the device is: Tested, labeled and packed
   - Replaced or repaired components
   - Performance of the device
   - Disinfected or decontaminated

9. Inspection of imported consignments at ports of entry

9.1. General

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

Each consignment should be accompanied by an import permit, an original proforma invoice, as applicable corresponding certificate of analysis for each batch and airway bill or bill of lading.

At the time of importation, medical devices must have a valid shelf life as indicated in medicine and medical device import export and wholesale directive of the Authority. This include the following remining expiry dates of the medical device at the time of arrival, at the ports of entry:

a. 30 months remaining, if its assigned expiry date is more than 48 months to 60 months, or

b. 24 months remaining, if its assigned expiry date is more than 36 months to 48 months, the remaining term is 24 months; or

c. 15 months remaining, if its assigned expiry date is more than 24 months to 36 months, or

d. 12 months remaining, if its assigned expiry date is 24 months or less

9.2. Medical device inspection and clearance procedures

The inspection and port clearance procedure involves review of documents, physical inspection and cross-checking with observation during physical inspection with the applicable documents.

1. **Documents Evaluation**

All required documents (administrative and technical) submitted by the applicants will be reviewed as per the requirements indicated on section 8 of this guideline will be reviewed.

2. **Physical Inspection**

Once the review of documents completer, the inspector should conducted physical inspection of the medical device consignment to ensure the packaging, labeling, and storage and transportation requirements of the device are met the applicable standards and labeling requirements indicated in section "6.2 Labeling requirements at port of entry" of this guideline.

During this physical inspection, EFDA inspectors may take samples of imported medical devices for further investigation when deemed necessary. The sample collection form Annex I will be used during sampling which will be signed in duplicate by EFDA inspector and the consignee and one copy will be issued to the consignee.

Later on, the sampled medical devices should be sent to Medicine Quality Control Directorate (MQCD) of EFDA using the form indicated in annex 2 of this guideline.

Investigation on sampled medical devices 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. However, the importer should not allowed to sale or distribute such medical devices before written final decision issued by the Authority to do so.

3. **Cross-checking of provided documents with the actual product**

At this stage, the inspector will confirm the consistency of all the documents submitted by the applicant (consignee) and the observation during physical inspection of the actual product.

The inspector is also confirm the consistency of information on the actual product labeling with the provided documents and the requirements indicated in section "6.2. Labeling

requirements at port of entry" of this guideline the remaining shelf life requirements indicated in section 9.1 of this guideline.

10. Actions after inspection of the consignment

Once the necessary document reviewed and inspection on the consignments conducted, the authority may decide.

1. An approval for release.
2. A query may arise whereby the consignment may be held at customs warehouse or owner's premises pending further investigation.
3. Rejection of the consignment pending re-exportation or destruction at owner's expenses.

11. Detentions of Medical device

The imported medical device may be detained by the inspector using the form provided annexed in Annex 3 if the device;-

1. Missing of any documents indicated above
2. Labeling and / or packaging problems
3. Storage condition problems
4. Any safety, quality and performance issues

Annex 1: MEDICAL DEVICES SAMPLING FORM

1. Sample code:.....
2. Name of consignee (importer/institution) responsible for import of medical devices:.....

   Physical address.....Postal address.....

   Telephone No..... .....Fax No.....

   Email address..... (if applicable)
3. Name of port of entry:……
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 port of entry:.....

    .....

    .....
12. Name and signature of the representative of the consignee where sample was collected:

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

S. No.	Full name inspector/sample officer	Title	Signature	Date

Note: Samples should be collected in their original containers

Annex 2: Sample sending form for Laboratory

PRODUCT QUALITY ASSESSMENT DIRECTORATE	FORM-PQAD-014.079
PQAD SAMPLE TEST REQUEST FORM	SOP/PQAD-GEN016

IMPORTER NAME:-_____ **Date: _____** **AWB: _____**

Types of Consignment: _____ **PIP: -_____**

S.N	*ITEM*	*BRAND*	*FORMULATION*	*COMPOSITION*	*PRESENTATION*	*MANUFACTURER/ COUNTRY*	*BATCH NO*	*MFD DATE*	*EXP DATE*	*QTY*	Batch Size
01											

Received by:-_____ **Completed by:_____** **Approved by:_____**

Date _____ **Date _____** **Date _____**

Signature: ---------- **Signature ---------** **Signature: ----------**

Annex 3: Medical device detention form

ETHIOPIAN FOOD AND DRUG AUTHORITY

CENTRAL ETHIOPIA BRANCH OFFICE

. **Date: _____**

Ref No_____

To: - ADDIS ABABA CARGO CUSTOM BRANCH OFFICE

The consignment imported by **_____AWb_____Invoice no_____**Declaration_____ EFDA regulated products ***detailed below*** which is intended to be distributed in Ethiopia contravenes the provision of the Ethiopian Food and Medicine authority proclamatio1112/2019; and regulations and guidelines to implement it. Now decision is made by the concerned bodies. Therefore, we hereby quarantine the said consignment therefore; and direct you to keep the said consignment under custody.

S.no	Description of product	Unit	Qty	Batch /Model	exp. date	manufacturer/ country	Reason for detention
1							
2							
3							
4							
5							

It known to you that Removal, Sale, Distribution, Distraction, Alternation or Interference in any way is with the said regulated product consignment **without notification** of the Authority is an offence

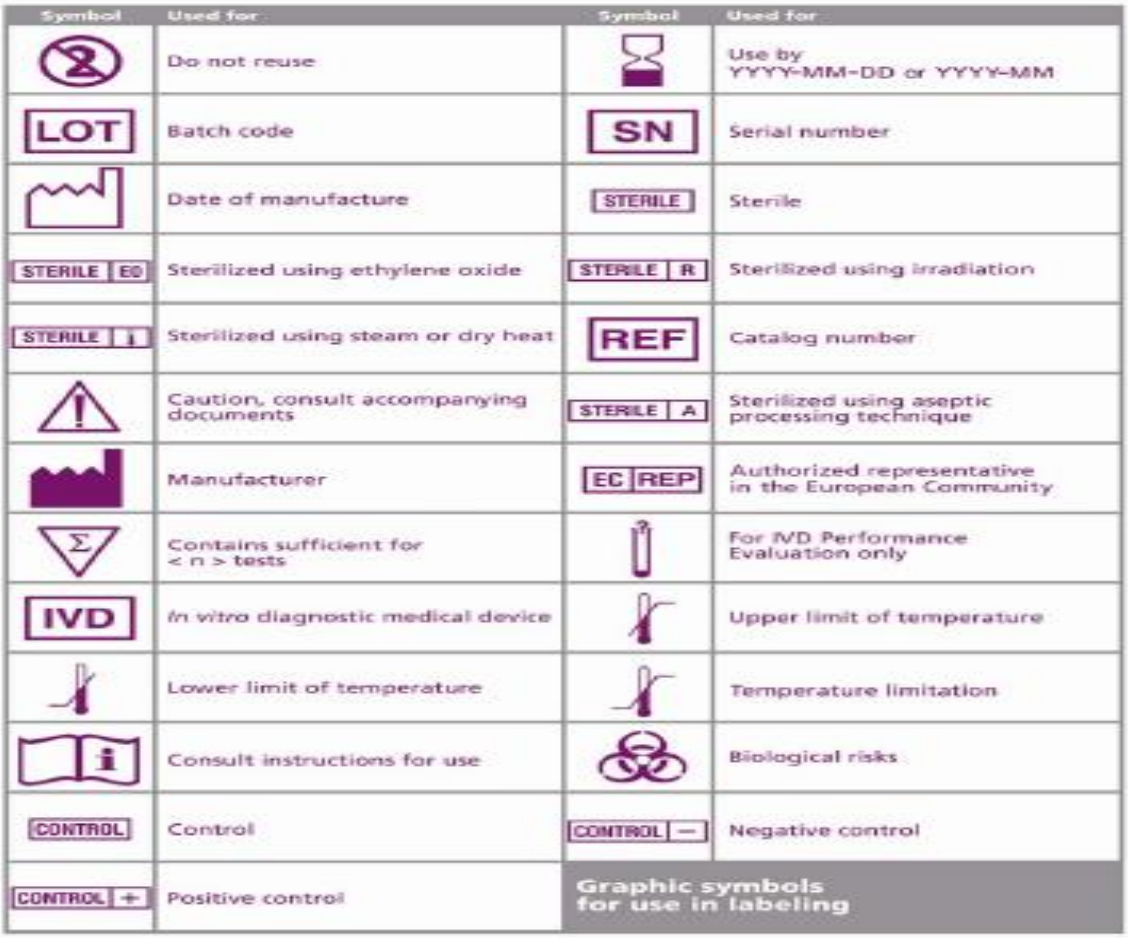
With best regards

Name _____

Signature_____

Date _____

Annex 4: Symbols for medical device label and labeling



Symbol	Used for	Symbol	Used for
	Do not reuse		Use by YYYY-MM-DD or YYYY-MM
LOT	Batch code	SN	Serial number
	Date of manufacture	STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide	STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat	REF	Catalog number
	Caution, consult accompanying documents	STERILE A	Sterilized using aseptic processing technique
	Manufacturer	EC REP	Authorized representative in the European Community
Σ	Contains sufficient for < n > tests		For IVD Performance Evaluation only
IVD	*In vitro* diagnostic medical device		Upper limit of temperature
	Lower limit of temperature		Temperature limitation
	Consult instructions for use		Biological risks
CONTROL	Control	CONTROL −	Negative control
CONTROL +	Positive control	**Graphic symbols for use in labeling**	

Annex 5: Medical device temperature storage values and definition

ON THE LABEL	GUIDANCE VALUES
Freezer	The temperature is thermostatically controlled between –20°C and –10°C.
Refrigerator	The temperature is thermostatically controlled between 2°C and 8°C.
Cold place	The temperature does not exceed 8°C.
Cool place	The temperature is between 8°C and 15°C.
Room temperature	The temperature is between 15°C and 30°C.
Warm	The temperature is between 30°C and 40°C.
Excessive heat	The temperature is above 40°C.
Do not store over 30°C	The temperature is between 2°C and 30°C.
Do not store over 25°C	The temperature is between 2°C and 25°C.
Do not store over 15°C	The temperature is between 2°C and 15°C.
Do not store over 8°C	The temperature is between 2°C and 8°C.
Do not store below 8°C	The temperature is between 8°C and 25°C.