Central Administration for Medical Devices
Central Administration for Pharmaceutical Policies and Market Support

Guideline

# Regulatory Guideline

# on the Rules and Procedures Governing the Importation and Exportation of Samples of Finished Medical Devices, Laboratory and Diagnostic Reagents, Including Their Raw Materials and Manufacturing Inputs

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## 1. Introduction

**This guideline pertains to the rules and procedures governing the import and export of samples of finished medical devices, laboratory and diagnostic reagents, raw materials, and related production inputs through customs ports.**

## 2. Definitions:

**Medical device as defined in the Egyptian Drug Authority Law issued under Law No. 151 of 2019:**

**Any device, instrument, apparatus, machine, equipment, implant, in-vitro diagnostic reagent, software application, material, or other similar or related article, including implantable or insertable products, that is manufactured by the manufacturer for human use, whether used alone or in combination, for one or more of the following purposes:**

- **Diagnosis, prevention, monitoring, treatment, or alleviation of disease.**
- **Diagnosis, monitoring, treatment, alleviation, or compensation for injury.**
- **Investigation, replacement, modification, or support of the anatomical or physiological process.**
- **Life support or life-sustaining purposes.**
- **Contraception**
- **Disinfection of medical devices.**
- **Providing information through laboratory examination of specimens derived from or obtained from the human body.**

**Provided that its primary intended purpose is not achieved by pharmacological, immunological, or metabolic means in or on the human body, although its intended function may be assisted by such means.**

- ✓ **Medical device as defined under the European Medical Devices Regulation "MDD93/42/ECC"**

**"Medical Device" means any "instrument, apparatus, appliance, software, material or other article,**

**whether used alone or in combination, including the software intended by its manufacturer to be used**

**specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,**

**intended by the manufacturer to be used for human beings for the purpose of:**

**• diagnosis, prevention, monitoring, treatment or alleviation of disease,**
**• diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,**
**• investigation, replacement or modification of the anatomy or of a physiological process,**
**• control of conception, and which does not achieve its principal intended action in or on the human body**
**by pharmacological, immunological or metabolic means, but which may be assisted in its function by such**
**means "**

- ✓ **Medical device as defined under the European Medical Devices Regulation MDR "REGULATION EU 2017/745"**

**"Medical Device" means any instrument, apparatus, appliance, software, implant, reagent, material or**

**other article intended by the manufacturer to be used, alone or in combination, for human beings for one**

**or more of the following specific medical purposes:**

**— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease**
**— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability**
**— investigation, replacement or modification of the anatomy or of a physiological or pathological process**
**or state**
**— providing information by means of in vitro examination of specimens derived from the human body,**
**including organ, blood and tissue donations, and which does not achieve its principal intended action by**
**pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted**
**in its function by such means. The following products shall also be deemed to be medical devices**
**— devices for the control or support of conception**

**— products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in**
**Article 1(4) and of those referred to in the first paragraph of this point.**

- ✓ **In vitro diagnostic reagent as defined under the European In Vitro Diagnostic Medical Devices Regulation (IVDR)**

**"Directive 98/79/EC"IVDD**

**"In Vitro Diagnostic Medical Device" means any medical device which is a reagent, reagent product,**
**calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in**
**combination,**
**intended by the manufacturer to be used in vitro for the examination of specimens, including blood and**
**tissue donations, derived from the human body, solely or principally for the purpose of providing**
**information:**

- **concerning a physiological or pathological state, or**
- **concerning a congenital abnormality, or**
- **to determine the safety and compatibility with potential recipients, or**
- **To monitor therapeutic measures.**

**Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles` are**
**those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary**
**containment and preservation of specimens derived from the human body for the purpose of in vitro**
**diagnostic examination.**
**Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view**
**of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic**
**examination.**

- ✓ **In vitro diagnostic reagent as defined under the European In Vitro Diagnostic Medical Devices Regulation (IVDR)**

**IVDR " REGULATION (EU) 2017/746 "**

**"In Vitro Diagnostic Medical Device" means any medical device which is a reagent, reagent product,
calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether
used alone or in combination, intended by the manufacturer to be used in vitro for the examination of
specimens, including blood and tissue donations, derived from the human body, solely or principally for the
purpose of providing information on one or more of the following:
(a)concerning a physiological or pathological process or state;
(b)concerning congenital physical or mental impairments;
(c)concerning the predisposition to a medical condition or a disease;
(d)to determine the safety and compatibility with potential recipients;
(e)to predict treatment response or reactions;
(f)to define or monitoring therapeutic measures.
Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices
Raw materials and production inputs: All materials and components utilized in the manufacturing and production of all types of medical devices and laboratory and diagnostic reagents.
domestic manufacturer / producing company: The actual manufacturer of medical devices or laboratory and diagnostic reagents.**

- ✓ **Medical Device Registration Notification / Marketing Authorization for Diagnostic Reagents: Approval granted by the Egyptian Drug Authority for the manufacture, sale, and marketing of a product within the Arab Republic of Egypt after review of the supporting product documentation.**
- ✓ **Domestic manufactured medical devices and medical equipment: Medical devices and equipment manufactured in facilities located within the Arab Republic of Egypt.**
- ✓ **Imported medical devices and equipment: Medical devices and medical equipment imported as finished products from outside the Arab Republic of Egypt for distribution within the Republic.**

- ✓ **Non-sterile medical device: A medical device manufactured without sterilization and intended to be used in its non-sterile state.**
- ✓ **Medical device intended to be sterilized: A medical device manufactured in a non-sterile condition and intended to be sterilized by the user prior to use.**
- ✓ **Sterile medical device: A medical device manufactured in a sterile condition and intended to be used in its sterile state.**
- ✓ **Domestic manufactured laboratory and diagnostic reagents: Laboratory and diagnostic reagents manufactured in facilities located within the Arab Republic of Egypt.**
- ✓ **Imported laboratory and diagnostic reagents: Laboratory and diagnostic reagents imported as finished products from outside the Arab Republic of Egypt.**
- ✓ **Non-diagnostic laboratory reagents: Laboratory reagents that are not used directly for the diagnosis of diseases or medical conditions, such as reagents used for scientific research, education, quality control, or support of production processes in various industries.**
- ✓ **Label: Written, printed, or graphic information appearing either on the medical device itself, on the packaging of each individual unit, or on the packaging containing multiple units.**

**3. Related Guidelines**

- **Regulatory Guideline for Issuing Import Approvals for All Types of Medical Devices**
- **Regulatory Guideline for the Procedures and Rules Governing the Obtaining of Import Approvals for Imported Laboratory and Diagnostic Devices and Their Accessories**
- **Regulatory Guideline for the Registration Procedures and Issuance of Import Approvals for Laboratory and Diagnostic Reagents**
- **Regulatory procedure for the importation and registration of medical devices, laboratory devices, and diagnostic reagents marketed in Great Britain (England, Wales, and Scotland), without requiring their circulation within the European Union.**
- **Regulatory procedure for the importation and registration of medical devices, laboratory devices, and diagnostic reagents marketed in accordance with the regulatory procedures and rules applicable in Japan.**
- **Regulatory Guideline on Requirements for Unique Device Identification (UDI) for Medical Devices**
- **Regulatory Guideline for Labeling Information of Medical Devices, Laboratory Devices, Diagnostic Reagents, and Production Components and Inputs**
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1. **Regulatory Rules and Procedures for the Importation by Domestic Manufacturers of Samples of Finished Medical Supplies, Laboratory and Diagnostic Reagents, Raw Materials, and Associated Manufacturing Inputs.**

| Category | Raw materials / Production inputs | Finished product |
|---|---|---|
| **Purpose of importation** | **Evaluation** | **R&D (Research & Development)**<br>**• Validation or Evaluation**<br>**• Reverse engineering**<br>**• Comparative study** |
| **Requirements** | **Limited quantity not intended for mass production.**<br>**- "Invoice with a value not exceeding USD 100 or its equivalent."**<br>**- Full customs Release shall be granted at the customs ports.**<br>**- Full customs Release shall be granted at the customs ports.** | **Medical device: Quantity not exceeding 50 units per item.**<br>**Diagnostic reagents: The quantity shall not exceed 5 packs of the minimum sales unit where the packaging consists of a box of 10 units or more, and 50 samples for single-unit items.** |
| **Scope of application** | **All raw materials and production inputs** | **All medical devices (sterile/non-sterile) (implantable/non-implantable) and laboratory and diagnostic reagents,** |

| | | | |
|---|---|---|---|
| | | | **excluding medical equipment, their parts, spare parts, and accessories.** |
| **Required documents** | **1** | **Application submitted for medical customs Release at customs ports (Annex 1).** | |
| | **2** | **An authorization issued by the manufacturer appointing the person responsible for liaising with the Egyptian Drug Authority, duly stamped with the company seal, signed by the company's responsible manager, and supported by bank authentication of the signature.** | |
| | **3** | **Manufacturer license issued by the competent authority, such as the General Authority for Industrial Development or the General Authority for Investment and Free Zones.** | |
| | **4** | **Technical operation license issued by the Egyptian Drug Authority (if applicable).** | |
| | **5** | **Invoice** | |
| | **6** | **Undertaking that the imported items are not intended for sale, trade, or human use (Annex 2).** | |
| | **7** | **MSDS (material safety data sheet)** | **Document clarifying the nature and specifications of the item, such as a catalog or IFU (Instructions for Use).** |
| **Facilitated procedures** | **1** | **The procedures outlined in the regulatory guideline for minimum data requirements shall not apply; therefore, the products are exempt from processing, subject to submission of the imported product name and the** | **The procedures outlined in the regulatory guideline for minimum data requirements shall not apply; therefore, the products are exempt from processing, subject to submission of the imported product name and the foreign manufacturer details only. (sample not for human use)** |

| | | | |
|---|---|---|---|
| | | **foreign manufacturer details only.**<br><br>**Note: Chemicals, liquids, and powders without labeling information shall be rejected.** | **- If labeling information is unavailable, an email from the foreign manufacturer must be provided specifying the imported item and confirming that the product is manufactured by the foreign manufacturer, to the following email address:**<br><br>**Icr.customs@edaedgypt.gov.eg** |

**3.1 Rules and procedures governing the importation by domestic manufacturers of samples of finished medical devices.**

1. **An application shall be submitted to the medical customs Release authority at the customs ports, accompanied by the required documents (as per the above table).**

2. **Medical customs Release shall be granted directly at the customs ports for the imported samples of medical devices and laboratory and diagnostic reagents.**

3. **A monthly inventory report shall be prepared and submitted to the Central Administration for Medical Devices through the activation of a shared electronic link between the Central Administration for Medical Devices and the Central Administration for Pharmaceutical Policies and Market Support.**

4. **The manufacturer shall maintain records of the imported samples in electronic and/or paper form.**

**4.2 Rules and procedures governing the importation by domestic manufacturers of samples of raw materials and production inputs:**

1. **An application shall be submitted to the medical customs Release authority at the customs ports, accompanied by the required documents (as per the above table).**
2. **Medical customs Release shall be granted directly at the customs ports for samples of raw materials and production inputs.**
3. **A monthly inventory report shall be prepared and submitted to the Central Administration for Medical Devices through the activation of a shared electronic link between the Central Administration for Medical Devices and the Central Administration for Pharmaceutical Policies and Market Support.**
4. **The manufacturer shall maintain records of the imported samples in electronic and/or paper form.**

**4.3 Rules and procedures governing the importation by local manufacturers of Medical equipment, lab and IVD equipment**

**4.4**

**A prior import approval shall be obtained through submission via the MeDevice electronic platform at the following link:**
**https://medevice.edaegypt.gov.eg**

**Import fees for devices shall be collected in accordance with the applicable fee category stipulated in the Executive Regulations of the Egyptian Drug Authority Law issued by Prime Ministerial Decree No. 777 of 2020, as provided under the regulatory guideline for issuing import approvals for medical devices, their accessories and spare parts, and the regulatory guideline for the procedures and rules governing the obtaining of import approvals for imported laboratory and diagnostic devices and their accessories.**

1. **Regulatory Rules and Procedures for the Importation by Importing Companies Registered with the Egyptian Drug Authority of Samples of Finished Medical Supplies and Laboratory and Diagnostic Reagents**

| Category | Finished medical device | Finished diagnostic reagent |
|---|---|---|
| **Authorized importing companies** | **Companies registered in the Importers Register issued by the Central Administration for Pharmaceutical Institutions Licensing in the field of medical devices.** | **Companies registered in the Importers Register issued by the Central Administration for Pharmaceutical Institutions Licensing in the field of diagnostic reagents.** |
| **Purpose of importation** | **Evaluation and study**<br>**(comparative study)** | |
| **Requirements** | **(Full customs Release shall be granted at the customs ports).** | **One sample of the smallest sale unit shall be permitted in the case of boxes containing 10 units or more, and 10 samples for individually supplied items, for the purposes of evaluation and market study for each diagnostic reagent from the same foreign manufacturer.**<br>**(Full customs Release shall be granted at the customs ports)** |
| **Scope of application** | **All medical devices (sterile/non-sterile) (implantable/non-** | |

| | | |
|---|---|---|
| | **implantable) excluding medical equipment, their parts, and spare parts, <u>with the exception of the following medical devices:</u>**<br><br>**1. Screws, nails, nuts, plate**<br>**2. All joint system**<br>**3. All anchors**<br>**4. All stent**<br>**5. All valves**<br>**6. Dental implants**<br>**7. All sutures, meshes**<br>**8. All prefilled syringe**<br>**9. Cochlear implants**<br>**10. Pacemakers**<br>**11. IOL**<br>**12. Glaucoma valve**<br>**13. All cardiovascular medical devices**<br>**14. All CNS medical devices** | **All diagnostic reagents** |

| Category | | Finished medical device | Finished diagnostic reagent |
|---|---|---|---|
| Required documents | 1 | Application submitted for medical customs Release at customs ports (Annex 3). | |
| | 2 | An authorization issued by the manufacturer appointing the person responsible for liaising with the Egyptian Drug Authority, duly stamped with the company seal, signed by the company's responsible manager, and supported by bank authentication of the signature. | |
| | 3 | Medical Devices Importers Register License issued by the Central Administration for Pharmaceutical Institutions Licensing<br><br>It is not mandatory for the importing company to act as a distributor or agent of the foreign manufacturer; accordingly, the company is not required to be added to the Medical Devices Importers Register license. | Laboratory and Diagnostic Reagents Importers Register License issued by the Central Administration for Pharmaceutical Institutions Licensing<br><br>It is not mandatory for the importing company to act as a distributor or agent of the foreign manufacturer; accordingly, the company is not required to be added to the Laboratory and Diagnostic Reagents Importers Register license. |
| | 4 | Medical device import invoice | |
| | 5 | Undertaking that the imported medical device is intended for testing and evaluation purposes only and not for sale, trade, or use on humans (Annex 4). | |
| | 6 | Document clarifying the nature and specifications of the item, such as a catalog or IFU (Instructions for Use). | |

1. **An application shall be submitted to the medical customs Release authority at the customs ports, accompanied by the required documents (as per the above table).**

2. **Medical customs Release shall be granted directly at the customs ports for the imported samples of medical devices and laboratory and diagnostic reagents.**

3. **A monthly inventory report shall be prepared and submitted to the Central Administration for Medical Devices through the activation of a shared electronic link between the Central Administration for Medical Devices and the Central Administration for Pharmaceutical Policies and Market Support.**

## 1. Appendices

### Appendix (1)

**Application Form for the Release of Medical Device / Diagnostic Reagent Samples Submitted for Medical Customs Release at Customs Ports**

**(For Domestic Manufacturers)**

**To: Egyptian Drug Authority**

**(Medical Customs Release at Customs Ports – General Administration for Import Approvals and Medical Customs Release – Central Administration for Pharmaceutical Policies and Market Support)**

**We, the manufacturer "(name as registered in the operating license issued by the Industrial Development Authority)," hereby apply for the release of the items covered by Invoice No. ……**

**Job Title: Manufacturer Manager or Authorized Representative**

**Name:**

**Signature:**

**Manufacturer Seal:**

**Note: In the event that the manufacturer manager authorizes another person to sign on his behalf, the authorization must be valid, signed, and stamped by the responsible manager, with the signature duly bank-authenticated. The authorization must explicitly state that the authorized person has the right to sign on behalf of the manufacturer manager.**

**Appendix (2)**

**Commitment for the Import of Samples Intended for Non-Commercial Purposes (For Domestic Manufacturers)**

**To: Egyptian Drug Authority**
**(Medical Customs Release at Customs Ports – General Administration for Import Approvals and Medical Customs Release – Central Administration for Pharmaceutical Policies and Market Support)**

**We, the manufacturer "(name as registered in the operating license issued by the Industrial Development Authority) ……..," undertake that the shipment included under Invoice No. …… is imported solely for the purpose of (state purpose) and shall not be sold, traded, or used on humans.**

**(Samples of finished medical devices and laboratory and diagnostic reagents imported by domestic manufacturers for non-commercial purposes, including Research and Development (R&D), Validation or Evaluation, or Reverse Engineering or Comparative study purpose)**

**Job Title: Manufacturer Manager or Authorized Representative**

**Name:**

**Signature:**

**Manufacturer Seal:**

**Note: In the event that the manufacturer manager authorizes another person to sign on his behalf, the authorization must be valid, signed, and stamped by the responsible manager, with the signature duly bank-authenticated. The authorization must explicitly state that the authorized person has the right to sign on behalf of the manufacturer manager.**

**Appendix (3)**

**Application Form for the Release of Samples Submitted for Medical Customs Release at Customs Ports (For Importing Companies)**

**To: Egyptian Drug Authority**

**(Medical Customs Release at Customs Ports – General Administration for Import Approvals and Medical Customs Release – Central Administration for Pharmaceutical Policies and Market Support)**

**We, the company "(name as stated in the Importers Register license)," hereby submit a request for the release of the shipment covered under Invoice No. ……**

**Job Title: Manufacturer Manager or Authorized Representative**

**Name:**

**Signature:**

**Manufacturer Seal:**

**Note: In the event that the manufacturer manager authorizes another person to sign on his behalf, the authorization must be valid, signed, and stamped by the responsible manager, with the signature duly bank-authenticated. The authorization must explicitly state that the authorized person has the right to sign on behalf of the manufacturer manager**

## Appendix (4)

**Commitment for the Import of Samples Intended for Non-Commercial Purposes (For importing companies)**

**(Imported samples of finished medical devices and laboratory and diagnostic reagents for import companies for evaluation purposes.**

**To: Egyptian Drug Authority**
**(Medical Customs Release at Customs Ports – General Administration for Import Approvals and Medical Customs Release – Central Administration for Pharmaceutical Policies and Market Support)**

**We, the company "(name as registered in the Importers Register)) ……..," hereby undertake that the shipment included under Invoice No. …… is imported solely for the purpose of (state purpose) and shall not be sold, traded, or used on humans.**

**Job Title: Company Manager or Authorized Representative**

**Name:**

**Signature:**

**Company Seal:**

**Note: In the event that the company manager authorizes another person to sign on his behalf, the authorization must be valid, signed, and stamped by the responsible manager, with the signature duly bank-authenticated. The authorization must explicitly state that the authorized person has the right to sign on behalf of the company manager.**

## 5. Rules and procedures governing the exportation by domestic manufacturers of samples of finished medical devices, laboratory and diagnostic reagents, and their raw materials and production inputs.

➢ **First: Areas of Application**

- **Finished medical devices and laboratory and diagnostic reagents, including their related raw materials and manufacturing inputs.**

➢ **Second: Required Documents**

| First: Medical Devices |
|---|
| **Exportation shall be permitted upon submission of the following documents:** |
| **1. Submission of an application to the medical customs Release authority at the customs ports stating the purpose of exporting the samples (research purposes, exhibitions, or any marketing purposes), together with an undertaking confirming that the shipment consists of samples and has no commercial purpose, and that the exportation is carried out under the sole responsibility of the company without any liability on the Egyptian Drug Authority. The application shall be issued on the company's official letterhead, stamped with the company seal, and signed by the responsible person.**<br>**2. Where the exporter is not the product owner, a duly authorized power of attorney authenticated by the bank shall be provided.**<br>**3. A valid operating license and industrial registration issued to the manufacturer by the Industrial Development Authority.**<br>**4. In the case of a sterile medical device, the medical device registration notification issued by the Egyptian Drug Authority and the manufacturer data certificate issued by the Egyptian Drug Authority shall be submitted (to verify that the production line is licensed by the Egyptian Drug Authority).**<br>**5. In the case of a non-sterile medical device, the medical device registration notification, if available, or the Declaration of Conformity in the case of an unregistered medical device, shall be submitted, with clarification of the device class.**<br>**6. Invoice including the following details:**<br>**o Name and address of the exporting company**<br>**o Name, address, and country of the importing company**<br>**o Currency**<br>**o Name of the medical device** |

- **For non-sterile medical devices, this must be clearly indicated on the invoice**
- **Code / size (if applicable)**
- **Registration number (if available)**
- **Pack size**
- **Quantity**
- **Unit price**
- **Total price**

| Second: Laboratory and Diagnostic Reagents |
|---|
| **Exportation shall be permitted upon submission of the following documents:** |
| 1. **Submission of an application to the medical customs Release authority at the customs ports stating the purpose of exporting the samples (research purposes, exhibitions, or any marketing purposes), together with an undertaking confirming that the shipment consists of samples and has no commercial purpose, and that the exportation is carried out under the sole responsibility of the company without any liability on the Egyptian Drug Authority. The application shall be issued on the company's official letterhead, stamped with the company seal, and signed by the responsible person.**<br>2. **Where the exporter is not the product owner, a duly authorized power of attorney authenticated by the bank shall be provided.**<br>3. **A valid operating license issued by the Industrial Development Authority.**<br>4. **Invoice including the following details:**<br>○ **Name and address of the exporting company**<br>○ **Name, address, and country of the importing company**<br>○ **Currency**<br>○ **Name of the laboratory reagent**<br>○ **For non-sterile medical devices, this must be clearly indicated on the invoice**<br>○ **Code / size (if applicable)**<br>○ **Registration number (if available)**<br>○ **Pack size**<br>○ **Quantity**<br>○ **Unit price**<br>○ **Total price** |

- **Third: General Requirements**

- **Permissible quantities for exportation as samples:**
- **Medical device: Quantity shall not exceed 20 units for each item.**
- **Diagnostic reagents: The permitted quantity shall be two packages of the smallest sale unit for products packaged in boxes of 10 units or more, and 20 samples for individually supplied items.**
- **Exportation shall be permitted directly through the customs ports.**
- **The company shall be committed to indicating the following information on the samples intended for export:**

**"Product name and manufacturer name and Samples Not for Commercial Use"**
**The purpose of exporting: (research purposes, exhibitions, or any marketing purposes).**

**Procedures for Exporting Equipment (Application Link and Required Documents):**

**Export approval application link**

https://forms.gle/hEvtVE3NNeaC541A9

**Including the regulatory guideline governing the rules and procedures for the exportation of pharmaceutical products and medical devices.**

https://drive.google.com/file/d/1SWf9b3xXJwGvUn2-49SE46Jv-Cuyh-UI/view?usp=sharing

## ➢ Export Application Form

**To be printed on the company's official letterhead and stamped with the company seal.**

**To: Egyptian Drug Authority**

**Greetings,**

**Kindly provide your response regarding the export of the items described below:**

| | | |
|---|---|---|
| **1.** | **Application Date** | |
| **2.** | **Company Name** | |
| **3.** | **Invoice No.** | |
| **4.** | **Invoice Date** | |
| **5.** | **Shipment Type (Samples)**<br>**(Specify the purpose of exporting the samples)** | |
| **6.** | **Invoice value (currency)** | |
| **7.** | **Export destination country** | |
| **8.** | **Customs port** | |

**Yours faithfully,,,,,**

**Responsible Manager: Job Title**

**Job Title:**

**Signature:**

**Date:**

Company Seal

**To be printed on the company's official letterhead and stamped with the company seal.**

**To: Egyptian Drug Authority**

**Greetings,**

**Company …… hereby undertakes the authenticity and validity of all documents related to Invoice No. …… intended for export to …… and submitted to your esteemed authority. The company further undertakes that the exportation of the consignment covered by the invoice shall be under the sole responsibility of the company without any liability whatsoever on the Egyptian Drug Authority.**

**The company further undertakes that the products listed in the invoice, including their raw materials, are under the responsibility of the manufacturing company and that no non-conformity decision has been issued against them.**

**Yours faithfully,,,,,**

**Responsible Manager: Job Title**

**Job Title:**

**Signature:**

**Date:**

Company Seal

## 8.Glossary and Abbreviations

| Abbreviation | Term |
|---|---|
| MDD | Medical Device Directive |
| MDR | Medical Device Regulation |
| IVD | In Vitro Diagnostics Directive |
| IVDR | In Vitro Diagnostics Regulation |
| UDI | Unique Device Identifier |
| R&D | Research and Development |
| IFU | Instructions for Use |