Regulatory Guideline for

The Procedures and Rules of Obtaining Import Approvals for Laboratory and Diagnostic Equipment and their Imported Accessories

Code: EDREX: GL. CAMD.004
Version number:2
Issue date: 01/09/2025
Effective date: 01/09/2025

Table of Contents

1. Introduction:

This guideline is concerned with the regulatory rules and procedures required to import laboratory and diagnostic equipment and their imported accessories

2. Definitions:

- In vitro diagnostic medical devices according to European directive 98/79/EC

In vitro diagnostic medical device: It 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;
- concerning a congenital abnormality;
- 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.

Accessory: means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to *in vitro* diagnostic medical devices".

- List of reference countries: Belgium, France, Germany, Italy, Luxembourg, Netherlands, Austria, Finland, Sweden, Norway, Denmark, Ireland, United Kingdom, Greece, Portugal, Spain, Bulgaria, Romania, Cyprus, Croatia, Czech, Republic, Estonia, Hungary, Latvia, Liechtenstein, Lithuania, Malta, Poland, Slovakia, Slovenia, Australia, New Zealand, USA, Canada, Japan, Iceland and Switzerland.

3. Procedures of obtaining import approval for importing laboratory and diagnostic equipment:

3.1. Receiving the file of obtaining an import approval for laboratory and diagnostic equipment:

3.1.1. Pursuant to the list of required documents indicated in Appendixes 1, 2 in this regulatory guideline, the Company shall apply on the electronic platform MeDevice at the following link: medevice.edaegypt.gov.eg

3.1.2. Within two (2) working days from the date of sending the request, the company shall, through the electronic platform, receive the response of accepting, refusing or suspending the request file until fulfilling the required documents.

3.1.2.1. In case of accepting the request file: The request file shall be forwarded to the Unit of Import Approvals to be studied, then the documents required to be fulfilled shall be sent to the company through the electronic platform.

3.1.2.2. In case of suspending the request file until fulfilling the required documents: The procedures of proceeding with the request file shall be suspended in the case of non-fulfillment of any of the required documents and data for a period of 90 days starting from the date of sending requests of fulfillment and the request shall be considered as rejected. The request procedures may be resumed within the following ninety days after paying the prescribed service consideration for one time only, otherwise the request shall be considered null and void.

3.1.2.3. In case of refusing the request file: The request shall be rejected in the cases that any of the clause data in the company's request do not conform with the receipt, the initial invoice is not available, or the department to which the request is forwarded is not concerned with the request.

3.2. Evaluation of the file of obtaining an import approval:

The file shall be reviewed and the documents required to be fulfilled shall be sent to the applicant through the platform within (5) five working days from the date of receiving the file.

3.3. Fulfillment of the file of obtaining an import approval:

The file shall be fulfilled through the platform.

3.4. Issuance of an import approval:

After fulfilling the file, the import approval shall be issued and a copy of the invoice shall be attached thereto.

4. Procedures for importing laboratory and diagnostic equipment for exhibitions, workshops and training:

- It is permitted to import laboratory and diagnostic equipment for the purpose of displaying them in exhibitions, workshops and training, provided that they shall be re-exported.
- The procedures 3.1. to 3.4. shall be implemented.

The following shall also be taking into account:

- The date of the conference or workshop shall be stated in the invoice (if applicable).
- The brochure of the exhibition shall be provided.
- The company shall be committed to submit a documented declaration that it shall re-export the equipment immediately after the end of the workshop or the conference.
- The company shall submit an undertaking issued by the event-hosting party that the received equipment shall not be used for diagnostic purposes.

5. Procedures for importing the laboratory and diagnostic equipment for the research purposes:

- Companies specialized in importing the laboratory and diagnostic equipment shall be permitted to import equipment for research use only, for investigational use or for performance evaluation.
- Records and data of the importing company shall be examined to verify the supplying parties through the representatives of the Egyptian Drug Authority in the Central Administration of Licensing of pharmaceutical institutions.

6. General requirements:

- The issued approval is personal and not assignable or transferable.
- Any crossing out, erasure, modification or addition to the approval shall make it null and void.
- The approval issued for an invoice is valid for total shipment only and it is indivisible.
- It is prohibited to advertise in any media outlet except after obtaining an approval from the Egyptian Drug Authority.
- The imported laboratory and diagnostic equipment shall be new and not used.
- The data of the imported laboratory and diagnostic equipment shall be identical with the data specified in the attached invoice.
- The invoice shall be valid for a maximum of one year from the date of its issuance, unless the supplier company indicates another expiration date.

- Any used laboratory equipment shall not be imported, whether for personal use or for commercial circulation, except after refereeing to the General Administration of medical devices marketing authorization to consider the extent to which these devices are allowed to be imported and circulated.

7. Appendixes

Appendix 1	**A list of the documents required to import laboratory and diagnostic equipment**
Appendix 2	**A list of the documents required to import laboratory and diagnostic equipment for research purposes**

Appendix 1

A list of the documents required to import laboratory and diagnostic equipment

First: Documents of the import approval applicant:

1. An authorization by the importing company for the person in charge of dealing with the Central Administration of Medical Devices. This authorization shall be signed and stamped by the eligible company manager with a valid bank signature.
2. The initial invoice.
3. Importers Register License (medical devices or kits) that shall meet the following criteria:

- It shall include the supplier company or the legal manufacturer based on the transaction relationship letter, and
- It shall state the valid license of the maintenance center.

4. C14 for agents.
5. A valid distribution or agency contract with the supplier company.
6. A documented relationship between the legal manufacturer and the supplier company (in case of they are not in the same company) indicating that the supplier company is eligible to supply imported medical devices to Egypt or the Middle East, which relationship shall be issued by the foreign manufacturer, attested by the Chamber of Commerce and notarized by the Egyptian Embassy.
7. A documented relationship showing the relationship between the supplier mentioned in the invoice and the supplier added to the Importers Register License (in case of discrepancy).

Second: Free Sale and Quality Certificate of laboratory and diagnostic equipment:

1. **Pursuant to the applicable rules of the European community based on the provisions indicated in the "IVD Directive 98/79/EEC"**:

Class	Certificates
General IVD	1. The DOC Certificate indicating IVD Directive and classification. 2. The Free Sale Certificate "FSC" issued by the country of origin or by one of the reference countries. 3. A Catalog showing the intended use.
IVDs for self-testing	1. The DOC Certificate indicating IVD Directive and classification. 2. The Free Sale Certificate "FSC" issued by the country of origin or by one of the reference countries. 3. The ISO:13485:2016 certificate. 4. CE annex III sec 6 certificate, or CE annex IV certificate excluding 4 and 6 CE annex V+VI certificate, or CE annex V+VII certificate. 5. A Catalog showing the intended use.
IVDs in Annex II List B (Moderate risk)	1. The DOC Certificate indicating IVD Directive and classification. 2. The Free Sale Certificate "FSC" issued by the country of origin or by one of the reference countries. 3. The ISO:13485:2016 certificate. 4. CE annex IV excluding 4 and 6 certificates, CE annex V+VI certificate, or CE annex V+VII certificate 5. A Catalog showing the intended use.
IVDs in Annex II List A (High risk)	1. DOC Certificate indicating IVD Directive and classification. 2. The Free Sale Certificate "FSC" issued by the country of origin or by one of the reference countries. 3. ISO:13485:2016. 4. CE annex IV excluding 4 and 6 + IV sec 4 or CE annex V+VII certificate 5. A Catalog showing the intended use.

2. Pursuant to the applicable rules in the USA based on the provisions indicated in FDA

Class	Certificates
Class I	1. The CFG without GMP. 2. The letter of declaration mentioning the classification and code of federal regulation: 21CFR 862, 21CFR 864 or 21CFR 866 3. A Catalog showing the intended use.
Class II, and III	1. The CFG with GMP, or CFG+ISO13485:2016 3. The letter of declaration mentioning the classification and code of federal regulation: 21CFR 862, 21CFR 864 or 21CFR 866 4. A Catalog showing the intended use.

3. Pursuant to the applicable rules in Canada:

Class	Certificates
Class1	1. The DOC acc. To Canadian regulation mentioning the classification 2. Manufacturer certificate to cover export of medical devices (= FSC) issued from: the HPFBI, Health Canada 3. Medical device establishment license 4. A Catalog showing the intended use.
Class II, III, IV	1. Medical device active licenses (In case Medical device active license is issued for medical device family, medical device group, or medical device group family) NB: The declaration letter will be sent to the Health Canada to confirm that the license covers the whole medical device list 2. Declaration of conformity acc. To Canadian regulation mentioning the classification 3. Manufacturer certificate to cover export of medical devices (= free sale) issued from: the HPFBI, Health Canada 4. ISO 13485: 2016 5. A Catalog showing the intended use.

Third: Documents required for accessories and spare parts:

1. Certificates of the device as mentioned in Clause "Second" concerning the accessories and spare parts.
2. One of the following documents shall be submitted to prove that the accessory or the spare part belongs to a laboratory and diagnostic equipment:
   - The manual of the device in which the imported accessories or spare parts are indicated.
   - The letter of the legal manufacturer in which the device name, accessories and spare parts are indicated.
   - The invoice stating that the accessories or the spare parts belong to the laboratory and diagnostic equipment.

Appendix 2

A list of the documents required to import laboratory and diagnostic equipment for research purposes

First: Documents of the import approval applicant:

1. An authorization by the importing company for the person in charge of dealing with the Central Administration of Medical Devices. This authorization shall be signed and stamped by the eligible company manager with a valid bank signature.
2. The initial invoice.
3. Importers Register License (medical devices or kits) that shall meet the following criteria:
   - It shall include the supplier company or the legal manufacturer based on the relationship letter, and
   - It shall state maintenance center data provided that the maintenance center license is valid.
4. C 14 for agents.
5. A valid and notarized distribution or agency contract with the supplier company.

Second: Documents of the device:

Note: FSC or quality certificates are not required.

1. Submitting material(s) proving that the imported device is for research use only

For example:

- Labels, IFU, Catalog, or declaration letter, declaration of conformity, indicating that the device is for research use only.

2. An undertaking by the importing company stipulating that the imported devices shall not be supplied to medical laboratories for the purpose of conducting diagnostic analyses, which undertaking shall be submitted to the representatives of the Egyptian Drug Authority in the Central Administration for Inspection on pharmaceutical institutions, without prejudice to the obligation to provide the proofs indicating that the imported devices are supplied to the importing bodies.
3. The foreign manufacturer shall put the following statement "**For Research Use Only**" clearly on the packages.

8. Glossary

- **CE**: Conformity European
- **CFG**: Certificate to Foreign Government
- **CFR**: Code of Federal Regulation
- **DOC**: Declaration of Conformity
- **EDA**: Egyptian Drug Authority
- **EEC**: European Economic Community
- **FDA**: Food and Drug Administration
- **FSC**: Free Sale Certificate
- **ISO**: International Organization for Standardization
- **IVDs**: In vitro Diagnostic Medical Devices
- **IVDR**: In vitro Diagnostic Device Regulation

9. Versions

Places of Amendments	Issue date	version
	07/12/2021	**First**
The name of the Central Administration for Operations has been updated to become the Central Administration for Inspection on pharmaceutical institutions or the Central Administration of Licensing of pharmaceutical institutions whenever they are mentioned in the guideline, depending on the specialization.	01/09/2025	**Second**