Guideline

# Regulatory Guideline of Issuance of Import Approvals of All Types Medical Devices Year 2025

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# Table of Contents

## 1. Introduction

This guideline concerns regulatory procedures related to the issuance of import permits approvals for medical devices of all types.

Purpose:

Developing guidance for granting import permit for a safe and effective medical device, to allow trading within the Arab Republic of Egypt.

Scope:

It includes an explanation of all work procedures for importers, distributors, and scientific offices to obtain import permit for medical devices, as well as for raw materials – inputs and components – used for production of locally manufactured medical devices.

## 2. Related guidelines

- Regulatory Guideline for Organization Procedures to Register Imported and Locally Manufactured Medical Devices with International Quality Certificates
- Regulatory Guideline for Organizational Procedures for Variations
- Regulatory Guideline for Registration and Trading of Laboratory Equipment and *in Vitro* Diagnostics

## 3. Definitions

1. Medical device**:** Any device, tool, means, machine, equipment, instrument, or application including what is transplanted, electronic program, material, or any other similar or related things that the manufacturer has manufactured for the purpose of human use, individually or collectively for one or more of the following purposes:

- Diagnosis, prevention, monitoring, treatment, and alleviation of disease.
- Diagnosis, monitoring, treatment, mitigation, and injury compensation.
- Verifying the replacement, modification or support of an anatomical or functional process.
- Life supporting or preserving.
- Pregnancy control.
- Sterilization of medical devices.

Provided that the primary purpose intended for the device is not achieved through a medicinal, immunological or metabolic effect in or on the human body, but the medical device can be assisted in its intended function by the aforementioned effects.

2. Imported medical device: Fully manufactured medical devices that are imported from abroad for trading within the Arab Republic of Egypt.

3. Locally manufactured medical devices: Medical devices that are manufactured in factories within the Arab Republic of Egypt.

4. Importing company: The first entity in the supply chain that imports medical devices manufactured abroad into the Arab Republic of Egypt.

5. Legal manufacturer: The entity that is responsible for designing, manufacturing, and packaging a medical device before putting it on the market in its name, regardless of whether these operations were carried out by that person himself, on his behalf, or by a third party, and he is responsible for the quality of the product.

6. Actual manufacturer: The place where the product is manufactured, packed and packaged for the legal factory.

7. Local factory: A local factory for medical devices.

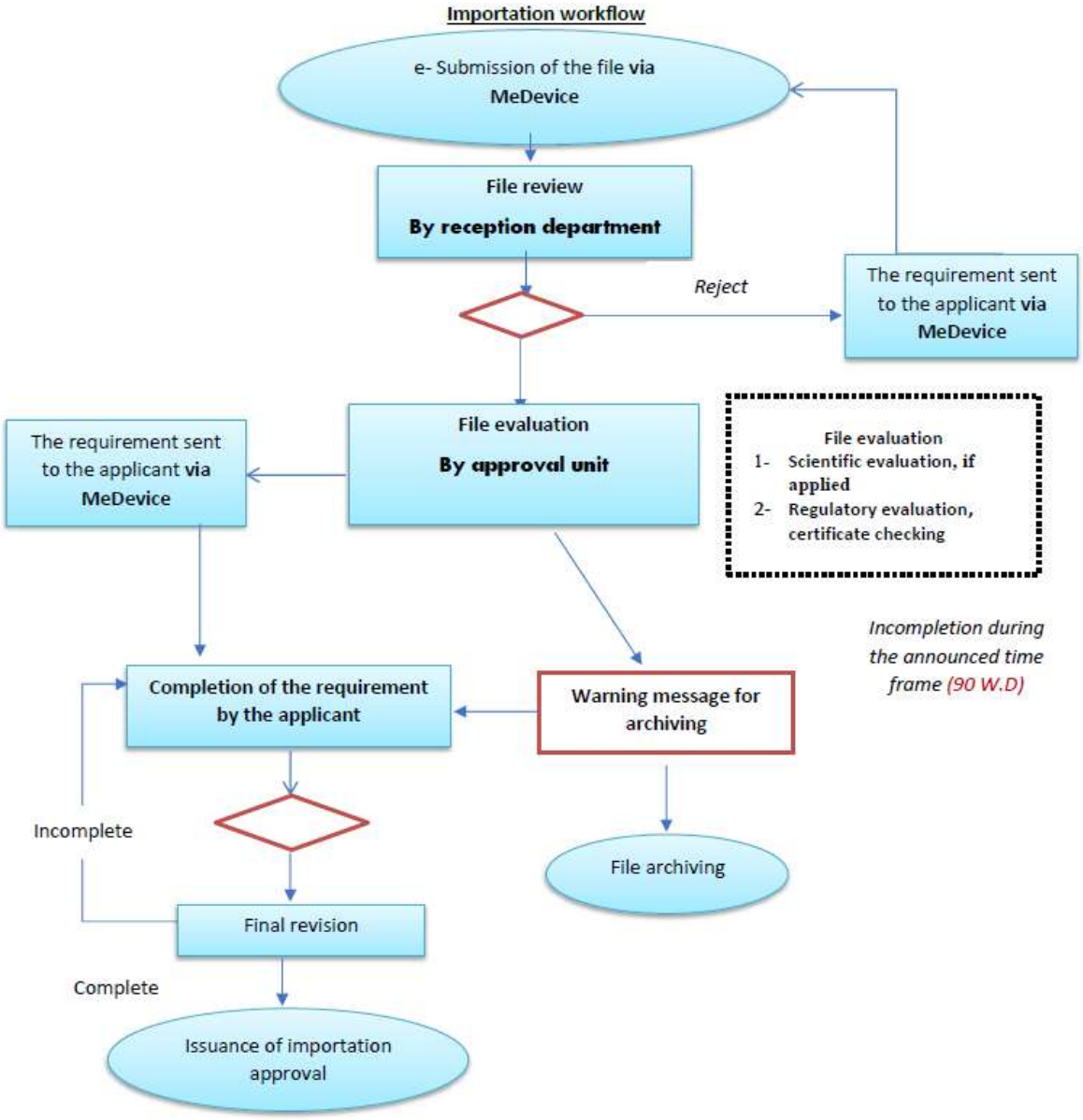
8. Reference Countries

Australia, Austria, Belgium, Bulgaria, Canada, Cyprus, Croatia, Czech Republic, Denmark, Estonia,
Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lichtenstein, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United States of America.

## 4. Procedures and rules governing the issuance of import permit

### 4.1 Procedures for issuing import permit for imported medical devices

**Importation workflow**



### 4.1.1 Procedures for receiving an import permit file:

1. Company applies at the following link:

https://medevice.edaegypt.gov.eg/

Fees are collected according to the fee category contained in the executive regulations of the law establishing the Egyptian Drug Authority (EDA) issued by Prime Minister's Decision No. 777 of 2020.

2. Company will receive the reply via medevice.edaegypt.gov.eg platform within two working days from the date of sending the request, stating the file is accepted, rejected or suspended until completion.

If the file is accepted: the application is forwarded to the Medical Devices Import approvals unit for study, and the requirements needed to be completed are then sent to the company via the medevice.edaegypt.gov.eg platform.

- In case the request is suspended until completion:

- If any of the required documents and data are not completed according to the list of documents required for each type of import approval within a period of 90 days starting from the date of sending the completion requests, the procedures for reviewing the file will be stopped, and the application will be considered rejected.

- The application procedures may resume through the same application number previously submitted within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

- If the application is rejected:

The request will be rejected if any of the data required in the company's request does not match the receipt or if the request does not fall within the jurisdiction of the requested department.

### 4.1.2 Procedures for evaluating import approval file

File is reviewed and the required completions are sent to the applicant via the platform medevice.edaegypt.gov.eg within three (3) working days from the date of receipt of the file.

### 4.1.3 Procedures for completing the file for obtaining import approval

The file is completed via the Me Device platform at the link: medevice.edaegypt.gov.eg

### 4.1.4 Issuing import permit:

After completing the file for obtaining import permit, an import permit is issued and will be valid for one year from the date of issuance.

### 4.1.5 Making an amendment to an import approval:

A request to amend import permit data is submitted on the Me Device platform at the link medevice.edaegypt.gov.eg, clarifying the required amendment and uploading documents supporting the request.

In case of amendment to the import permit (without affecting the value of the invoice) after its issuance:

- Fees for services are collected in accordance with the decision issued by EDA chairman in this regard.

- After completing the required documents, the amended import permit will be issued

In case the amendment is in the invoice value:

- The remainder of the fee is collected according to the invoice category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

- The amended import permit is issued

## 4.2 Procedures for importing medical devices for exhibitions, workshops and training

### 4.2.1 Procedures for receiving a file to obtain import approval

Applications are made on the Me Device electronic platform at the following link:

https://medevice.edaegypt.gov.eg/

Fees are collected according to the fee category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

2. Company will receive the reply via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request, stating that the file is accepted, rejected or suspended until completion.

- If the file is accepted:

- The request is forwarded to the Medical Devices Import approvals unit Unit for study, and the needed requirements are then sent to the company via the platform medevice.edaegypt.gov.eg

- If the request is suspended until completion:

- The procedures for proceeding with the file will be suspended if any of the documents and data required in accordance with Appendix II are not completed within a period of 32 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may be resumed using the same application number previously submitted within the following 90 days after paying the service fee for one time only. Otherwise, the application will be considered null and void.

- If the application is rejected:

- The request will be rejected if any of the data required in the request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

**4.2.2 Procedures for evaluating the file for obtaining import approval:**

The file is reviewed and the applicant will receive the requirements via the platform medevice.edaegypt.gov.eg within three working days from the date of receipt of the file.

**4.2.3 Procedures for completing the file for obtaining import approval:**

The file is completed via the platform medevice.edaegypt.gov.eg

**4.2.4 Issuing import permit:** After completing the file for obtaining import permit, an **import approval** is issued that is valid for one year from the date of issuance.

**4.2.5 Making an amendment to an import approval:**

A request to amend import permit data is submitted on the medevice.edaegypt.gov.eg platform, clarifying the required amendment and uploading documents supporting the request.

In case of an amendment to the import permit (without affecting the value of the invoice) after its issuance:

- Fees for services are collected in accordance with the decision issued by the EDA chairman in this regard.

- After completing the required documents, the amended **an import approval** will be issued

In the case that the amendment is in the invoice value:

- The remainder of the fee is collected according to the invoice category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

- The amended import permit is issued

**4.3 Procedures for importing medical devices for a research protocol**

**4.3.1 Procedures for receiving a file to obtain import approval:**

1. Application is made on the Me Device platform at the following link:

https://medevice.edaegypt.gov.eg/

Fees are collected according to the fee category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

2. The applicant will receive a response via the medevice.edaegypt.gov.eg platform within two working days from the date of sending the application, stating that the file is accepted, rejected or suspended until completion.

- If the file is accepted:

The application is forwarded to the Medical Devices Import approvals unit for study, and the applicant will receive the requirements via the platform: medevice.edaegypt.gov.eg

- If the request is suspended until completion:

- The procedures for proceeding with the file will be stopped if any of the documents and data required in accordance with Appendix IX are not completed for a period of 90 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may be resumed using the same previously submitted application number within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

- If the application is rejected:

The request will be rejected if any of the data required in the request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

### 4.3.2 Procedures for evaluating the file for obtaining import approval:

The file is reviewed and the required documents are sent to the applicant via the platform edevice.edaegypt.gov.eg within three working days from the date of receipt of the file.

### 4.3.3 Procedures for completing the file for obtaining import permit:

The file is completed via the platform medevice.edaegypt.gov.eg

### 4.3.4 Issuing import permit:

After completing the file for obtaining import permit, an import permit is issued and will be valid for one year from the date of issuance

### 4.3.5 Making an amendment to an import permit:

A request to amend import permit data is submitted on the medevice.edaegypt.gov.eg platform, clarifying the required amendment and uploading documents supporting the request.

In the case of an amendment to the import permit (without affecting the value of the invoice) after its issuance:

- Fees for services are collected in accordance with the decision issued by EDA chairman in this regard.

- After completing the required documents, the amended import permit will be issued

In that the amendment is in the invoice value:

- The remainder of the fee is collected according to the invoice category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

- The amended import permit is issued

## 4.4 Procedures for importing production inputs, components, and raw materials for local medical devices factories

### 4.4.1 Procedures for receiving a file to obtain import approval:

1. Company applies at the following link:

https://medevice.edaegypt.gov.eg/

The service fee issued by the head of EDA is collected.

2. Company will receive a response via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request, stating that the file is accepted, rejected or suspended until completion.

- If the file is accepted:

The request is forwarded to the Medical Devices Import approvals unit Unit for study, and the company will receive the requirements via the platform medevice.edaegypt.gov.eg

- If the request is suspended until completion:

- The procedures for proceeding with the file will be stopped if any of the documents and data required in accordance with Appendix IV are not completed for a period of 90 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may be resumed using the same previously submitted application number within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

If the application is rejected:

The request will be rejected if any of the data required in the company's request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

### 4.4.2 Procedures for evaluating a file for obtaining import approval:

The file is reviewed and the applicant will receive the requirements via the medevice.edaegypt.gov.eg platform within 2 working days from the date of receipt of the file.

### 4.4.3 Procedures for completing a file for obtaining import approval

File requirements are uploaded via the platform medevice.edaegypt.gov.eg

### 4.4.4 Issuing import permit:

After completing the file for obtaining the import permit, an import permit is issued and will be valid for one year from the date of issuance.

### 4.4.5 Making an amendment to an import approval:

A request to amend import permit data is submitted on the Me Device platform at the link medevice.edaegypt.gov.eg, clarifying the required amendment and uploading documents supporting the request.

In case of an amendment to the import permit (without affecting the value of the invoice) after its issuance:

- Fees for services are collected in accordance with the decision issued by EDA chairman in this regard.

- After completing the required documents, the amended import permit will be issued

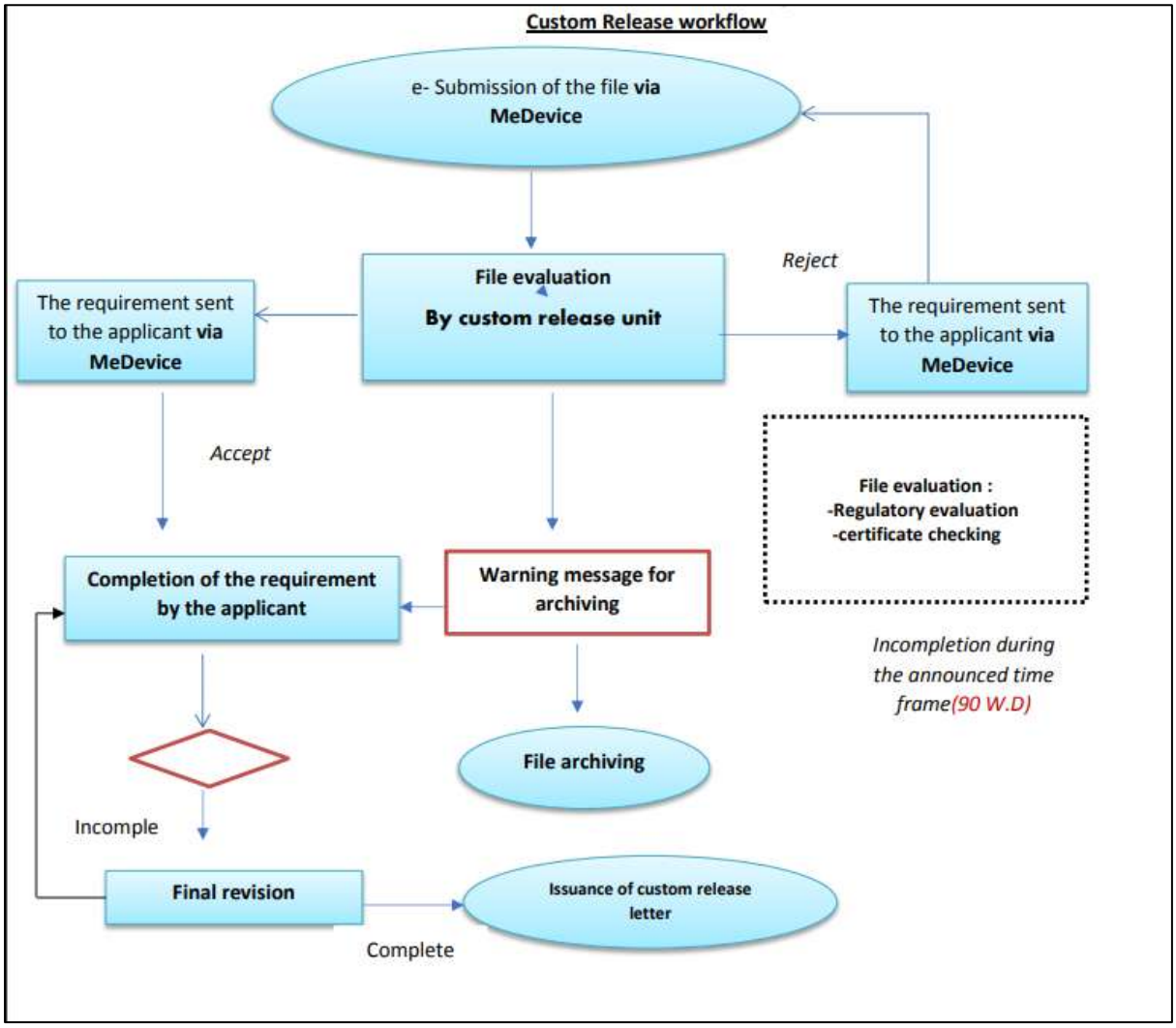
In case the amendment is in the invoice value:

- The remainder of the fee is collected according to the invoice category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

- The amended import permit is issued.

## 4.5 Procedures for issuing approval for custom release

**Custom release workflow**




Procedures for the release of medical devices for which import permit has been issued (for each individual invoice or annual plan) are conditional on the medical customs clearance and include:

- Import approval for registered medical devices,
- Registration samples,
- Raw material analysis samples,
- Import permits obtained by the approval's unit,
- Medical Devices with annual import plans,
- Intragastric balloon.

### 4.5.1 Procedures for receiving a file for obtaining customs release

1. Company applies at the following link:

https://medevice.edaegypt.gov.eg

Fees are collected according to the fee category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2022.

2. Company will receive a response via the platform medevice.edaegypt.gov.eg, stating that the file is accepted, rejected or suspended until completion on the same day of submission if it is submitted before two o'clock in the afternoon and after a working day if submitted after two o'clock in the afternoon.

- If the file is accepted:

- The request is forwarded to the Customs Release Unit for study, and the company will receive the requirements.

- In case the request is suspended until completion:

- The procedures for reviewing the file will be stopped if any of the documents are not completed in accordance with Appendix V for a period of (90) days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may be resumed using the same previously submitted application number within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

If the application is rejected:

- The request will be rejected if any of the data required in the company's request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

### 4.5.2 Procedures for evaluating a file and obtaining approval for customs release:

The file will be reviewed and the required documents will appear on the platform medevice.edaegypt.gov.eg on the same day of submission if submitted before two o'clock in the afternoon and after a working day if submitted after two o'clock in the afternoon.

### 4.5.3 Procedures for completing a file to obtain approval for customs release:

The file is completed via the Me Device platform at the link: medevice.edaegypt.gov.eg

### 4.5.4 Issuing approval for customs release:

After completing the file for obtaining customs release, approval is issued.

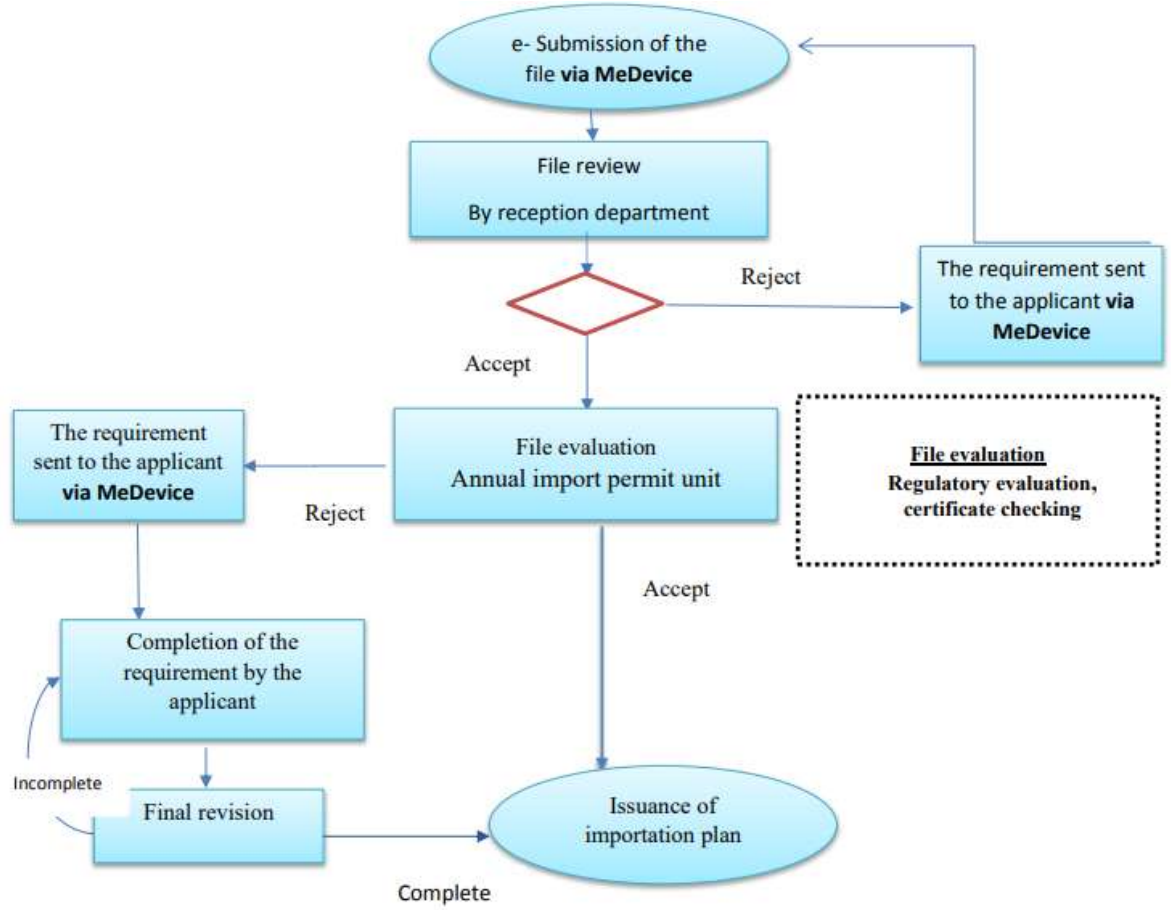
### 4.5.5 Make an amendment to customs release permit:

- A request to amend the approval data made on the Me Device platform at the link medevice.edaegypt.gov.eg, clarifying the required amendment and uploading documents supporting the request.

- After completing the required documents, the amended customs release letter will be issued.

## 5. Procedures for issuing an annual import plan through the Medical Devices Import Plans Unit

**Annual Importation Plan Flow Chart**




### 5.1 Procedures for receiving a file to obtain an annual plan:

1. Company applies via the platform at the following link:

https://medevice.edaegypt.gov.eg

The service fee issued by EDA chairman in this regard shall be collected.

2. Company will receive a response via the platform medevice.edaegypt.gov.eg within 3 working days from the date of sending the request, stating that the file is accepted, rejected or suspended until completion.

- If the file is accepted:

The request is forwarded to the Medical Devices Import Plan Unit for study, and requirements are sent to the company.

- If the request is suspended until completion:

- The procedures for proceeding with the file will be stopped if any of the documents and data required in accordance with Appendix VI are not completed for a period of 90 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may resume through the same application number previously submitted within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

- If the application is rejected:

The request will be rejected if any of the data supplied in the company's request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

## 5.2 Procedures for evaluating a file for obtaining an annual import plan:

The file is reviewed and requirements are sent to the applicant via the platform medevice.edaegypt.gov.eg within three working days from the date of receipt of the file.

## 5.3 Procedures for completing a file to obtain an annual import plan:

The file is completed via the MeDevice platform at the link medevice.edaegypt.gov.eg

## 5.4 Issuing annual import plan:

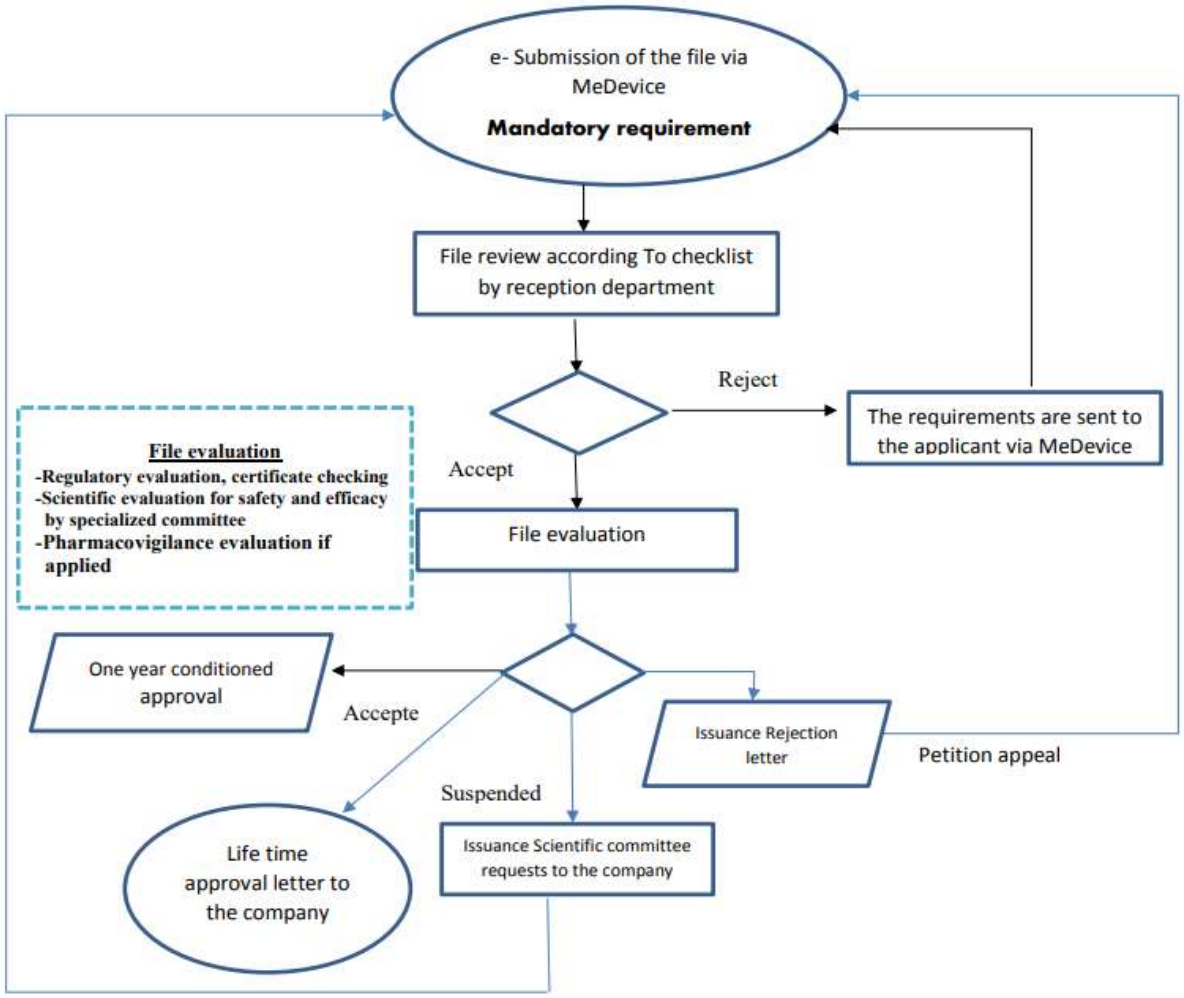
After completing the file for obtaining an import plan, an annual import plan will be issued and will be valid for one year from the date of issuance.

## 5.5 Making an amendment to the annual plan:

- A request to amend the annual plan is submitted on the MeDevice platform at the link medevice.edaegypt.gov.eg, clarifying the required amendment and uploading documents supporting the request.

- After completing the required documents, the amended plan will be issued

## 6. Procedures and rules governing the scientific evaluation unit




- Scientific committees are divided into different specializations and files are presented to them according to the purpose of use of the device,

Devices that are subject to evaluation by specialized scientific committees as a prior step to obtaining an import permit are as follows:

1) Devices classified as Class IIb, Class III and whose country of origin is a non-reference country,
2) Non-sterile medical devices in dosage form of all types,
3) Devices manufactured in a non-reference country that works with new technology, whatever their classification,
4) Inquiries received from the Egyptian Tax Authority to determine whether or not the product is transplantable and prosthetic, and to communicate the Tax Authority with the technical opinion to take the necessary measures regarding whether or not the product is subject to value-added tax.

## 6.1 Procedures for receiving a file to obtain permit from Scientific Evaluation Unit

1. Apply at the following link:

https://medevice.edaegypt.gov.eg

The service fee issued by EDA chairman in this regard shall be collected.

2. Applicant will receive a response via the medevice.edaegypt.gov.eg platform within three working days from the date of sending the application, stating that the file is accepted, rejected or suspended until completion.

- If the file is accepted:

- The request is forwarded to the Scientific Evaluation Unit for study

- Requirements are sent to the applicant via the medevice.edaegypt.gov.eg platform

- If the request is suspended until completion:

- The procedures for reviewing the file will be stopped if any of the documents and data required in accordance with Appendix VII are not completed for a period of 90 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may resume through the same application number previously submitted within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

- If the application is rejected:

The request will be rejected if any of the data required in the company's request does not match the receipt or the request does not fall within the jurisdiction of the requested department.

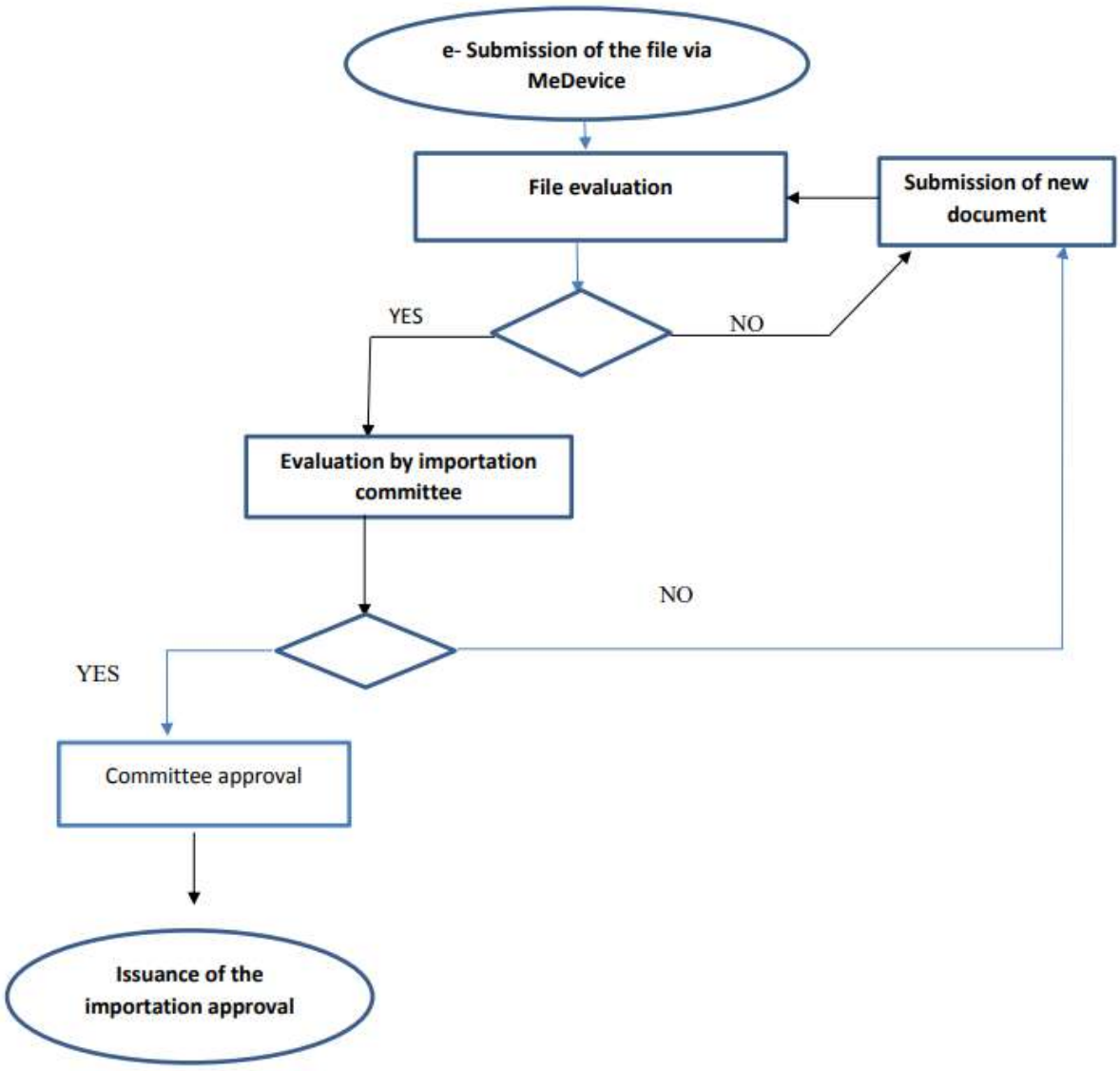
## 6.2 File evaluation procedures for obtaining permit from Scientific Evaluation Unit

1. File is presented to the specialized scientific committee which issues its decision, either by acceptance, postponement, or reasoned rejection.

2. In case of rejection: Applicant has the right to file an appeal against the committee's decision, provided that applicant submits new documents that have not previously been submitted to the committee, or presents a scientific explanation for the points of rejection.

3. In that the committee's decision is issued for a period of one year, with re-evaluation by the Medical Devices Safety Department: After the conclusion of the Scientific Committee's decision, a signed and sealed list of the names of the hospitals supplied with the device shall be submitted so that the Safety Department can conduct questionnaires to verify the safety and effectiveness of the device and present them to the Scientific Evaluation Committee.

## 7. Import procedures for import requests for the Special Import Requests Evaluation Unit




### 7.1 Types of special import requests include the cases when the medical device is:

- Donation for hospitals,
- Imported by a hospital,
- Imported by individuals for personal use,
- Imported by a physician,
- Imported by a company that does not have an activity related to importing medical devices,
- Imported by a company for a hospital or patient and the company has an activity related to medical devices and importing devices.

## 7.2 Steps to obtain import permit from Special Import Application Evaluation Unit:

### 7.2.1 Procedures for receiving a file to obtain import permit

1. Applicant applies at the following link:

https://medevice.edaegypt.gov.eg

The service fee issued in this regard will be collected.

2. Company will receive a response via the platform medevice.edaegypt.gov.eg within three working days from the date of sending the request, stating that the request is accepted, rejected or suspended until completion.

- If the file is accepted:

- The request is forwarded to the Special Import Requests Evaluation Unit,

- Requirements are sent to the applicant via the medevice.edaegypt.gov.eg platform.

- If the request is suspended until completion:

- The procedures for proceeding with the file will be stopped if any of the documents and data required in accordance with Appendix VIII are not completed within a period of 90 days starting from the date of sending the completion requests, and the request is considered rejected.

- The application procedures may resume through the same application number previously submitted within the following 90 days after paying the service fee for one time only, otherwise the application will be considered null and void.

- If the application is rejected:

The application will be rejected if any of the required data in the submitted application does not match the receipt or the application does not fall within the jurisdiction of the requested department.

### 7.2.2 Procedures for evaluating a file for obtaining special import permit

The file is reviewed and the requirements will appear on the medevice.edaegypt.gov.eg platform within 3 working days from the date of receipt of the file.

### 7.2.3 Procedures for completing a file for obtaining a special import permit

File requirements are uploaded via the platform medevice.edaegypt.gov.eg.

- If the applications are met, the file will be presented to the committee.

- Import Committee issues its decision either by acceptance, postponement or rejection, explaining the reasons for the rejection or postponement.

- In case of rejection, the applicant has the right to submit an appeal against the committee's decision, provided that the applicant submits new documents that have not previously been submitted to the committee, or presents a scientific clarification for the points of rejection.

### 7.2.4 Issuing import permit

After obtaining the committee's approval, an import permit will be issued and will be valid for one year from the date of issuance

### 7.2.5 Procedures for making amendment to an import permit

A request to amend import permit data is submitted on the Me Device platform at the link medevice.edaegypt.gov.eg, clarifying the required amendment and uploading documents supporting the request.

In case of an amendment to the import permit (without affecting the value of the invoice) after its issuance:

- Fees for services are collected in accordance with the decision issued by EDA chairman in this regard,

- After completing the required documents, the amended import permit will be issued.

In case that the amendment is in the invoice value:

- The remainder of the fee is collected according to the invoice category contained in the executive regulations of the law establishing EDA issued by Prime Minister's Decision No. 777 of 2020,

- The amended import permit is issued.

## 8. List of required documents:

Appendix I: Documents required to obtain import permit for imported medical devices

8.1.1 Documents required to obtain import permit for registered sterile devices

8.1.2 Documents required to obtain import permit for non-sterile medical devices

8.1.3 Documents required to obtain import permit for medical devices as samples

Appendix II: Documents required to obtain import permit for devices imported for medical activities

Appendix III: Documents required to obtain import permit for incoming devices for a research protocol

Appendix IV: Documents required to obtain import permit for inputs, production components, and raw materials for local medical devices factories

Appendix V: Documents required for custom release

8.5.1 In the case of importing samples for registration

8.5.2 In the case of importing devices for which an import permit has been issued

8.5.3 In the case of importing export devices that have an annual import plan

Appendix VI: Documents required to obtain annual import plans

Appendix VII: Documents related to requests for presentation to specialized scientific committees

8.7.1 (Orthopaedic Committee)

8.7.2 In the case of medical devices in dosage forms

8.7.3 Medical devices of all types (general)

Appendix VIII: Documents required for special import requests

8.8.1 In the event that the imported device is a donation for hospitals

8.8.2 In the event that the hospital is the importer

8.8.3 In the event that an individual imports a product for personal use

8.8.4 In the event that the device is imported by a physician

8.8.5 In the event that the device is imported by a company with activities related to medical devices

8.8.6 In the event that the device is imported by a company with activities not related to medical devices

Appendix IX: Documents required to issue a letter of lack of jurisdiction

Appendix X: Quality and trading certificates according to classification

## Appendix I

### 8. Documents required for each type of application

### 8.1.1 Documents required to request import approval for registered medical devices

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| 1. The importing company's mandate to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. Payment receipt with the invoice number supplied and stamped with the Authority's stamp. |
| 3. Proforma invoice |
| 4. In the case of repair and restoration of cochlear implant: the invoice with which the export was made is required |
| 5. The report on the repair and restoration of cochlear implant |
| 6. In the case of tenders for the Unified Purchasing Authority: It is required to determine whether the storage location is in the warehouses of the Authority or in the importing company. |
| 7. A license of medical devices importers registerer, in addition to the importing or manufacturing company |
| 8. Form-14(c14) for agents if indicated in the registration license |
| 9. The distribution or agency contract with the supplier is valid, if referred to in the registration license or mentioning the term "for some products", authenticated by the Chamber of Commerce and the Egyptian Embassy.<br><br>- In the case of tenders: A tender contract and authorization of the agent is required to complete the procedures for obtaining the necessary import permits. |
| 10. In the case that the manufacturing company and supplier are different: The relationship shall be shown, including the supplier's right to supplying the devices imported into Egypt, issued by the foreign factory and authenticated by the Chamber of Commerce and the Egyptian Embassy. |
| 11. A valid notification of registration issued by the General Administration of Registration |
| 12. In the case of variation of a registered medical device (the presence of any discrepancy between the notification data and the device data indicated in the invoice): Submit letters issued by the Variations Department at the General Administration of Registration regarding notification of registration.<br>Or<br>Submit the initial acceptance number for requesting variations to the General Administration of Registration |
| 13. In the event of certificates including different postal codes: Submit a clarification letter issued by the manufacturer stating that the change appearing in some numbers in the manufacturer's address is a change in the postal code. |
| 14. If some data related to what is required in the notification is not clear when compared with the invoice or renewed quality certificates: Manufacturer's manual(catalogue)l is presented, explaining the use of the product, its models and codes. |
| 15. If some data is not clear after matching the notification, invoice, and renewed certificates, a Declaration Certificate will be requested, including but not limited to the address of one of the manufacturers and the classification of the product. |
| 16. In the event of the expiration or invalidity of the trading and quality certificates (free sale +CE or FDA) mentioned in the notification of registration: They shall be submitted as indicated in the classification shown in Appendix X. |

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| 17. If the FDA certificate contains a factory under the name Owner/ Operator, the legal factory shall submit a letter explaining the status of each of them is submitted. |
| 18. The specialized scientific Committee's decision to approve the import of the devices (in the case of individuals or hospitals importing sterile devices that are not registered or custom made). |
| 19. If the registration applicant name mentioned in the valid notification of registration (an item previously registered for another entity) differs from that of the applicant and the original notification is not present with the new agent, the following shall be submitted:<br>- The notarized contract between the new agent and the foreign company,<br>- A letter issued by the foreign supplier stating the end of the contractual with the old agent,<br>- The initial acceptance number for the registration file at the General Administration of Registration.<br>Note: Refer to Item No. 1 in the instructions below. |

**Special guidance:**

1. As for medical devices submitted for registration (new registration), they will not be released except after the issuance of their notification of registration, except in the following two cases:

- The item was previously registered and there is a change in the raw materials of the item submitted for registration from the registered item.
- The item was previously registered with only a change in the name of the applicant and other variations within the variation list.

In both cases, the company is given a period of one year for release, starting from the date of acceptance of the file by the General Administration of Registration.

2. Regarding medical devices submitted for re-registration:

- The file acceptance number is provided by the General Administration of Registration

If the data provided to the administration is identical with that coming from it, the company will be given a period of one year for release, starting from the date of acceptance of the file.

### 8.1.2 Documents required to obtain an import approval for non-sterile medical devices

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| 1. The importing company's mandate to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. Proforma invoice |
| 3. The registration license of medical devices importers register:<br>* Added to the supplier or manufacturer based on the relationship letter |
| 4. Form-14 for agents if indicated in the registration license. |
| 5. The distribution or agency contract with the supplier is valid and authenticated by the Chamber of Commerce and the Egyptian Embassy<br>- In case of tenders, the tender contract and the agent's authorization are presented. |
| 6. In the event that the manufacturing company differs from the supplier: the relationship between them is presented, including the right of the supplier to device the devices imported into Egypt, issued by the foreign factory, authenticated by the Chamber of Commerce and the Egyptian Embassy. |

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| 7. The payment receipt, stamped by the administration and the invoice number is written on it. |
| 8. Regarding hospitals:<br><br>Submit the hospital license issued by the Free Therapy Administration and the Commercial Registry stating that the hospital's activities include the importing of medical devices or that it is subject to the Investment Authority Law. |
| 9. A valid notification of registration issued by the General Administration of Registration<br><br>or<br><br>Provide the initial registration file acceptance number for the devices subject to registration |
| 10. In the case of variations (the presence of any discrepancy between the notification data and the data of the requirement mentioned in the invoice), submit the letters issued by the Variations Department at the General Administration of Registration with respect to the notification of registration.<br><br>or<br><br>submit the initial acceptance number for requesting variations to the General Administration of Registration. |
| 11. If the name of the applicant for registration in the valid notification of registration (a device previously registered for another entity) differs from that of the applicant and the new agent does not have the original notification, submit the following:<br><br>- The notarized contract between the new agent and the foreign company.<br>- A documented letter issued by the foreign supplier stating the end of the contractual relationship with the old agent<br>- The initial acceptance number for the registration file at the General Administration of Registration |
| 12. If the postal codes in the certificates are different, submit a clarification letter issued by the manufacturer stating that the apparent difference in some numbers in the manufacturer's address is a change in the postal code of quality certificates. |
| 13. The manufacturer's manual showing the medical devices contained and their conformity (model or code), indicating the intended use.<br><br>If the manual does not explain how to use it, submit a letter from the manufacturer explaining the intended use. |
| 14. the trading and quality certificates required according to the classification: Appendix X |
| 15. If the device is in dosage form, refer the device together with the above documents - according to classification – to the specialized scientific committees to obtain import permit. |
| 16. In the case of dental devices, the following must be submitted:<br><br>- Hand pieces: Provide evidence that they are autoclavable by submitting the original factory manual, a certified letter of origin from the manufacturer, or the manufacturer's official website.<br>- In the event of importing components, adhesives, amalgam capsules, files, burs, examination gloves (or any new items in accordance with the decision of the Scientific Committee): A sample shall be drawn annually from the incoming shipment for analysis at one of the agencies |

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| accredited by EDA, to be determined by the competent administration before issuing the import permit.<br>If a decision is issued to conform to the specifications, an import permit will be issued. |
| 17. In the event of importing medical gas outlets, ceiling pendant or bed head unit from a non-reference country, a free sale certificate from a reference country shall be presented. |

**Instructions for obtaining an import permit for a non-sterile medical device:**

1. Regarding non-sterile surgical instruments, non-sterile laparoscopic surgery instruments, and non-sterile orthopaedic surgical devices that are transplanted within the body coming from a non-reference country:

Samples are drawn from the first shipment for analysis at an accredited body determined by the competent administration, and its technical report is considered valid for a full year for the same manufacturing materials and same manufacturer.

2. Regarding orthopaedic devices that are transplanted within the body coming from a non-reference country, inspectors of the Central administration of inspection on pharmaceutical institutions shall take samples for the purpose of analysis for each category at the Faculty of Engineering, Ain Shams University, and its technical report will be valid for a full year for the same manufacturing materials and same manufacturer.

3. Class IIb & III medical devices coming from non-reference countries are referred to specialized scientific committees.

4. Imported non-sterile medical gloves must be powder free, their brand name and the register of medical devices importers be written in the certificates, and samples be taken for analysis annually at the Faculty of Dentistry, Ain Shams University.

5. Import of oral and nasal route medical devices is only allowed after obtaining a notification of registration.

6. As for medical devices submitted for registration (new registration), they will not be released except after the issuance of their notification of registration, except in two cases:

- It was previously registered and there is a change in the raw materials of the device submitted for registration from the registered item.
- It was previously registered with only a change in the name of the applicant and other variations within the list of variations.

In both cases, the company is given a period of one year for release, starting from the date of acceptance of the file by the General Administration of Registration.

7. Regarding medical devices submitted for re-registration:

- The file acceptance number is provided by the General Administration of Registration.

If the data provided to the administration is identical with that coming from it, the company will be given a period of one year for release, starting from the date of acceptance of the file.

**8.1.3 Documents for requesting an import approval for samples for any of the following purposes:**

- Evaluation and study
- Presentation to scientific committees
- Analysis
- Marketing

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| 1. The importing company's mandate to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. Proforma invoice |
| 3. A license of medical devices importers registerer,<br>Or the license of the scientific office and the importing company. |
| 4. In the case that the manufacturing company and supplier are different: The relationship shall be shown, including the supplier's right to supplying the devices imported into Egypt, issued by the foreign factory and authenticated by the Chamber of Commerce and the Egyptian Embassy. |
| 5. In the case of importing samples for evaluation for the first time, a letter is required from the manufacturer stating that there is no agent in Egypt. |
| 6. Regarding hospitals:<br><br>Submit the hospital license issued by the Free Therapy Administration and the Commercial Registry stating that the hospital's activities include the importing of medical devices or that it is subject to the Investment Authority Law. |
| 7. The payment receipt stamped with the Authority's seals and the invoice number is written on it. |
| 8. For the registered devices, submit a valid notification of registration issued by the General Administration of Registration.<br>To apply for registration, provide the acceptance number of the initial registration file for the devices subject to registration. |
| 9. For variations (the presence of any discrepancy between the notification data and the data of the requirement stated in the invoice), submit the letters issued by the Variations Department at the General Administration of Registration regarding the notification of registration.<br>or<br>Submit the initial acceptance number for the variation request to the General Administration of Registration. |
| 10. The manufacturer's manual showing the medical devices contained and their conformity (model or code) and explaining the intended use. |
| 11. If the device is in dosage form, refer the device together with the above documents - according to classification – to the specialized scientific committees to obtain import permit. |

**Instructions for importing samples:**

1. Importing samples for evaluation or study:

* Samples for sterile medical devices:

- It is allowed to import a sample of each size or type, provided that the invoice quantity does not exceed 10 pieces.

- Submit certificates according to classification (Appendix X).

- For a single item, samples are allowed to be imported only once for the same manufacturer, and the company is excluded from all quality certificates except the DOC and CE certificates.

- If proof is presented that the product contained in a non-sterile form or in demo form is exempt from quality certificates

* Samples for non-sterile devices:

- Only one sample of each size or type is allowed to be imported, provided that the invoice quantity does not exceed 10 pieces.

- All quality certificates are excluded and the declaration certificate will be considered sufficient, with the company's pledge that if goods are brought, the company will be committed to all quality certificates.

2. Importing samples for scientific evaluation for presentation to the scientific committee:

Invoice quantities must not exceed one piece of each item, with proof that the import is required for scientific evaluation and its quality certificates must be submitted in full according to the classification of the item.

3. Importing samples for analysis at the Faculty of Engineering to be presented to the specialized scientific committee:

- The quantities mentioned in the invoice are required to be 3 pieces of each type.

- In the absence of a contract with the manufacturer (supplier), the company is obligated to submit a letter from the factory stating that it does not have an agent in Egypt.

- Quality certificates are provided according to classification.

4. Samples for marketing (advertising):

Only scientific offices have the right to import samples for the purpose of advertising and marketing, printed on them that they are samples for advertising and not for sale. The central administration of licensing of pharmaceutical institutions shall verify this, and importing scientific offices are obliged to provide all quality certificates for the medical device according to its classification.

## Appendix II

**Documents required to obtain import approval for imported devices for medical events**

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| 1. The importing company's mandate to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. ID card of the authorized person by the company |
| 3. Proforma invoice indicating the date of the conference or the workshop if possible. |
| 4. If the applicant is a company that imports medical devices, a license is required to register in the registerer of medical devices importers. |

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| - In the event that the importing applicant is a scientific office, the license of the scientific office is required, in addition to the supplier |
| 5. The manufacturer's manual, indicating imported item. |
| 6. For hospitals:<br>- Submit the hospital license issued by the Free Therapy Administration<br>- Submit the Commercial Registry stating that the hospital's activities include the importing of medical devices or that it is subject to the Investment Authority Law. |

**Instructions for requesting an import approval for devices imported for medical events:**

Instructions for requesting an import permit for non-sterile medical devices:

- For the imported items that are used for workshops, training, conferences and scientific exhibitions, provided that they are not used on humans and are used on plastic models or human specimens in the Anatomy Department, import may be allowed, taking into account the following:

- The date of the conference or workshop is mentioned in the invoice (if possible)

If it is not mentioned in the invoice, submit a letter from the party hosting the event stating its date and venue.

- The company is committed to providing proof of re-export immediately after the end of the workshop or conference, Central administration of inspection on pharmaceutical institutions

- The party hosting the event shall submit a pledge that the imported item will not be used on humans.

## Appendix III

**Documents required to obtain import approval for imported devices for a research protocol**

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| 1. The importing company's mandate to the university or person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped, with the signature being verified by the bank. |
| 2. ID card of person mandated from the company, university or research body applying for import. |
| 3. Proforma invoice indicating the No. of protocol, name of the researcher, and name of the university. |
| 4. If the applicant is a company that imports medical devices, a license is required to register in the registerer of medical devices importers.<br>- In the event that the importing applicant is a scientific office, the license of the scientific office is required. |
| 5. Approval of the institutional committee for reviewing medical research ethics in the research body registered with the Supreme Council for Review of Clinical Medical Research Ethics, stating the protocol number, the name of the researcher, and the entities in which the clinical trials are being conducted. |
| 6. A letter from the foreign factory stating the manufacturing locations, the country of origin of the imported items, and the country of origin if it differs from the supplier. |
| 7. The manufacturer's manual, indicating the content. |
| 8. The payment receipt is stamped with the General Administration of Registration's seals and the invoice number is written on it. |

**Instructions for submitting an import permit for a research protocol:**

In the event that companies or hospitals import sterile or non-sterile devices for use in protocols approved by the institutional committee for reviewing medical research ethics at the research entity, the available quality certificates will be issued (if available).

Or

Notification of registration, based on the original protocol provided.

## Appendix IV

**Documents required to obtain import approval for production inputs, components, and raw materials for local medical devices factories**

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| 1. The importing company's mandate to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. Proforma invoice for items to be released. |
| 3. Factory license (indicating factory's activities) or factory data certificate issued by The central administration of licensing of pharmaceutical institutions affiliated with the Central Department of Operations |
| 4. A valid industrial register (indicating factory's activities) |
| 5. Commercial register |
| 6. Tax card |
| 7. Operating license from the General Authority for Industrial Development |
| 8. CE certificate for finished product |
| 9. ISO13485:2016 certificate for the factory |
| 10. An analysis certificate for the imported raw materials indicating their manufacturing standards |
| 11. Declaration of conformity certificate |
| 12. Valid notification of registration for the finished product (in the case of sterile devices) |
| 13. In the case of submitting a re-registration file, submit the initial admission number |
| 14. Conformity of materials and components stated in the notification of registration or composition statement if the final product is not sterile |
| 15. List of approved suppliers for the factory. |
| 16. Pledge of the factory's responsibility for the availability of complete data on imports, without any responsibility on the part of EDA |

**Special instructions:**

1. Medical devices directly related to human blood are not permitted to be released in non-sterile bulk form, with the exception of medical gloves only.

2. Local factories may not import finished medical devices other than samples received for study and evaluation or similar manufacturing of single-use medical devices.

3. Imported raw materials and components must contain at least the following information:

- Trade name (if present)

- Product name

- Product code or Ref. (if applicable)

- Batch number or lot no (if necessary)

- Any special handling precautions (if present).

- Any special storage precautions (if present).

- Expiry date (at least in terms of year and month) in accepted format (if applicable):

i.e., clear identification of the time limit for using the product (in month/year format at least).

For example: expires on 12-2025

Or manufacturing date and shelf-life time;

For example: manufactured on 12-2020, shelf life: 3 years

4. No raw materials or components will be released to produce any medical devices that do not meet the conditions for trading in the local market under any name.

5. Import is allowed if the factory wishes to import samples of raw materials or components for the purpose of production for evaluation or testing of the production line.

6. In the event of the imported shipment containing large quantities, the evaluation is carried out through the Import Committee.

7. In the case of variations (the presence of any difference in the raw materials stated in the notification of registration), the factory is obligated to submit letters issued by the Variation Department of the General Administration of Registration stating the necessary change to the notification of registration or the documents required to prove that the received raw materials conform to the specifications.

8. Factory is fully committed to using the imported materials and components contained for the purposes for which they were approved.

9. In the case of raw materials for dental devices, it is not permitted to import raw mercury or amalgam powder except to local factories that manufacture amalgam capsules, in accordance with the industrial registry.

10. In the event of importing polyurethane, it will be released until its expiration date.

## Appendix V

**Documents required for custom release**

**8.5.1 For importing samples for registration, the following are required:**

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| 1. A pledge on the importing company's letterhead, signed and stamped by the manager in charge, stating that the imported item is for the purpose of registration and not for sale or trade. |
| 2. The importing company's mandate to the person in charge of dealing with the General Administration of (marketing authorization), signed and stamped by the company's manager, with the signature being verified by the bank. |

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| 3. Commercial invoice, stamped by the factory, indicating the sequence of the number of pages and the country of origin for each item.<br>Note: If the original commercial invoice is not submitted, provide a written pledge stating that the submitted invoice is identical to the original invoice submitted at the Customs Department and uploaded to the ACI system. |
| 4. Company's plan to submit a registration file with a pledge not to sell or trade and to hold legal responsibility for any violation. |
| 5. Packing list included with the shipment. |
| 6. A bill of lading linked to the commercial invoice. |

### 8.5.2 For importing devices with import approval, the following are required:

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| 1. A pledge on the importing company's letterhead, signed and stamped by the manager in charge, stating that the invoice will not be opened unless an inspector from the Central administration of inspection on pharmaceutical institutions |
| 2. The importing company's mandate to the person in charge of dealing with the General Administration of (marketing authorization), signed and stamped by the company's manager, with the signature being verified by the bank. |
| 3. Commercial invoice, stamped by the factory, indicating the sequence of the number of pages and the country of origin for each item.<br>Note: If the original commercial invoice is not submitted, provide a written pledge stating that the submitted invoice is identical to the original invoice submitted at the Customs Department and uploaded to the ACI system. |
| 4. Company's plan to submit a registration file with a pledge not to sell or trade and to hold legal responsibility for any violation. |
| 5. The import approval (stamped) that the company previously obtained from the General Administration of (marketing authorization), accompanied by the proforma invoice. |
| 6. Certificate of origin linked to the commercial invoice (in case the origin is not clearly stated on the invoice) |
| 7. Packing list included with the shipment. |
| 8. A bill of lading linked to the commercial invoice. |
| 9. (Registration license) on which the invoice items are matched by numbers. |
| 10. (Free sale) and quality certificates required according to the classification in the event they are expired/invalidated in the import permit. |

### 8.5.3 For importing medical devices with annual import plan, the following are required:

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| 1. A pledge on the importing company's letterhead, signed and stamped by the manager in charge, stating that the invoice will not be opened unless an inspector from the Central administration of inspection on pharmaceutical institutions |
| 2. The importing company's mandate to the person in charge of dealing with the General Administration of (marketing authorization), signed and stamped by the company's manager, with the signature being verified by the bank. |
| 3. Commercial invoice, stamped by the factory, indicating the sequence of the number of pages and the country of origin for each item.<br>Note: If the original commercial invoice is not submitted, provide a written pledge stating that the submitted invoice is identical to the original invoice submitted at the Customs Department and uploaded to the ACI system. |

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| 4. License of medical devices importers registerer, provided that it should include the importing or manufacturing company in accordance with the relationship letter |
| 5. Form-14 for agents if indicated in the registration license |
| 6. Valid distribution or agency contract with the supplier, if found in the license. |
| 7. In the case that the manufacturing company and supplier are different: The relationship shall be shown, including the supplier's right to supplying the devices imported into Egypt, issued by the foreign factory and authenticated by the Chamber of Commerce and the Egyptian Embassy. |
| 8. If the address of the importing company in the invoice differs from its address in the License of medical devices importers registerer, submit the tax card and commercial register of the importing company. |
| 9. The valid import plan the company had previously obtained from the General Administration of (marketing authorization). |
| 10. (Free sale) and quality certificates required according to the classification in the event that they expire/are not valid in the import plan. |
| 11. Certificate of origin linked to the commercial invoice (in case the origin is not clearly stated on the invoice). |
| 12. Packing list included with the shipment. |
| 13. A bill of lading linked to the commercial invoice. |
| 14. Valid Registration License |

## Appendix VI

### Documents required to obtain annual import plans

### First: Registered medical devices

1. The importing company's mandate to the person in charge of dealing with the General Administration of Marketing Authorization, signed and stamped by the company's manager, with the signature being verified by the bank.

2. License of medical devices importers registerer, in addition to the importing or manufacturing company in accordance with the relationship letter

3. Form-14 for agents

4. The distribution or agency contract with the supplier, valid and authenticated by the Chamber of Commerce and the Egyptian Embassy if it is referred to as a registration license or mentions the term for some products.

5. In case of the manufacturer differs by notifying the said company of the licence to register, a contract shall be requested between them, including the supplier's entitlement to supply supplies to Egypt or the Middle East issued by the foreign factory documented by the Chamber of Commerce and the Egyptian Embassy.

6. A valid Registration License issued by the General Administration of Registration.

7. In the case of variations, submit letters issued by the General Administration of Registration (Variation Administration) regarding the Registration License.

8. If there is a change in the Registration License (for example, cancellation of codes or change in factory data):

- Provide the variation file acceptance number for the notification of registration,
- Provide a pledge to complete the import plan before one year has passed from the date of acceptance of the variation file.

9. In the event of cancellation of codes or packages:

- Manufacturer shall submit a letter indicating its responsibility and explaining all the reasons for deleting the code or packaging,
- Importer shall submit a pledge to adhere to the procedures followed by the General Administration for Pharmaceutical Vigilance.

11. In the event that some data related to what is required in the notification or renewed quality certificates is not clear, present the manufacturer's manual, explaining the use of the product, its models, and its codes.

12. A clarification letter in case some data mentioned in the notification and documents are not clear.

13. The last import plan obtained for renewing the plan.

14. If the postal codes in the certificates are different, submit a clarification letter issued by the manufacturer stating that the apparent difference in some numbers in the manufacturer's address is a change in the postal code.

15. In the event that one or all of the Free Sale and quality certificates are expired or no longer valid in the Registration License, the valid renewed certificates shall be submitted according to classification (Appendix 10).

## Second: Production raw materials and components for manufacturing medical devices for all raw material suppliers to the factory

The procedure is optional for the factory, as the factory has the right to apply for an annual import plan for its raw materials or to apply for an import permit for each invoice separately.

The Central Administration for Medical Devices issues an annual import plan for raw materials and production components for the production of medical devices to all suppliers of raw materials to the factory for the fiscal year.

The Central Administration for Medical Devices examines the applications and issues an annual import plan that includes the list of required documents, which are as follows:

1) A statement of suppliers list signed and stamped by the factory's manager,

2) Data certificate issued by the central administration of licensing of pharmaceutical institutions

3) The factory's mandate to the person in charge of dealing with the General Administration of Marketing Authorization, signed and stamped by the company's manager, with the signature being verified by the bank,

4) Factory license (indicating the factory's activities),

5) A valid industrial register (indicating the factory's activities),

6) Commercial register,

7) Tax card,

8) Valid CE certificate for finished product,

9) Valid ISO 13485:2016 certificate for the factory,

10) Finished product Registration License (in case of sterile devices)

11) Pledge of the factory's responsibility for having complete data on imported items and submitting a request to update the supplier list in the event of adding or changing a raw material or a supplier,

12) Material safety data sheet for each material from each supplier,

13) Excel sheet stating the following:

Name of the material, name of the supplier/s, name of the final product, and numbers of Registration License that are used in manufacturing the product.

14) A pledge from the factory, signed and stamped by the factory's manager, stating the factory's commitment to update the documents and data provided in the event of any update or change and once a year at least 20 working days before the annual import permit renewal date.

- The annual import plan is effective as of 1st July until 30th June of each year.

- The submitted documents are updated according to the situation (i.e., if one or some of the documents expire or are updated).

An approval shall be issued for the final release of each invoice separately after comparing the items with the invoice received with the annual import plan and ensuring the validity of the certificates and documents on which the plan was issued.

**General guidance for import plans**

1. For the following cases:

- Registered medical devices for which a request has been submitted to amend data in the Registration License with the Variations Department: Annual import plans are issued for registered medical devices based on the data actually stated in the Registration License, and then the annual import plan is completed after a letter is issued approving the changes.

- Cancelling codes or cancelling a package and the code or package has been deleted from the certificates (free sale and/or CE certificate): An import plan is be issued for the codes and packages mentioned only in the renewed certificates, and:

✓ Submit a letter on the manufacturer's responsibility, indicating all the reasons for deleting the code or packaging,

✓ Adhere to the procedures followed by the General Administration for Pharmaceutical Vigilance.

- Deleting or changing the name of an actual factory and/or its address in the certificates (free sale, CE certificate and/or declaration of conformity): An import plan is be issued only for the factories mentioned in the certificates submitted.

2. The annual import plan for each registered medical device is submitted and approvals for this plan are obtained once a year through the Customs Release Unit and Follow-up through the Inspection Department of the Central administration of inspection on pharmaceutical institutions.

3. Quantities are not specified in the import plan by importing companies.

4. Each invoice is released separately.

5. In the event of importing items not included in the annual import permit, an import Approval will be issued for each invoice separately based on the company's request.

## Appendix VII

### Documents related to requests for presentation to specialized scientific committees

- The required trading and quality certificates are provided in accordance with the classification (Appendix X)
- Submit a sample for presentation to the scientific committee.
- If the committee issues a decision valid for one year providing for re-evaluation by the Medical Supplies Safety Department, then after the issuance of the Scientific Committee's decision, a signed and sealed list of the names of hospitals to which the supply was made will be submitted, so that the Safety Department can conduct questionnaires to verify the safety and effectiveness of the device and present them to the Scientific Committee for evaluation

### 8.7.1 For Orthopaedic devices, the following are required:

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| 1. Analysis result of non-sterile orthopaedic devices conducted by the Faculty of Engineering, Ain Shams University, |
| 2. catalogue |
| 3. Quality and trading certificates as shown in the certificate table according to the classification |
| 4. In the absence of a trading certificate from a reference country and the presence of previous approvals, submit a signed and stamped list of the names of hospitals to which the device was made so that the Safety Department can conduct questionnaires to verify the safety and effectiveness of the device. |

### 8.7.2 Medical devices in dosage forms

| |
|---|
| 1. Declaration from manufacturer showing intended use, each ingredient and its function |
| 2. catalogue or inner leaflet +Art work |
| 3. Quality and trading certificates as shown in the table of certificates according to classification |
| 4. Clinical studies (if requested by the Scientific Committee) |

### 8.7.3 Medical devices of all kinds

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|---|
| 1. Intended use certificate: The items written in the DOC must be for the same intended use. |
| 2. In the absence of a trading certificate from a reference country for medical devices classified as Class IIb, submit a signed and sealed list of the names of hospitals to which the devices were made so that the Safety Department can conduct questionnaires. |
| 3. A catalogue |
| 4. Quality and trading certificates as shown in the certificates table according to the classification. |
| 5. Clinical studies (if requested by the Scientific Committee). |

## Appendix VIII

## Documents required for special import requests

### 8.8.1 If the imported device is a donation for hospitals, the following are required:

1. A letter of acceptance of the donation for any institution or ministry. The letter must be issued by an authorized body, and must be signed and sealed by the general manager of the institution or facility (based on Cabinet Resolution No. 1818 of 2019).

If the value of the invoice exceeds one million pounds and does not exceed 10 million pounds, the approval of the competent minister or whoever has his authority shall be included in the request submitted by applicant in accordance with Prime and if the value exceeds 10 million pounds, the approval of the Council of Ministers must be brought.
2. A declaration signed and stamped with the seal of the hospital or medical center (with the signature being validated for non-governmental facilities) providing that the imported device is not for sale or trade and that it is under their full responsibility without any responsibility on the part of EDA.

3. The license of the hospital or Medical Centre issued by department of non-governmental curative institutions &licenses, as well as the basic activity list for associations and civil society institutions.

### 8.8.2 In the event that a hospital imports, the following are required:

1. A declaration signed and stamped with the seal of the hospital or medical centre (with the signature being validated for non-governmental facilities) providing that the imported device is not for sale or trade and that it is under their full responsibility without any responsibility on the part of EDA.

2. The license of the hospital or medical centre issued by department of non-governmental curative institutions &licenses, as well as the basic activity list for associations and civil society institutions.

3. The hospital's commercial register (indicating the import activity or being subject to the Investment Authority Law No. 8 of 1997 or 72 of 2017.

- In the event that the commercial register does not state that the hospital is not subject to the Investment Authority Law, submit a letter from the Investment Authority stating that the medical facility is subject to the investment law.

If there is no mention of the import activity in the commercial register or if the hospital is not subject to the Investment Authority Law, refer to the Import Committee.

### 8.8.3 If an individual imports a product for personal use, the following are required:

1. The item imported from abroad must be suitable for the treatment of the case and must be new and unused.

If the imported item is used, the applicant will be notified to apply to the Import Committee.

2. A clear medical report on the case.

3. The imported product must be suitable for home use. If the case is under medical supervision, the treating physician must provide an acknowledgment of full responsibility for the use of the medication and a pledge not to use it for any other cases.

4. A pledge by the patient or one of his first-degree relatives (in the case of an incapacitated patient) that the imported product is not for sale or trade and that its use falls under their full responsibility without any responsibility on the part of EDA. The acknowledgment must be confirmed by one of the methods of proving the authenticity of signature.

**8.8.4 In the event that a doctor imports, the following documents are required:**

1. Quality certificates necessary for the release of the incoming device according to the classification of the incoming item.

2. The clinic's license from department of non-governmental curative institutions &licenses,

3. The doctor's license to practice the profession.

4. The specialized scientific committee's decision with respect to the device if the device has to be approved by specialized scientific committees.

5. The doctor is not allowed to import sterile products required for use in operating rooms unless there is a license for a hospital or specialized medical centre and a pledge is made by the facility that the import is the responsibility of the facility without any responsibility on the part of EDA.

**8.8.5 In the event that a company with an activity related to importing medical devices for a hospital, the following documents are required:**

1. A clear medical report on the case for whom the items were imported.

2. A declaration signed and stamped with the seal of the hospital or medical centre (with the signature being validated for non-governmental facilities) providing that the imported device is not for sale or trade and that it is under their full responsibility without any responsibility on the part of EDA.

3. The license of the hospital or medical centre issued by department of non-governmental curative institutions &licenses

,, as well as the basic activity list for associations and civil society institutions

**8.8.6 If the device is imported by a company that does not import medical devices, the following documents are required:**

1. The company's commercial register, indicating its activity.

2. A pledge that the import is for use within the facility and not for trade.

3. A clear manual explaining the purpose of use.

Taking into account the following:

- The presence of a physician working within the company,
- Doctor's license to practice the profession,
- The presence of a clinic within the company.

**Guidance regarding special import requests**

- Quality certificates for the medical devices must be submitted. If quality certificates are not available, a pledge must be submitted from the user, whether it is for personal use or for a medical centre or hospital, indicating that they know that there are no quality certificates for the product and that importing the devices is on their responsibility without any responsibility on the part of EDA.
- The import of commercial quantities is not permitted in all special import cases.

In the event that the imported medical device is subject to registration:

- A notification of registration issued by the General Administration for the Registration of Medical Devices shall be submitted.

In the event that the notification is not available, the user should provide a pledge indicating whether the product is for personal use or for a medical centre or hospital, and that they know that there is no notification of registration for the product and that the medical device falls on their responsibility without any responsibility on the part of EDA.

If the value of the invoice exceeds one million pounds and does not exceed 10 million pounds, or the value exceeds 10 million pounds, the approval of the competent minister or whoever can replace him shall be included in the request submitted by applicant in accordance with Prime Minister's Decision No. 1818 of 2019 amending the Prime Minister's Decision No. 869 of 2010 regarding the rules and controls for accepting grants, gifts, and donations from foreign or national entities.

## Appendix IX

### Documents required to issue a letter of lack of jurisdiction

| |
|---|
| 1. The mandate issued by the importing company or importing body to the person in charge of dealing with the General Administration of Registration to permit trading, signed and stamped by the company's manager, with the signature being verified by the bank. |
| 2. In the event that the import is for personal use, the ID card of the importer or of the person authorized by the importing entity or company is required if the import is requested by a specific entity or company. |
| 3. Proforma invoice. |
| 4. The manufacturer's manual explaining the imported device. |
| 5. The payment receipt is stamped by the Authority and the invoice number is written on it. |
| 6. In the case of a dental laboratory, submit the laboratory license issued by the Ministry of Health. |
| 7. In the case of a local dental factory, submit the industrial register. |

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| 8. Provide the commercial register and tax card if the importer is a company whose activities do not include importing medical devices. |
| 9. A declaration of conformity certificate stamped and signed by the legal manufacturer and validated by the Chamber of Commerce and the Egyptian Embassy, indicating that the imported product is not a medical device.<br>If the DOC does not state the intended use, a clarification letter signed and stamped by the manufacturer shall be submitted, indicating the use of the device. |

## Appendix X

### Quality and trading certificates required according to classification

**In accordance with the established rules in the European community**

| Class | Certificates |
|---|---|
| Class I non-sterile | Declaration of conformity certificate (a statement from the manufacturer of the validity of the certificate) or a free sale certificate. |
| Class I sterile | Declaration of conformity certificate (a statement from the manufacturer of the authenticity of the certificate) and a free sale Certificate |
| Class II a | 1. Declaration of conformity certificate (a statement from the manufacturer of the validity of the certificate)<br>2. Free sale certificate<br>3. CE certificate |
| Class IIb / III from a reference country | 1. Declaration of conformity certificate (a statement from the manufacturer of the validity of the certificate)<br>2. Free sale certificate<br>3. CE certificate |
| Class IIB / III from a reference country | 1. Declaration of conformity certificate for imported models (a statement from the manufacturer of the validity of the certificate)<br>2. Free sale certificate<br>3. CE certificate<br>4. In the event of presenting the device to a scientific committee, attach the approval of the specialized scientific committee |
| ISO13485:2016 certificate | |

In accordance with the established rules in the USA, based on what is stated in FDA:

| Class | Certificates |
|---|---|
| Class I | 1. CFG certificate |

| | |
|---|---|
| | 2. Letter of declaration certificate stating the classification according to the American rules |
| Class II, and III | 1. CFG certificate<br>2. Letter of declaration certificate stating the classification according to the American rules |

**In accordance with the established rules in Canada**:

| Class | Certificates |
|---|---|
| Class I | 1.DOC acc. To Canadian regulation mentioning the classification<br>**According to the rules published on Health Canada website**<br>**https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/forms/declaration-conformity-forms-medical-devices.html**<br>2.Manufacturer certificate to cover export of medical devices (= FSC) issued from: the HPFBI, Health Canada<br>3. Medical device establishment license |
| Class II, III, IV | 1.Medical device active license<br>(In case medical device active license is issued for medical device family, medical device group, or medical device group family)<br>Ensure it is still valid through the link:<br>**Active license data base**<br>**https://health-products.canada.ca/mdall-limh/prepareSearch-preparerRecherche.do;jsessionid=2243EC9EFE11F2466DD71F7934514E89?type=active**<br>**Archived license data base**<br>**https://health-products.canada.ca/mdall-limh/prepareSearch preparerRecherche.do;jsessionid=2243EC9EFE11F2466DD71F7934514E89?type=archived_archive** |

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|---|---|
| | N.B: the declaration letter will be sent to the health Canada to confirm that the license covers the whole medical device list<br><br>2.Declaration of conformity acc. To Canadian regulation mention the classification<br><br>3.Manufacturer certificate to cover export of medical devices (= free sale) issued from: the HPFBI, Health Canada<br><br>4. MDSAP<br><br>**https://www.fda.gov/media/131149/download** |

**The above certificates should include the following data**:

| Certificate | Issued by | Including |
|---|---|---|
| ● statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer<br>● Name of the legal and actual manufacturers (if present)<br>● full address of the legal and actual manufacturers (if present)<br>● Trade name of the medical device<br>● medical device description<br>● Variants either:<br>Codes, models, sizes, references, manual number….<br>● Classification in accordance with the rules set out in Annex IX in MDD or Annex VIII of the EUMDR<br>● Complying with Medical Device Directive 93/42/EEC or EUMDR 2017/745<br>● Name and identification number of the notified body. (If applicable)<br>● CE no. (if applicable)<br>● Intended use. If not stated, it can be submitted in a separate clarification letter.<br>● Place and date of issue of the declaration, name and function of | Legal manufacturer | (D.O.C) Declaration of conformity signed and stamped |

| | | |
|---|---|---|
| the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature. | | |
| ● Name of the legal and actual manufacturers (if present)<br>● full address of the legal and actual manufacturers (if present)<br>● trade name of the medical device<br>● medical device description<br>● Variants either:<br>Codes, models, sizes, references, manual number….<br>● Certificate No<br>● Issuance date<br>● Validity<br>● Stating the manufacturer's compliance with current good manufacturing practice requirements for the product. or submitting CFG Without GMP+ISO13485:2016 | (USFDA) The US Food and Drug Administration | (CFG) certificate to foreign government<br>Signed |
| ● Name of the legal and actual manufacturers (if present) where applicable<br>● full address of the legal and actual manufacturers (if present) where applicable<br>● trade name of the medical device<br>● medical device description (if present)<br>● Variants either:<br>Codes, models, sizes, references, manual number……<br>● Issuance date<br>● Certificate No. (if present)<br>● Validity (if present)<br>● Complying with Medical Device Directive 93/42/EEC or EUMDR 2017/745 | Control authority in country of issuance | Free sale certificate<br>signed |
| ● Name of the legal and actual manufacturers (if present)<br>● full address of the legal and actual manufacturers (if present)<br>● trade name of the medical device (in case of EC –Type Examination or EC Design Examination) | | CE<br>signed<br>final product<br>Class I Sterile: CE (Annex V or Annex II.3) |

| | | |
|---|---|---|
| ● Variants ((in case of EC –Type Examination or EC Design Examination)) either: Codes, models, sizes, references, manual number……. ● Certificate No ● Issuance date ● Validity ● Scope of certificate (category/family for submitted products) | Accredited Notified body note: list of Accredited Notified body is found on the NANDO website https://ec.europa.eu/erowth/tools-databases/nando/ | Class IIa: CE (Annex V or Annex II.3) Class IIb: CE Annex II.3 or CE Annex V + CE Annex III Class III: CE Annex II Section 3 + CE Annex II Section 4 or CE Annex III + CE Annex V |
| ● Name of the actual manufacturer ● full address of the actual manufacturer ● Certificate No. ● Scope of certificate mentioning production, /manufacture of medical devices ● Issuance date ● validity | Certification body with accreditation recognized by IAF note: list of accreditation Bodies https://iaf.nu/en/accreditation-bodies/ | ISO 13485:2016 signed (Quality management system of the manufacturer) |

- It is not required to validate quality certificates for medical devices (CFG, Free Sale, CE, ISO13485:2016) issued by reference countries (the Chamber of Commerce and the Egyptian Embassy in the country of origin) and whose authenticity has been verified by the Administration from the authorities that issue these certificates.
- In the event that these certificates are not validated by these authorities, these certificates must be validated by the Chamber of Commerce and the Egyptian Embassy.
- If the entity does not respond within 3 (three) months from the date of receiving the file, the file will be transferred for safekeeping and resubmitted after documentation again according to the list of documents announced at the time of resubmission.
- CFG from USFDA certificates are not required to be validated by the Chamber of Commerce and the Egyptian Embassy in the event that the required data mentioned in them is verified on the website of:
- FDA CDRH export certificate validation and Premarket Notification for medical devices classified as Class II
- FDA CDRH Export certificate validation and PMA (Premarket Approval) for medical devices classified as class III

## 9. General requirements for obtaining import permits

1. Import permit is issued to its holder and may not be waived or transferred.

2. Any violation of the consent renders it invalid.

3. Import permit is valid for total shipment only and is not divisible.

4. Importation is carried out on a proforma invoice, and any items imported from abroad are not shipped except after obtaining the necessary import permit. In the event of shipping goods, the

company holds full responsibility and does not request the issuance of approval except after completing all documents and presenting them to the specialized committees if necessary.

5. Medical devices may not be advertised in any media except after obtaining the approval of EDA.

6. The imported device must be new and unused.

7. The imported device must be identical to the attached invoice.

8. Applying for an import permit more than once with one invoice is not permitted.

9. Invoice is considered valid for one year only from the date of issuance if the supplier does not mention a specific expiration date.

10. Importing any used medical devices is not permitted, whether for private use or for trade, except after consulting the General Administration for Allowing Trading to consider whether the device can be imported and traded.

11. In the event that the applicant is a scientific office, a scientific office license is required, in addition to the supplier, and reference is made to the EDA Chairman's Decision No. 315 of 2021 regarding the organization of scientific offices.

12. Submitting the application on the Authority's website means that the manufacturer and its representative are fully responsible for all the data and documents submitted.

13. In the event of violating any of the previous guidance, importer shall take responsibility for any financial, legal, or administrative consequences.

## 10. Regulatory decisions

| **1. Regarding analysis at the Faculty of Engineering** |
|---|
| - With regard to non-sterile orthopaedic devices and surgical instruments that are analysed in one of the bodies approved by EDA, as determined by the competent administration, the goods are seized until the results of the Faculty of Engineering's conformity analysis are issued.<br>- For local bone factories, sampling is limited to the final product and not production raw materials<br>- A maximum of three samples are drawn from five different categories. This concerns surgical instruments and not transplants, provided that the analysis is repeated one year after the date for collecting the sample is determined by the General Administration to allow trading. |
| **2. Regarding local factories** |
| - Regarding the release of production devices and raw materials for factories:<br>Licensed medical devices factories are allowed to import raw materials and components used in the manufacture of their sterile medical devices once their notifications of registration expire, provided that they are submitted for re-registration and are given a period of one year from the date of submitting the re-registration file.<br>If the re-registration procedures are not completed, the case will be referred to the specialized scientific committee for evaluation. |

- In the event that some local factories produce medical devices and export them abroad, and in some cases the product is rejected by the importing companies, then the factory shall submit a request to recall these products. The recalled export (samples) is approved to study the customer's complaint, and modifications to the product is allowed, provided that it is released and the completion of the modifications is followed up under the supervision of Central administration of inspection on pharmaceutical institutions. Then the product is permitted to be re-exported and the documents proving the exportation shall be provided.
Each case is studied individually.
It is approved for a manufacturer to export a small quantity of the finished product with the aim of introducing some development to it and then taking it back to study the efficiency of the product after modification.

**3. Regarding the expiration/invalidity of quality and trading certificates in the notifications, or attaching an old version of quality certificates.**

Evidence is provided, stating that the product was produced before the expiration date of the quality or trading certificate, and importation is allowed for a period of 6 (six) months, provided that the notification is valid for the registered medical product.

**4. Regarding importing a device for new registration**

Any sterile medical devices submitted for new registration shall not be released until the company receives the notification of registration, as it does not have a notification number because it is a new registration and therefore cannot be tracked after trading.

**5. Regarding ambulances**

Regarding the Egyptian Ambulance Authority's request to release ambulances with medical equipment and blood collection ambulances, they are released without quality certificates and without the need to present them to the specialized scientific committee for the study, production and import of medical devices and equipment.

**6. Regarding gastric balloons**

The following controls shall be taken into account when releasing gastric balloons, which include the printing of the following data:

**First: Motives for use (indications):**

1. Obesity of BMI 41 to 31
2. Overweight of BMI 21 to 26, after patient has failed in several dietary attempts,
3. Overweight of BMI over 61-55 (super obesity) in the following cases only:

- Anaesthesia risk: Balloon is used as a first step to reduce weight and then perform the optimal obesity surgery,
- Patient does not want to undergo surgery despite being informed that surgery is the ideal treatment for their weight.

**Second: Contraindications**

1. Morbid obesity (BMI higher than 40)
2. Pregnancy and breastfeeding
3. Stomach has been subjected to any type of surgery previously
4. There is a diaphragmatic hernia of more than 4 cm or third- or fourth-degree oesophageal reflux
5. It is not recommended for use in a psychiatric patient committed to psychological or mental treatment

**Third: Instructions for use**

1. Patient must be informed of all available methods for treating obesity and the reason for choosing one method over another.
2. Patient must be informed that placing the balloon inside the stomach is a step that helps control the quantity of food (appetite), not its type, and that losing weight is a complete lifestyle, and that the balloon is part of a whole in this context, and patient must adhere to sound food and health culture.

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| 3. Explain all the complications and warnings of using the balloon to the patient and the treatments required during the stages of the balloon being in the stomach.<br>4. Find an effective means of communication with the patient to communicate in emergency situations.<br>*** A registered import permit is issued and the Inspection Department and the Central administration of inspection on pharmaceutical institutions are contacted to ensure that warnings are written regarding all types of gastric balloons manufactured in reference countries. |
| **7. Regarding examination gloves** |
| It is necessary to test all examination gloves either in one of the facilities approved by EDA and determined by the competent administration. |
| **8. Regarding changing classification** |
| For medical devices that have a valid notification of registration and the classification has been changed in their country of origin, import is allowed for one shipment, provided that:<br>- A pledge to submit the registration file, knowing that these goods will carry the same notification of registration number,<br>- New quality and trading certificates,<br>- A letter from the factory explaining the reason for changing the classification.<br>After the registration file is accepted by the General Administration of Registration, a period of one year is given for importing, staring from the date of acceptance of the registration file. |
| **9. Regarding used devices** |
| It will be presented to the specialized scientific committee for the study, production and import of medical devices and devices to evaluate the following:<br>✓ Devices are used for workshops, training, conferences and scientific exhibitions, provided that they are not used on humans,<br>✓ Devices are used for research or medical purposes,<br>✓ Devices are used for personal use such as:<br>• Full or partial dentures and some dental devices that patient uses, such as:<br>• Dentures (full or partial), orthotic device, including braces,<br>• Medical hearing aid,<br>• Belly belt or back belt,<br>• Prosthetic limbs and their components (prosthetic devices),<br>• Bedpan. |
| **10. With regard to refurbishing or replacement of parts related to cochlear implant** |
| - Export takes place as soon as the company sends an invoice with the serial number and it is linked to the invoice of export.<br>- After completing the refurbishing or replacement, manufacturer sends a detailed invoice with each serial number and the procedures that were performed on it, whether it was refurbishing or replacement.<br>- The approval is issued, stating the word “repair”, “refurbishing” or “valid replacement”. If the spare parts are very small and difficult to repair, they will be replaced with new ones. |
| **11. Regarding the lancets attached to diabetic care devices** |
| Shipments of blood glucose measuring devices containing test samples will be finally released after reviewing the sterility and analysis certificates included with each shipment, without the need to withdraw samples from them and analyse them in the Administration’s laboratories, provided that approval is obtained to ensure that the data contained in the invoice matches the sterility and analysis certificates. |
| **12. Regarding dental devices** |
| - All procedures are applied to release medical devices, each according to its type (sterile, non-sterile, raw material for factory), and all procedures shall be referred to scientific committees. |

- With regard to sterile dental devices subject to registration, they will be released according to the following:
    - Registration requirements: Device is released by submitting the initial file acceptance number and attaching it to the required documents,

In the event that the file is not submitted to the General Administration of Registration: Importer submits a plan to apply for registration within one year, stating the name of the item, its code, the manufacturer of this item, the country of origin, and the planned date for applying for registration, dated by month and year, with the company's pledge to adhere to these dates so that it is not impossible to issue import permit beyond this date.

### 11. Terms and abbreviations

| Abbreviation | Term |
|---|---|
| EDA | Egyptian Drug Authority |
| MOH | Ministry of Health |
| MD | Medical Device |
| MDR (2017/745) | Medical Device Regulations |
| MDD (93/42/EEC) | Medical Device Directive |
| ISO | International Organization for Standardization |
| CE or EC | European Conformity |
| FDA | Food & Drug Administration |
| CFG | Certificate for Foreign Governments |
| FSC or CFS | Free Sale Certificate or Certificate of Free Sale |
| NB | Notified Body |
| DOC | Declaration of Conformity |
| REF. | Reference |
| GMP | Good Manufacturing Practice |
| ACI | Advance Cargo Information |

## 12. History Table

| Version | Issue date | Place of amendments Changes |
|---|---|---|
| First | 02/2022 | |
| Second | 09/2025 | The name of the Central Administration of 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. |