Regulatory guideline for issuing import approvals for medical equipment and their accessories

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1. Introduction:

This guide concerns the regulatory procedures for issuing import approvals of medical equipment and their accessories.

Purpose: The purpose of this guideline sets the required instructions for importing a safe and effective medical equipment permitted to be marketed in the Arab Republic of Egypt.

Scope: Includes all procedures of clarifying work procedures for both of the importer, distributor and scientific offices required to obtain import approval for medical equipment and their accessories.

2. Relevant Regulatory Guidelines:

- Regulatory Guideline of Issuing Import Approvals for Medical devices of All Types.
- Regulatory Guideline of Issuing Import Approval for Laboratory equipment.
- Regulatory Guideline of the Label Data for Medical devices, IVDs and Laboratory equipment, and Production Components and Inputs.
- Regulatory Guideline of Using International Barcodes (UDI)

3. Definitions:

✓ Medical Device: It refers to any device, tool, method, machine, equipment, or application, including any inserted or implanted device, any electronic program, material or any other similar or related devices that a company manufactures to be used singly or in combination by humans for one or more of the following purposes:

- Diagnosis, prevention, monitoring, treatment, mitigation of disease.
- Diagnosing, monitoring, treating, mitigating, rehabilitating an injury.
- Verification of replacement, modification or support of an anatomical or functional process.
- Supporting or maintaining life.
- Control of pregnancy.
- Disinfection of medical device

provided that the intended primary purpose cannot be achieved by the pharmacological, immunological or metabolic effect in or on the human body; however, the medical device can be assisted in its intended function by the aforementioned effects.

✓ **Imported medical equipment**: They are fully manufactured overseas imported for circulation in the Arab Republic of Egypt.

✓ **Importing Company**: It the first entity in the supply chain that imports medical equipment manufactured overseas into the Arab Republic of Egypt.

Legal Manufacturer: It is the entity responsible for designing, manufacturing, packaging and labeling the medical equipment before circulating it on the market in its own name, regardless of whether these were carried out by this entity himself

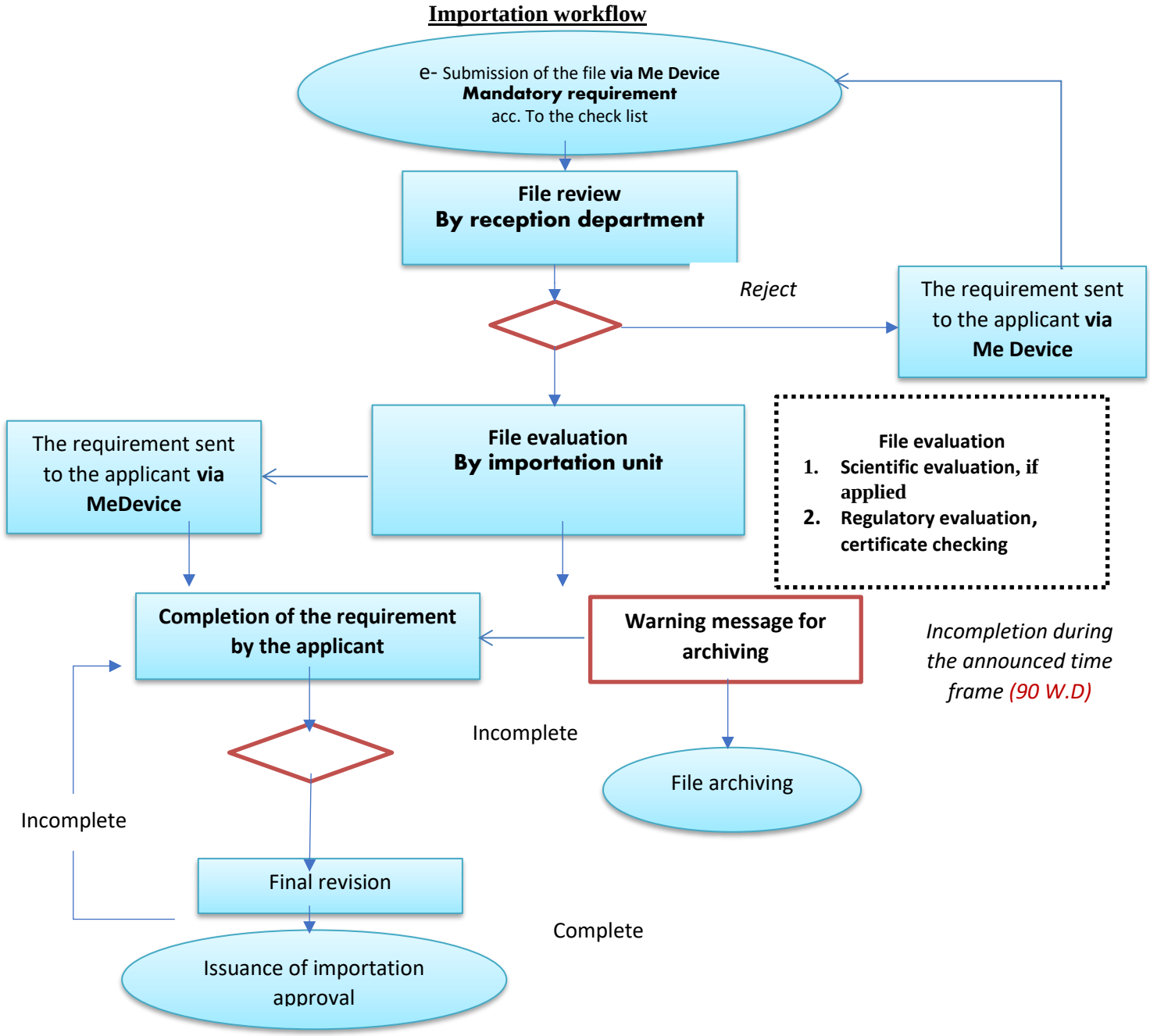
✓ or on his behalf or by a third party. The legal manufacturer shall be responsible for the quality of the product.

✓ **The Actual Manufacturer**: It is the entity where the medical equipment is physically manufactured, packaged and packed on behalf of the legal manufacturer.

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

4- Regulating Procedures and Rules:

4.1 Procedures of issuing import approval for the medical equipment:



4.1.1 Procedures of receiving a file to obtain an import approval:

A. A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/
B. The fees shall be collected according to the fee category stated in the executive regulations of the Egyptian Drug Authority law promulgated by Prime Minister's Decision No. (777) of 2020.
C. The applicant shall receive a respond via the platform within two working days from the date of sending the request of accepting or not accepting the file or suspending the request until fulfilling.

*** In case of file acceptance:**

The request shall be directed to the medical equipment Import Approvals Unit for study, after which the required documents shall be sent by the company via the platform medevice.edaegypt.gov.eg

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file shall be suspended in case of failure to fulfill any of the documents and data required in accordance with Appendix No. (1) for a period of 90 days starting from the date of sending a request of the required documents and the request shall be rejected.
- It is permissible to resume the request procedures by the same request number previously submitted within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

4.1.2. Procedures for evaluating the file for obtaining import approval:

The file shall be reviewed and the applicant shall be notified by the required documents via the platform medevice.edaegypt.gov.eg within 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 shall be fulfilled via the platform medevice.edaegypt.gov.eg.

4.1.4. Issuing import approval:

After completing the file of obtaining an import approval, a valid import approval for one year from the date of its issuance, will be issued.

4.1.5 Procedure of amending an import approval:

A request to amend the import approval data shall be uploaded on the platform medevice.edaegypt.gov.eg, clarifying the required amendment in addition to upload the documents supporting the request.

In case of an amendment required to be implemented to the import approval (not concerning the invoice value) after its issuance:

- The services fees shall be collected in accordance with the decision Promulgated by the Egyptian Drug Authority's Chairman in this regard.
- The amended import approval shall be issued after submitting the required documents.

In case of amendment concerning the invoice value:

- The fee remainder shall be collected according to the invoice category stated in the executive regulations of the law establishing the Egyptian Drug Authority Promulgated by Prime Minister's Decision No. (777) of 2020.
- The amended import approval shall be issued.

4.2. Procedures of importing medical equipment for medical events (exhibitions, workshops and training):

Importing medical equipment for the purpose of display in exhibitions, workshops and training, then re-export them, shall be permitted.

4.2.1. Procedures for receiving a file to obtain import approval:

1. A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/

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

2. The applicant shall receive a respond of accepting or not accepting the file or suspending the request until fulfilling via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request.

*** In case of file acceptance:**

The request shall be directed to the medical equipment Import Approvals Unit for study, then the company shall be notified with the required documents via the platform medevice.edaegypt.gov.eg

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file shall be suspended in case of failure to fulfill any of the documents and data required in accordance with Appendix No. (2) for a period of 90 days starting from the date of sending a request of the required documents and the request shall be rejected.
- It is permissible to resume the request procedures by the same request number previously submitted within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern addressed department.

4.2.2. Procedures for evaluating the file of obtaining import approval:

The file shall be reviewed and the applicant shall be notified by the required documents via the platform medevice.edaegypt.gov.eg within 3 working days from the date of receipt of the file.

4.2.3. Procedures for completing the file of obtaining import approval:

The file shall be fulfilled via the platform medevice.edaegypt.gov.eg.

4.2.4. Issuing an import approval:

After completing the file of obtaining an import approval, a valid import approval for one year from the date of its issuance, shall be issued.

4.2.5 Procedure of amending an import approval:

A request to amend the import approval data shall be uploaded on the platform medevice.edaegypt.gov.eg, clarifying the required amendment in addition to upload the documents supporting the request.

In case of an amendment required to be implemented to the import approval (not concerning the invoice value) after its issuance:

- The services fees shall be collected in accordance with the decision Promulgated by the Egyptian Drug Authority's Chairman in this regard.
- The amended import approval shall be issued after submitting the required documents.

In case that the amendment concerning the invoice value:

- The fee remainder shall be collected according to the invoice category contained in the executive regulations of the law establishing the Egyptian Drug Authority Promulgated by Prime Minister's Decision No. (777) of 2020.
- The amended import approval shall be issued.

Instructions for requesting import approval for medical equipment imported for medical events:

- The date of the conference or workshop shall be indicated in the invoice if applicable.

In case of non- indicating it in the invoice, a letter by the entity hosting the event indicating the date and place of the event shall be submitted.

- The company shall be committed to submit evidence of re-exporting the medical equipment immediately after the end of the workshop or conference and the Central Administration for Inspection on pharmaceutical institutions shall be followed up.

- A pledge by the entity hosting the event stipulating that the imported medical equipment will not be used by humans, shall be submitted

- The imported devices used for workshops, training, conferences and scientific exhibitions, shall be permitted to be imported, provided that they shall not be used by humans and they shall be used only on plastic models or human samples in the Anatomy Department.

4.3 Procedures importing medical equipment for research purposes:

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

A. A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/

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

B. The applicant shall receive a respond of accepting or not accepting the file or suspending the request until fulfilling via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request.

*** In case of file acceptance:**

The request shall be directed to the medical equipment Import Approvals Unit for study, then the applicant shall be notified with the required documents via the platform medevice.edaegypt.gov.eg

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file shall be suspended in case of failure to fulfill any of the documents and data required in accordance with Appendix No. (3) for a period of 90 days starting from the date of sending a request of the required documents and the request shall be rejected.
- It is permissible to resume the request procedures by the same request number previously submitted within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

4.3.2. Procedures for evaluating the file of obtaining an import approval:

The file shall be reviewed and the applicant shall be notified by the required documents via the platform medevice.edaegypt.gov.eg within 3 working days from the date of receipt of the file.

4.3.3. Procedures for completing the file of obtaining import approval:

The file shall be fulfilled via the platform medevice.edaegypt.gov.eg.

4.3.4. Issuing an import approval:

After completing the file of obtaining an import approval, a valid import approval for one year from the date of its issuance, shall be issued.

4.3.5 Procedure of amending an import approval:

A request to amend the import approval data shall be uploaded on the platform medevice.edaegypt.gov.eg, clarifying the required amendment in addition to upload the documents supporting the request.

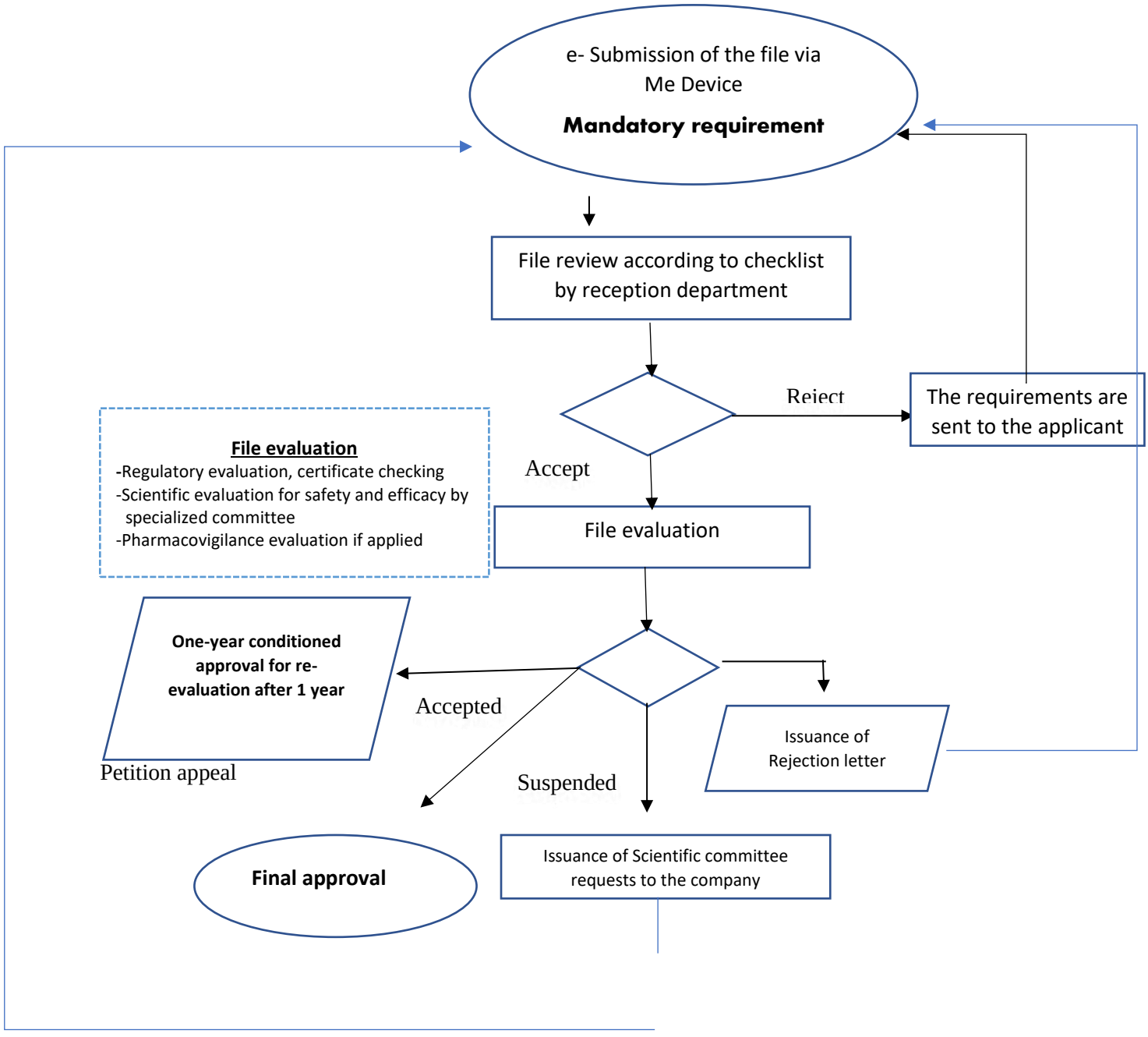
In case of an amendment required to be implemented to the import approval (not concerning the invoice value) after its issuance:

- The services fees shall be collected in accordance with the decision Promulgated by the Egyptian Drug Authority's Chairman in this regard.
- The amended import approval shall be issued after submitting the required documents.

In case that the amendment concerning the invoice value:

- The fee remainder shall be collected according to the invoice category stated in the executive regulations of the law establishing the Egyptian Drug Authority Promulgated by Prime Minister's Decision No. (777) of 2020.
- The amended import approval shall be issued.

5. Procedures and rules governing the scientific evaluation unit:



Scientific committees shall be divided into different specializations and the medical equipment shall be presented to them according to the intended purpose.

- The medical equipment that are subjected to evaluation by specialized scientific committees as a prior procedure for obtaining an import approval are as follows:

1) medical equipment classified as Class IIb, Class III and imported from a non-reference country.
2) All incubation devices (Phototherapy & infant warmers) classified as Class IIa manufactured in one of the non-reference countries.
3) Sterile non-implantable accessories of medical equipment and exclusively used with the medical equipment
4) medical equipment manufactured in one of the non-reference countries that operate with new technology, regardless of their classification.

5.1. Procedures for receiving a file to be presented to the scientific evaluation unit:

A. A request shall be uploaded on the MeDevice electronic platform at the following link: https://medevice.edaegypt.gov.eg/

Fees stipulated by the Authority chairman in this regard shall be collected.

B. The applicant shall receive a respond of accepting or not accepting the file or suspending the request until fulfilling via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request.

*** In case of file acceptance:**

- The request shall be directed to the Scientific Evaluation Unit for study.
- The applicant shall be notified by required documents via the platform medevice.edaegypt.gov.eg

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file examination shall be suspended in case of failure to fulfill any of the documents and data required in accordance with Appendix No. (4) for a period of 90 days starting from the date of sending a request of the required documents and the request shall be rejected.
- It is permissible to resume the request procedures within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

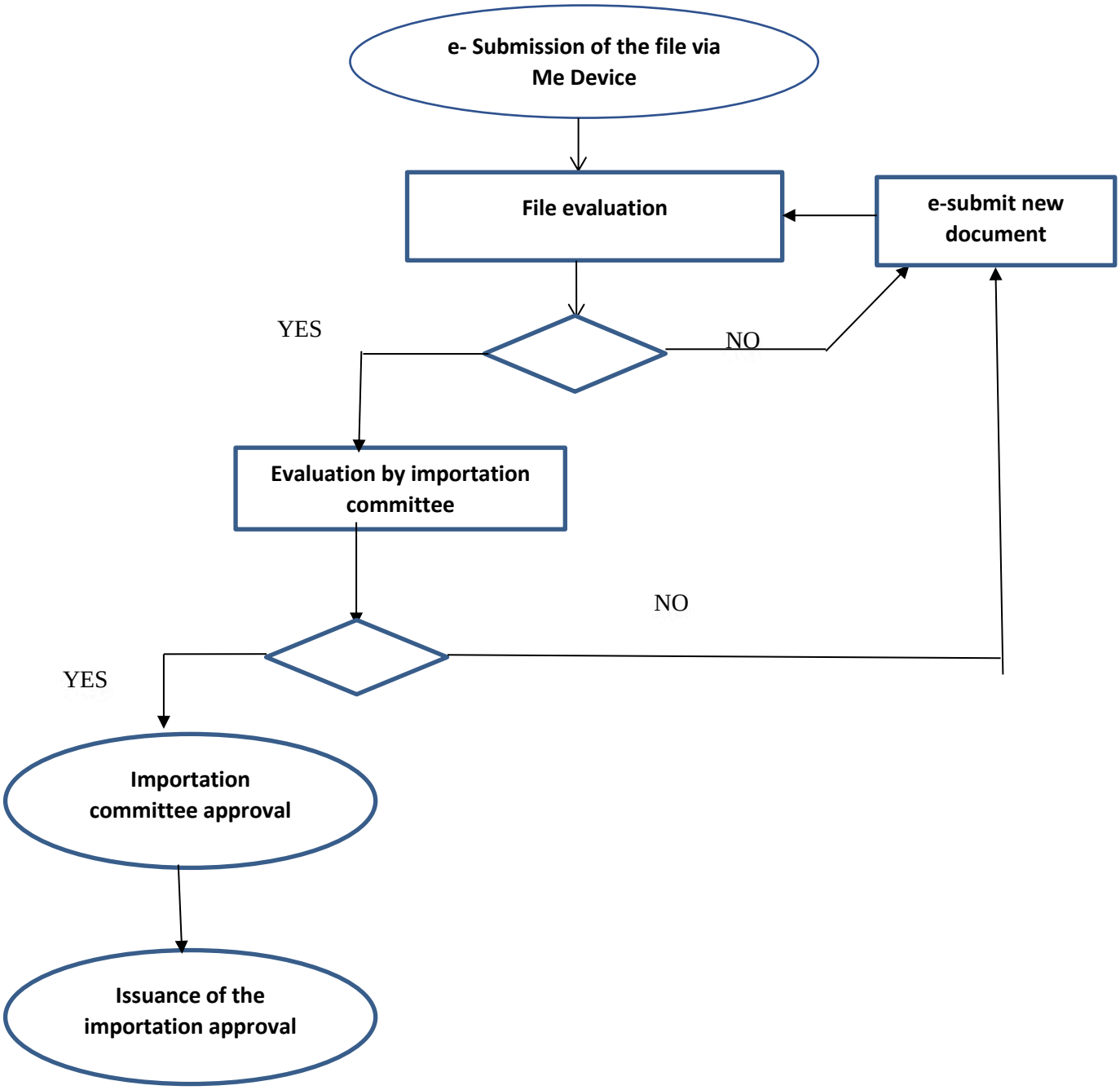
*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

5.2 Procedures of evaluating the file to be presented to the Scientific Evaluation Unit:

A. It shall be presented to the Specialized Scientific Committee and it shall issue its decision either by approval, postponement, or reasoned rejection.
B. In case of rejection, the applicant has the right to file an appeal against the committee's decision, provided that new documents that have not previously been presented to the committee shall be submitted, or submitting a scientific explanation for the rejection reasons, if any.
C. In case of committee issued a decision of re-evaluating after a year by the medical devices Safety Department, and the validity of this decision ends, a signed and sealed list of the names of the hospitals receiving devices shall be submitted so that the Safety Department can conduct questionnaires to verify the safety and effectiveness of the devices and present them to the Scientific committee for evaluation

6. Documents required for issuing an annual import approval for a medical equipment



Types of special import requests:

- If the imported device is a donation for hospital.
- If the device is imported by a hospital.
- If the device is imported by individual for personal use.
- If the device is imported by a doctor.
- If the device is imported by a company that has an activity not concerning importing medical equipment
- If the device is imported by a company has an activity concerning importing of medical equipment for the benefit of a hospital or patient

6.2 Procedures of obtaining an import approval by the Special Import Request Evaluation Unit:

6.2.1 Procedures for receiving a file to obtain import approval

A. A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/
B. The applicant shall receive a respond via the platform of accepting or not accepting the file or suspending the request until fulfilling within three working days from the date of sending the request.

*** In case of file acceptance:**

The request shall be directed to the Special Import Request Evaluation Unit.

The applicant shall be notified by required documents via the platform medevice.edaegypt.gov.eg

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file examination shall be suspended and the request shall be rejected in case of failure to fulfill any of the documents and data required in accordance with the Appendix No. (5) for a period of 90 days starting from the date of sending a request of the required documents.
- It is permissible to resume the request procedures within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

6.2.2 Procedures of evaluating the file for obtaining a special import approval:

The file shall be reviewed and the required documents are uploaded via the platform medevice.edaegypt.gov.eg within 3 working days from the date of receiving the file.

6.2.3 Procedures of completing the file of obtaining a special import approval:

The required documents shall be uploaded to the platform medevice.edaegypt.gov.eg.

- In case of fulfilling the required documents, the file shall be presented to the committee.

- The Import Committee shall issue its decision either by approval, postponement, or rejection. In case of postponement or rejection, the reasons shall be indicated.

In case of rejection, the applicant has the right to file an appeal against the committee's decision, provided that new documents and have not previously been presented to the committee shall be submitted, or submitting a scientific explanation for the rejection reasons, if any.

6.2.4 Issuance of an import approval:

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

6.2.5 Procedure of amending an import approval:

A request to amend the import approval data shall be uploaded on the platform medevice.edaegypt.gov.eg, clarifying the required amendment in addition to upload the documents supporting the request.

In case of an amendment required to be implemented to the import approval (not concerning the invoice value) after its issuance:

- The services fees shall be collected in accordance with the decision Promulgated by the Egyptian Drug Authority's Chairman in this regard.
- The amended import approval shall be issued after submitting the required documents.

In case of amendment concerning the invoice value:

- The remainder fee shall be collected according to the invoice category contained in the executive regulations of the law establishing the Egyptian Drug Authority Promulgated by Prime Minister's Decision No. (777) of 2020.
- The amended import approval shall be issued.

Instructions on special import requests:

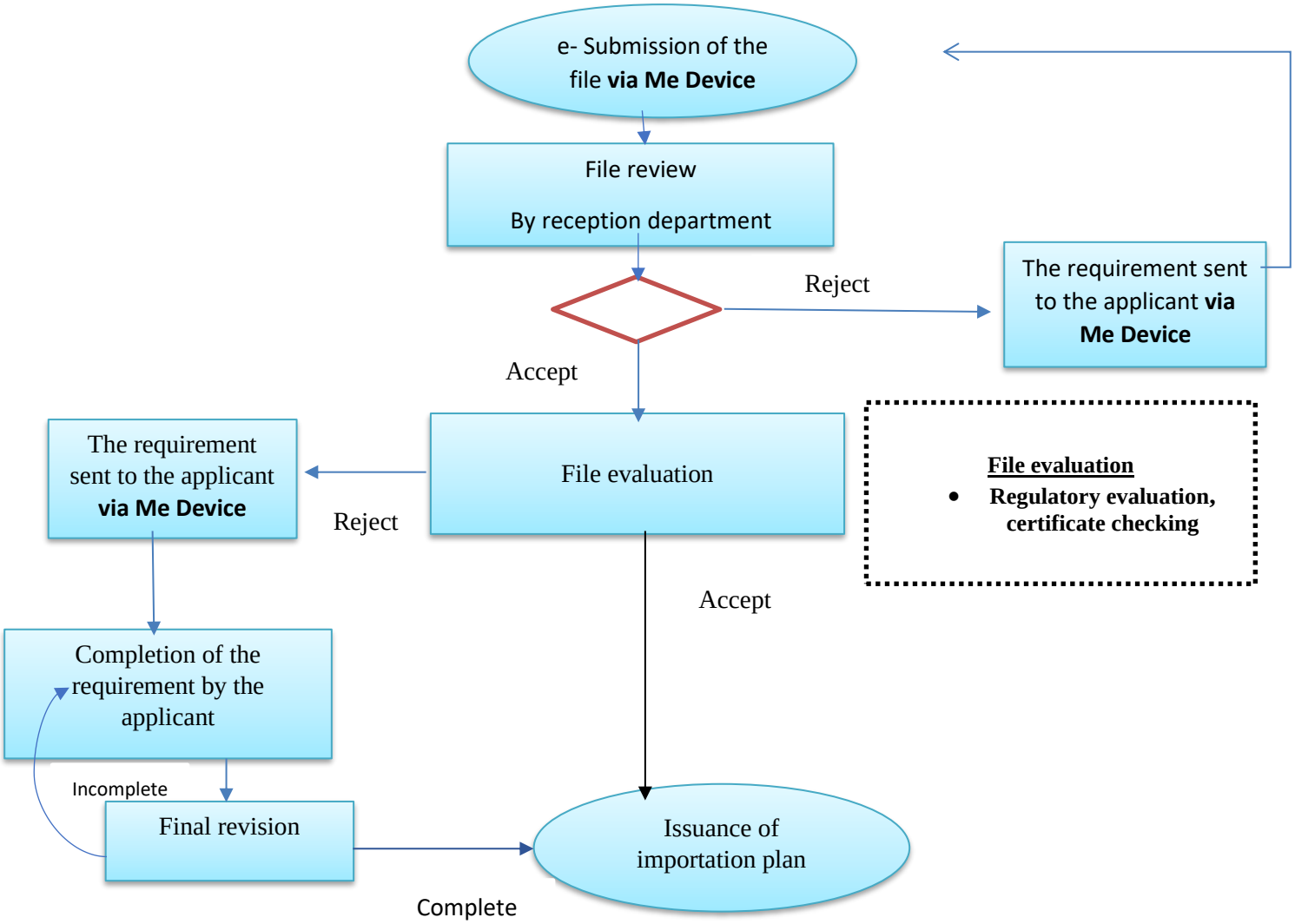
- The quality certificates of the medical equipment shall be submitted. In case of lack to them, a pledge shall be submitted by the user, whether the imported device is for personal use, a medical center or a hospital, stipulating their awareness of lack of quality certificates for the product and that the medical equipment is imported on their responsibility without any responsibility on the part of the Egyptian Drug Authority.

In all special import cases, it is not permitted of importing in commercial quantities.

- In the case of the invoice value exceeded one million LE and did not exceed ten million LE, or the value exceeded ten million LE, the approval of the minister shall be submitted in accordance with the decision of the person in charge of the entity submitting the request, whoever has its authority, the competent minister, whoever has its authority or the Prime Minister, as the case may be, in accordance with Prime Minister's Decision No. (1818) of 2013 amending the Prime Minister's Decision No. (863) of 2012 on the rules and regulations of accepting grants, gifts and donations from foreign or national entities.

7. Procedures of issuing an annual import approval for a medical equipment, its spare parts and accessories not classified as medical device:

Annual Importation Plan Flow chart



7.1 Procedures for receiving a file to obtain annual import approval for a medical equipment, its spare parts and accessories not classified as medical devices

A. A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/

Fees stipulated by the Egyptian Drug Authority chairman in this regard shall be collected.

B. The applicant shall receive a respond of accepting or not accepting the file or suspending the request until fulfilling via the platform medevice.edaegypt.gov.eg within three working days from the date of sending the request.

*** In case of file acceptance:**

The request shall be directed to the medical equipment Approvals Unit for study and notifying the company with the required documents.

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with the file examination shall be suspended and the request shall be rejected in case of failure to fulfill any of the documents and data required in accordance with the Appendix No. (6) for a period of 90 days starting from the date of sending a request of the required documents.
- It is permissible to resume the request procedures by the same request number previously submitted within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

7.2 Procedures of evaluating a file for obtaining an annual import approval:

The file shall be reviewed and the applicant shall be notified by the required documents via the platform medevice.edaegypt.gov.eg within 3 working days from the date of receiving the file.

7.3 Procedures of completing the file of obtaining an annual import approval:

The file shall be fulfilled via the platform at the following link: medevice.edaegypt.gov.eg.

7.4 Issuing an annual import approval

Upon completion of the file an annual import approval valid for one year from the date of its issuance, shall be issued.

7.5 Procedure of amending an annual import approval:

- A request to amend the annual import approval data shall be uploaded on the platform MeDevice on the following link medevice.edaegypt.gov.eg, clarifying the required amendment in addition to upload the documents supporting the request.

- The amended import approval shall be issued after submitting the required documents

7.6 Procedure of obtaining an import approval for each invoice of a medical equipment has an annual import approval, accessories classified as affiliated to the device and spare parts:

7.6.1 Procedures for receiving a file to obtain an import approval:

A request shall be uploaded on the Me Device electronic platform at the following link: https://medevice.edaegypt.gov.eg/

The fees shall be collected according to the fee category contained in the executive regulations of the law of establishing the Egyptian Drug Authority promulgated by Prime Minister's Decision No. (777) of 2020.

The applicant shall receive a respond of accepting or not accepting the file or suspending the request until fulfilling via the platform medevice.edaegypt.gov.eg within two working days from the date of sending the request.

***If the file is accepted:**

The request shall be directed to the medical equipment Import Approvals Unit for study, after which the required documents shall be sent by the company via the platform medevice.edaegypt.gov.eg.

*** In case of suspending the request until fulfilling:**

- The procedures of proceeding with examination the file shall be suspended in case of failure to fulfill any of the documents and data required in accordance with the Appendix No. (7) for a period of 90 days starting from the date of sending a request of the required documents and the request shall be rejected.
- It is permissible to resume the request procedures by the same request number previously submitted within the following ninety days after paying the stipulated service fees only for once, otherwise the request shall be considered never filed.

*** In case of file non-acceptance:**

The request shall be rejected if any of the device data contained in the request does not match those in the receipt or if it doesn't concern the addressed department.

7.6.2 Procedures of evaluating the file of obtaining an import approval for each invoice:

The file shall be reviewed and the applicant shall be notified by the required documents via the platform medevice.edaegypt.gov.eg within the same working day in which the file was received.

7.6.3 Procedures of completing the file of obtaining an import approval for each invoice:

The file shall be fulfilled via the platform medevice.edaegypt.gov.eg.

7.6.4 Issuance of an import approval for each invoice:

After completing the file, approval for release will be obtained within 24 working hours of completion, which will be valid for one year from the date of issuance.

7.6.5 Making an amendment to the import approval for each invoice:

A request to amend the import approval data shall be uploaded on the platform medevice.edaegypt.gov.eg, clarifying the required amendment in addition to uploading the documents supporting the request.

In case of an amendment required to be implemented to the release approval (not concerning the invoice value) after its issuance:

- The services fees shall be collected in accordance with the decision Promulgated by the Egyptian Drug Authority's Chairman in this regard.
- The amended import approval shall be issued after submitting the required documents.

In case of amendment concerning the invoice value:

- The remainder fee shall be collected according to the invoice category contained in the executive regulations of the law establishing the Egyptian Drug Authority Promulgated by Prime Minister's Decision No. (777) of 2020.
- The amended import approval shall be issued.

7.7 Implementing a variant on an annual import approval:

The following changes are allowed:

- ✓ **Changes related to the medical equipment:**
- Moving the place of manufacturing / adding a country of origin / adding a place of manufacturing to the same legal factory.
- Change the of the foreign manufacturer name while keeping the same address.
- Change the address of the legal manufacturer.
- Changing or adding the legal manufacturer (provided that keeping the same actual manufacturer).
  - ✓ **Changes related to the list of spare parts and accessories not classified as medical equipment:**
- ✓ Add spare parts and / or accessories not classified as medical equipment to the issued list.

The procedures 7.1 to 7.4 shall be applied.

8. List of required documents:

Appendix 1: Documents required to obtain an import approval for medical equipment, their spare parts and accessories

Appendix 2: Documents of required for obtaining an import approval for medical equipment imported for medical events (exhibitions, workshops and training)

Appendix 3: Documents required for obtaining an import approval of medical equipment imported for research purposes

Appendix 4: Documents of the request to be presented to specialized scientific committees.

Appendix 5: Documents required for special import requests.

5.1 If the imported device is a donation for hospitals.

5.2 If the device is imported by a hospital.

5.3 If a device for personal use imported by an individual.

5.4 If a device is imported by a doctor for use in the clinic.

5.5 If a device is imported by a company has an activity concerning importing medical devices and equipment (for the benefit of a hospital).

5.6 If a device is imported by a company has an activity not concerning importing medical devices and equipment.

Appendix 6: Documents required to issue an annual import approval for a medical equipment

Appendix 7: Documents required to issue an import approval for an invoice of a, medical equipment accessories classified as affiliated to the device and spare parts for which has an annual import approval.

Appendix 8: Documents required in case of lack to jurisdiction.

Appendix 9: Quality certificates required according to the classification

Appendix 1

Documents required to obtain an import approval for medical equipment, their spare parts and accessories

First: Documents of the import approval applicant:

1. A delegation by the importing company for the person responsible to deal with the General Administration of medical equipment Marketing Authorization to receive and deliver all the company's documents. This delegation shall be signed and stamped by the responsible manager with bank authentication of the signature.
2. Fee payment receipt stamped with the Authority's seal and holding the invoice number.
3. Proforma invoice.
4. medical equipment Importer Register License, added to it:

   - A valid license of maintenance center, and

   - The supplying / manufacturing company based on the relationship letter.

5 Form 14 for agents, if it is recorded in the importers' registry.

6 The valid and authenticated by the Chamber of Commerce and the Egyptian Embassy distribution / agency contract with the supplying company, if it is mentioned in the Register license or the term "for some products" is indicated.

In the case of tenders, the tender contract and authorization of the agent shall be required to complete the procedures of obtaining the necessary import approvals.

7 In case of the manufacturing company is different from the supplying company, the documents of the relationship issued by the foreign manufacturer shall be submitted and it shall indicate the right of the supplying company to supply the devices imported to Egypt issued by the foreign manufacturer. The relationship document shall be authenticated by the Chamber of Commerce and the Egyptian Embassy.

8 If the request is received from the Unified Procurement Authority, the following documents shall be submitted:

- Authorizing by the importing company to the Unified Procurement Authority.
- Authorizing by the Unified Procurement Authority to the representative of the importing company to deal with the Egyptian Drug Authority.
- The contract concluded between the concerned parties signed and indicating the items mentioned in the invoice and their origin.

The storage location shall be determined, weather in the authority or the company stores

A purchase order for the beneficent or using entity of the imported device in case of UPA invoices

9. In the case of tenders, the tender contract and agent authorization shall be submitted.
10. The device and its accessories quality certificates according to the classification (Appendix 9).
11. In the case of sterilization devices imported from a non-reference country, a Free Sale certificate from a reference country shall be submitted.
12. In the case of Dental Units, an evidence of an Anti-retraction valve is installed in the unit shall be submitted by a factory catalog, a letter from the manufacturer authenticated by the Chamber of Commerce and the Egyptian Embassy or the manufacturer's official website on the Internet, taking

into account the necessity of clarifying the unit's accessories in the invoice and conforming them to the catalog.

13. The manufacturer's catalog indicating the device received, its conformity and the Intended Use.

Second: Documents required for spare parts:

- ✓ The device certificates as indicated in Clause (10) to which the spare parts are affiliated.
- ✓ One of the following documents must be submitted to prove that the accessory or spare part affiliate to the medical equipment:

- The device's manual shows the accessories or spare parts imported.
- The device's catalog shows the accessories or spare parts imported.
- A letter from the legal manufacturer stating the device name, its accessories and spare parts.
- The invoice indicating that the spare parts affiliate the medical equipment.

Third: Documents required for accessories:

Accessories not classified as medical equipment:

- ✓ The device certificates as indicated in Clause (10) to which the accessories are affiliated.
- ✓ One of the following documents must be submitted to prove that the accessory affiliates to the medical equipment:

- The device's manual shows the accessories imported.
- The device's catalog shows the accessories imported.
- A letter from the legal manufacturer stating the device name and its accessories.
- The invoice indicating that the accessory affiliates the medical equipment.

Accessories classified as medical equipment:

Quality certificates according to the classification as shown in the Appendix No. 9.

Appendix 2

Documents of required for obtaining an import approval for medical equipment imported for medical events (exhibitions, workshops and training)

1. A delegation by the importing company for the person responsible to deal with the General Administration of medical equipment Marketing Authorization to receive and deliver all the company's documents. This delegation shall be signed and stamped by the responsible manager with bank authentication of the signature.
2. ID of the person delegated by the company.
3. Proforma invoice, provided that indicating the date of the conference or workshop, if applicable.
4. If the applicant is a company has an activity concerning of importing of the medical equipment, medical equipment Importer Register License shall be required.

- If the import applicant is a scientific office, a scientific office license shall be required.

5. The manufacturer's catalog or manual, indicating the imported devices.
6. In the case of hospitals:

- The hospital license shall be obtained from the Free Therapy Administration and the commercial registry indicating the activity of importing medical equipment or indicating its affiliation to the Investment Authority law.

Appendix 3

Documents required for obtaining an import approval of medical equipment imported for research purposes

1. A delegation by the importing company or the university for the person responsible to deal with the General Administration of medical equipment Marketing Authorization to receive and deliver all the documents. This delegation shall be signed and stamped by the responsible manager with bank authentication of the signature.
2. ID of the person authorized by the company., university or research entity submitting an import request.
3. Proforma invoice, provided that indicating the protocol No., researcher name and university name.
4. If the applicant is a company has an activity concerning of importing of the medical equipment, a license of record of medical equipment importers will be required.

- If the import applicant is a scientific office, a scientific office license will be required.

5. Approval of the Institutional Committee for Reviewing Medical Research Ethics in the research entity registered in the Supreme Council for Review of Clinical Medical Research Ethics, stating the protocol number, researcher name and the entities in which the clinical trials are conducted.
6. A letter from the foreign manufacturer specifying the manufacturing locations and country of origin of the imported items and the country of origin if it differs from the supplier.
7. The manufacturer's catalog or manual, indicating the imported devices.
8. Payment receipt stamped with the authority's seal and bearing the invoice number.

Special instructions:

- In case of importing devices by companies or hospitals to be used in protocols approved by the Institutional Committee for Reviewing Medical Research Ethics at the research entity, the release shall be based on the available quality certificates (if applicable).
- The companies specialized in importing medical equipment shall be allowed to import devices for investigational use, for research use only or for performance evaluation.

The records and data of the importing company shall be followed up to verify the supplying entities by the representatives of the Egyptian Drug Authority in The Central Administration for Inspection on pharmaceutical institutions

Appendix 4

Documents of the request to be presented to specialized scientific committees

The required Free Sale and quality certificates shall be submitted according to the classification listed in the Appendix No. (9).

Non implantable sterile accessories

1. Declaration of conformity certificate from the manufacturer stating the classification and directive for all items and their intended use.
2. A letter indicating the following:

   Letter of exclusivity from manufacturer declaring that the sterile accessories (codes and name of the accessory) are exclusively used with the medical equipment (code and name of the device) and does not work alone and the medical equipment cannot function without it
3. A catalog showing the device and its components.

Medical equipment:

1- a signed and sealed list of the names of the hospitals receiving devices shall be submitted so that the Safety Department can conduct questionnaires.

2- Clinical studies (if any).

3- Catalog.

4- medical equipment presented to the (premature babies) committee, a calibration certificate for the device issued by the accredited calibration centers (for example: the Arab Organization for Industrialization or the medical equipment Calibration Laboratory at the Faculty of Engineering, Cairo University)

General rules for the scientific evaluation unit:

1- Accessories and consumables implanted inside the body are subject to registration and shall not be presented to the specialized scientific committee affiliated with the General Administration of medical equipment Marketing Authorization to allow marketing.

2- In case of Scientific Committee's decision issued an initial approval to the device for a period of one year, provided that it shall subject to re-evaluation by the medical equipment Safety Department and the decision expires, the device shall not be allowed to be imported until after issuance of the safety report and re-presenting to the Specialized Scientific Committee for evaluation.

In case of the device did not import throughout the validity period of the decision issued by the Scientific Evaluation Unit, the decision shall be renewed for another year without the need to re-presenting to the specialized scientific committee, provided that the company shall submit a request accompanied by a stamped pledge of not importing the device signed by the company manager and a valid bank signature and verifying that no import approvals have been issued.

Appendix 5

Documents required for special import requests

5.1 If the imported device is a donation for hospitals:

A. The letter of accepting a donation for any institution or ministry must be issued by the authority delegated to issue this type of letters and must be signed and stamped by the manager of the institution or facility. (In accordance with the Cabinet's Decision No. (1818) of 2019).
B. A declaration signed and stamped with the seal of the hospital or medical center (certified by evidence proofing the signature authenticity for non-governmental institutions) indicating that the imported device is not for sale or trade and that they hold full responsibility for it without any responsibility on the part of the Egyptian Drug Authority.
C. The hospital or medical center license from the Administration of Free Treatment and a regulation of the basic activity of civil society organizations and institutions.

5.2 If the device is imported by a hospital:

A. A declaration signed and stamped with the seal of the hospital or medical center (certified by materials proofing the signature authenticity for non-governmental institutions) indicating that the imported device is not for sale or trade and that they hold full responsibility for it without any responsibility on the part of the Egyptian Drug Authority.
B. The hospital or medical center license from the Administration of Free Treatment and the regulation of the basic activity for civil society organizations and institutions.
C. The commercial registry of the hospital (stipulating the import activity or affiliation to the Investment Authority Law No. (8) of 1997 or No. (72) of 2017. In case of the commercial registry does not stipulate the affiliation to the Investment Law, a letter by the Investment Authority indicating that the medical institution is subject to the Investment Law.
D. If the commercial registry has no import activity or if the institution does not subject to the Investment Authority Law, it shall be presented to the Import Committee.

5.3 If a device for personal use imported by an individual:

A. The device imported from abroad must be new, unused and suitable for treating the patient.

If the imported device is used, each case shall be evaluated separately by the Import Committee.

B. Submitting a clear medical report for the patient.
C. The imported device must be suitable for home use. If the patient is under medical supervision, the treating physician must provide an acknowledgment of his full responsibility for using of the imported device and stipulating of using it for the treated patient only not for any other patient.
D. An undertaking by the patient or one of his first-degree relatives (in the case of patient is not eligible person) that the imported device is not for sale or trade and that he holds the full responsibility for using it without any responsibility on the part of the Egyptian Drug Authority. The undertaking must be confirmed by one of the methods of proving the signature authenticity.

5.4 If the device is imported by a doctor for use in the clinic:

A. Quality certificates required for release of the imported device in accordance with the classification of the imported device.
B. The clinic's license from the Administration of Free Treatment to which the clinic is affiliated.
C. The profession license of the doctor.
D. The decision of the specialized scientific committee regarding the device if it is subject to be presented to the specialized scientific committees.
E. An undertaking that the imported device is for using in the doctor own clinic and not for trade.
F. A catalog for the imported device.

5.5 In case of importing by a company has an activity concerning importing medical equipment (for the benefit of a hospital):

A. A clear medical report on the case for which the devices were imported.
B. A declaration signed and stamped with the seal of the hospital or medical center (certified by materials proofing the signature authenticity for non-governmental institutions) indicating that the imported device is not for sale or trade and that they hold full responsibility for it without any responsibility on the part of the Egyptian Drug Authority.
C. License of the hospital or medical center from the Administration of Free Treatment and the regulation of the basic activity of the civil society organizations and institutions.

5.6 In case of importing by a company has an activity not concerning importing medical equipment, the following documents shall be submitted:

A. The company's commercial register, specifying the activity.
B. An undertaking that the imported device is intended for use within the facility and not for the purpose of trade.
C. A clear catalog explaining the intended use.
D. In the case of importing medical equipment, the following shall be provided in addition to the aforementioned documents:
   - An available human physician working within the company.
   - Doctor's professions practicing license
   - Presence of a clinic within the company.

Appendix 6

Documents required for issue an annual import approval for a medical equipment

First: Documents of the import approval applicant:

1. The importing company's authorization for the person responsible for dealing with the General Administration of medical equipment Marketing Authorization to allow circulating. The authorization shall be signed and stamped by the responsible manager of the company, with bank authentication of the signature.
2. ID of the person authorized by the company.
3. medical equipment Importer Register License, in addition to:
   - A valid license of maintenance center, and

   - The supplying / manufacturing company based on the relationship letter:
4. Form 14 for agents.
5. The valid and authenticated by the Chamber of Commerce and the Egyptian Embassy distribution / agency contract concluded with the supplying company.
6. In case of manufacturing company is different from the supplying company, the documents of the relationship issued by the foreign factory shall be submitted and it shall indicate the right of the supplying company to supply the devices imported into Egypt issued by the foreign factory. The relationship document shall be authenticated by the Chamber of Commerce and the Egyptian Embassy.
7. Payment receipt for the service.

Second: The documents of the device and its accessories:

1. The manufacturer's catalog or manual containing the device, spare parts, accessories matching the device.
2. A letter from the manufacturer with all non-sterile device accessories for which an annual approval will be issued.
2. Quality certificates of the medical equipment (Appendix 9).
4. Approval of the specialized scientific committee on the devices and their accessories.

Third: Documents required for amending an annual import approval:

1. The approval of the specialized scientific committee for the devices if the device is subject to be presented to the specialized scientific committees.
2. In the case of changes related to the medical equipment:

(**Moving the place of manufacturing / adding a country of origin / adding a place of manufacturing to the same legal manufacturer, changing the foreign manufacturer name while keeping the same address, changing the legal manufacturer address, changing or adding the legal manufacturer (provided that keeping the same actual manufacturer)**

- ✓ The certificates indicating the change, shall be submitted in accordance with Appendix No. (9).

3. In case of amendments related to the list of spare parts and accessories not classified as medical equipment (add spare parts and / or accessories that are not classified as medical equipment to the issued list), the following shall be submitted:

- ✓ The manufacturer's catalog or manual containing the device, spare parts, accessories matching the device.
- ✓ A letter from the manufacturer with all non-sterile device accessories for which an annual approval will be issued.

Appendix 7

Documents required to issue a release approval for an invoice of a medical equipment, accessories classified as affiliated to the device and spare parts for which has an annual import approval

1. A delegation by the importing company for the person responsible to deal with the General Administration of medical equipment Marketing Authorization to receive and deliver all the company's documents. This delegation shall be signed and stamped by the responsible manager with bank authentication of the signature
2. Record of medical equipment importers (latest version), in addition to:

- A valid license of maintenance center, and

- The supplying / manufacturing company based on the relationship letter.

3. The invoice.
4. The annual import approval.
5. Free Sale and quality certificates required according to the classification in case of their expiration / invalidity in the import approval.

Appendix 8

Documents required in case of lack to jurisdiction

1. A delegation by the importing company for the person responsible to deal with the General Administration of medical equipment Marketing Authorization to receive and deliver all the company's documents. This delegation shall be signed and stamped by the responsible manager with bank authentication of the signature.

2. In case of the importing for personal use, the ID of the importer himself or the person delegated by the importing entity / company in case of import applicant is a certain entity or company.

3. In case of the importer is a company has no activity concerning importing of medical equipment, the commercial register and tax card are required.

4. For local factories, the industrial register indicating the activity is required.

5. Proforma invoice.

6. The manufacturer's catalog or manual, indicating the included devices.

7. The payment receipt stamped with the Authority's seals and holding the invoice number.

8. A stamped, signed and notarized Declaration of Conformity Certificate by the legal factory includes the following:

- Legal manufacturer responsibility (Name and full address of the legal and actual manufacturers (intended use, if applicable)

- Indicating that the imported item is not a medical device or IVDs: (according to medical device directive & IVD directive).

9. If the Declaration of Conformity does not indicate the intended use, a clarification letter from the manufacturer stating the intended use, signed and stamped, is required.

Appendix 9

Circulating and quality certificates required according to the classification

Pursuant to the rules applied in the European community

Class	Certificates
Class 1 non sterile	1. Declaration of Conformity Certificates (statement by the company of the certificate authenticity) 2. Free Sale certificate.
Class I Sterile	1. Declaration of Conformity Certificates (statement by the company of the certificate authenticity). 2. Free Sale certificate. 3. CE certificate.
Class II a	1. Declaration of Conformity Certificates (statement by the company of the certificate authenticity). 2. Free Sale certificate. 3. CE certificate.
Class IIb/ III from a reference country	1. Declaration of Conformity Certificates (statement by the company of the certificate authenticity). 2. Free Sale certificate. 3. CE certificate.
Class IIb / III from a non-reference country	1. Declaration of Conformity Certificates (statement by the company of the certificate authenticity). 2. Free Sale certificate. 3. CE certificate. 4. In case of presenting to a scientific committee, the approval of the specialized scientific committee is required.
- ISO 13485: 2016 certificate	

Based on the rules applied in the USA and relying on the provisions indicated in FDA

Class	Certificates
Class I	1. CFG with GMP certificate 2. letter of declaration certificate indicating the classification based on the USA rules
Class II and III	1. CFG with GMP certificate or CFG without GMP + ISO 13485:2016 2. letter of declaration certificate indicating the classification based on the USA rules

Pursuant to the rules applied in Canada:

Class	Certificates
Class I	1. DOC acc. To Canadian regulation mentioning the classification according to the form published on Health Canada website: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/md_doc_im_ddc-form_eng.pdf 2. Manufacturer certificate to cover export of medical equipment (= FSC) issued from: the HPFBI, Health Canada 3. medical equipment establishment license
Class II, III,IV	1. medical equipment active license (In case medical equipment active license is issued for medical equipment family, medical equipment group, or medical equipment group family) its validity shall be assured via the following link: Active license data base https://health_products.canda.ca/mdall-limh/prepareSearch-preparerRecherche.do;jessionid=2243EC9EFE11F2466DD71f7934514E89?type=active Archived license data base http://health-products.canda.ca/mdall-limh/prepareSearchpreparRecherche.do;jsessionid=2243C9EFE11F2466DD/71F7934514E89?type=archived_archive **N.B**: the declaration letter will be sent to the health Canada to confirm that the license covers the whole medical equipment list. 2. Declaration of conformity acc. To Canadian regulation mention the classification 3. Manufacturer certificate to cover export of medical equipment (= free sale) issued from: the HPFBI, Health Canada 4. MDSAP https://www.fda.gov/media/131149/download

Provided that the for mentioned certificates shall contain the following information:

Certificate	Issued by	Certificate contents
(D.O.C) **Declaration of conformity** **Signed and stamped**	**(Legal manufacturer)**	• statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer • Name of the legal and actual manufacturers (if present) • full address of the legal and actual manufacturers (if present) • Trade name of the medical equipment • medical equipment description Variants either: Codes, models, sizes, references, catalogue number. • Classification in accordance with the rules set out in Annex IX in MDD or Annex VIII of the EUMDR • Complying with Directive 93/42/EEC or EUMDR 2017/745 • Name and identification number of the notified body, (if applicable) • CE no. (if applicable) • Intended use. If not stated, it can be submitted in a separate clarification letter. • Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for and on behalf of whom, that person signed, signature.
(CFG) **certificate to foreign government** **signed**	**(USFDA)** **The US Food and Drug Administration**	• Name of the legal and actual manufacturers (if present) • full address of the legal and actual manufacturers (if present) • trade name of the medical equipment • medical equipment description • Variants either: Codes, models, sizes, references, catalogue number. • Certificate No • Issuance date • Validity • Stating the manufacturer's compliance with current good manufacturing practice requirements for the product, or submitting CFG Without GMP+ISO13485:2016
(Free sale certificate) **signed**	**Competent authority in the origin country or any other country**	• Name of the legal and actual manufacturers (if present) where applicable • full address of the legal and actual manufacturers (if present) where applicable • trade name of the medical equipment • medical equipment description (if present • Variants either: Codes, models, sizes, references, catalogue number.

		• Issuance date • Certificate No. (if present) • Validity (if present) • Complying with Medical Device Directive 93/42/EEC or EUMDR 2017/745
CE Signed **For the finishes product** **Class 1 Sterile:** **CE (Annex V or Annex 11.3)** **Class IIa:** **CE (Annex V or Annex 11.3)** **Class IIb:** **CE Annex 11.3 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**	**Accredited Notified body note: list of Accredited Notified body is found on the NANDO website https://ec.europa.eu/growth/tools-/databases/nando**	• Name of the legal and actual manufacturers (if present) • full address of the legal and actual • manufacturers (if present) • trade name of the medical equipment (in case of EC -Type Examination or EC Design Examination) • Variants (in case of EC -Type Examination or EC Design Examination) either: Codes, models, sizes, references, catalogue number. • Certificate No • Issuance date • Validity • Scope of certificate category/family for submitted products)
ISO 13485:2016 signed (Quality management system) of the manufacturing company	**Certification body with accreditation recognized by IAF note: list of accreditation Bodies https://iaf.nu/en/accreditation-bodies/**	• Name of the actual manufacturer • full address of the actual manufacturer • Certificate No. • Scope of certificate mentioning production, /manufacture of medical equipment • Issuance date • validity

NB:

- It is not required to authenticate the quality certificates (CFG, Free Sale, CE or ISO13485:2016) of the medical equipment issued from reference countries (by the Chamber of Commerce and the Egyptian Embassy in the country of origin) which the administration verified its authenticity from the authorities issuing these certificates.

In case of the issuance authenticity of these certificates by these authorities is not assured, these certificates must be presented after being authenticated by the Chamber of Commerce and the Egyptian Embassy.

In case of lack to respond by the entity within 3 months from the date of receiving the file, the file shall be transferred for shelving and resubmitting after re-authentication according to the list of documents published at the time of resubmission.

CFG issued by USFDA certificates are not required to be authenticated by the Chamber of Commerce and the Egyptian Embassy in case of required information stipulated in them is verified through the websites of:

- FDA CDRH Export certificate validation and Premarket Notification for medical equipment classified as Class II, and

- FDA CDRH Export certificate validation and Premarket Approval for medical equipment classified as class IIII.

9. Special requirements for importing medical equipment:

A. **In case of importing a laser device or its spare parts that contain a laser source**, the approval of the National Institute of Laser Sciences shall be submitted for the imported devices according to the number of the devices listed in the same invoice data or by a description letter from the National Institute of Laser Sciences.

B. **Regarding submitting the approval of the National Institute of Laser Sciences for each invoice that contains laser devices and this approval is issued for the final invoice**, the condition of presenting it to the Laser Institute shall be indicated in the import approval, as the imported devices shall be reviewed by the institute upon their actual arrival.

C. **In case of expiring the maintenance center license in the importers' registry**, the renewed license shall be added to the importers' registry and a two-month grace period for importing from the date of expiry of the maintenance contract, shall be granted.

D. **In the case of the devices that its manufacturing has been stopped**, their non-sterile spare parts or accessories shall be permitted to be imported, provided that the following documents shall be submitted:

- A letter issued by the legal manufacturer explaining the reason for stopping of manufacturing the device models to which the imported spare parts affiliate. The letter shall be authenticated by a chamber of commerce and the embassy or verifying its authenticity by the administration's e-mail.

The letter must indicate:

- The time period for supplying spare parts.
- The company undertaking of supplying spare parts for these devices.
- The reason for stopping manufacturing.
- A pledge by the importing company that these devices have not subjected to recall or caused harm to patients and that they hold full responsibility for them, without any responsibility on the part of the Egyptian Drug Authority.
- A signed and stamped letter by the director of the importing company listing the devices for which spare parts are supplied and the locations of supplying them.

In the case of importing sterile spare parts or accessories, the decision of the Scientific Committee shall be submitted.

E. **In case of importing spare parts or consumables for sterile and non-sterile devices that were presented to the specialized scientific committees and issued a decision of approval for a period of one year and the decision was not renewed after its expiration:**

The previous approval for the device and a catalog, manual or letter from the company shall be presented stating that the imported spare parts are for the device that has previously obtained an approval from the Scientific Committee.

F. **It is prohibited to import samples of medical equipment**, but the sterile accessories for the devices shall be allowed to be imported to be presented to the scientific committee.

G. **It is prohibited to import any used medical equipment or accessories** (except in the case of display at exhibitions and conferences or for evaluation by the Import Committee, provided that the used devices shall be returned).

H. medical equipment accessories, whether sterile or non-sterile, which are classified as a medical equipment and for which certificates separate from the device are issued, these certificates shall be submitted in accordance with the Appendix No. 9.

10. General requirements:

A. The approval is issued to the sake of the approval holder and should not be waived or transferred.
B. Any erasure, deletion, amendment or addition to the approval turn it nullified.
C. The approval issued for an invoice shall be valid for the FCL shipment only and is not divisible.
D. The importation shall take place based on a proforma invoice and it is prohibited to ship any items imported from abroad except after obtaining the necessary import approval. In case of shipping the goods, the company shall hold the full responsibility and it has not the right to apply to issue the approval except after completing all the documents and submitting them to the specialized committees if necessary.
E. Advertising in any media shall not be permitted except after obtaining of the Egyptian Drug Authority's approval.
F. The device must be new and unused.
G. The imported device data must conform to the data mentioned in the attached invoice.
H. The invoice shall be considered valid for a maximum period of one year from the date of its issuance if the supplying company does not indicate another expiry date.
I. It is not permissible to import any used medical equipment, whether for private use or for trade, except after consulting the General Administration to permit circulation to consider the extent of the permissibility of import and circulation.
J. It is not permitted to apply for obtain an import approval for a single invoice more than once.
K. In case of the applicant is a scientific office, the scientific office license is required, in addition to the supplying company and considering the decision of the Egyptian Drug Authority's chairman No. (315) of 2021.
L. Submitting the request on the Authority’s website means that the manufacturer and its representative are fully responsible for all the data and documents submitted.
M. In case of violating any of the previous instructions, the factory shall hold any resulting financial, legal or administrative consequences.

11- Regulatory Decisions

A. Regarding samples and DEMO

Companies shall not be allowed to import Demo devices classified higher than Class I, such as patient monitors and electrosurgical devices as these companies do not have a registration license and therefore, they have no maintenance center.

B. With regard to medical equipment to be exported for repair and return

The examination shall be carried out by the Customs Authority, as it is the authority responsible for examining and conforming the devices in terms of quantities and brands and ensuring that they are the same devices that were exported for repair and return.

C. Regarding the expiration / invalidity of quality and trade certificates

Submitting evidence stating that the equipment was manufactured before the expiry date of the quality or free sale certificate then the import shall be permitted.

D. Regarding spare parts for a device whose agency has expired

In case of the importer of spare parts is a company whose agency / distribution contract is not valid and there is a valid maintenance contract and this company was the supplier of the device, the company shall be allowed to import spare parts.

E. Regarding the used devices

It shall be presented to the Specialized Scientific Committee to Study, Produce and Import medical devices and equipment to evaluate the following:

- ✓ Devices imported for research or medical purposes.
- ✓ Items permitted to be imported as personal use include the following:
- Wheel chairs for people with disabilities.
- Oxygen concentrator
- Patient lift
- Stethoscope

12- List of abbreviations:

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

13.Versions:

Places of Amendments	Issue date	version
	06/04/2022	**First**
The name of the Central Administration for Operations has been updated to become the Central Administration for Inspection on pharmaceutical institutions or the Central Administration of Licensing of pharmaceutical institutions whenever they are mentioned in the guideline, depending on the specialization.	01/09/2025	**Second**