Central Administration of Medical devices

Notice to Applicant

Essential Requirements for Receiving Applications for Importation Approvals, Precautionary Release, and Annual Importation Plans via the MeDevice Electronic Platform.

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1. Essential Requirements for Receiving an Importation Approval File

- An electronic payment receipt that has not been previously used.
- Proforma Invoice.
- Quality and circulation certificates as specified in the certificates table according to the classification in the Regulatory Guide for Issuing Importation Approvals for Medical Devices of All Types.
- Registration license in the Register of Medical Device Importers issued by the Central Administration for Licensing of Pharmaceutical institutions.
- A valid registration notification for sterile and non-sterile items that have obtained a registration license.
- Registration file numbers for non-sterile devices.
- **For Local Manufacturers:**
    - **Sterile Devices:** Industrial register issued by the General Authority for Industrial Development; technical operating license issued by the Egyptian Drug Authority; Certificate of Analysis for the raw material; final device notification for the sterile item; and quality certificates for the Egyptian factory if registered with quality certificates.
    - **Non-Sterile Devices:** Industrial register issued by the General Authority for Industrial Development; industrial development license; Certificate of Analysis for the raw material and the final device; and a Declaration of Conformity.
- Scientific Committee decision for non-sterile medical devices classified from Class II and above originating from a non-reference country.
- A valid registration license is required for medical devices in dosage form for all classifications, except for oral, nasal, otic, and buccal.
- For events: Submission of the event brochure/manual for the conference or the hosting entity.
- For applications to amend importation approvals: Submission of an importation approval for which one year has not passed since its issuance date.

2. Essential Requirements for Receiving a Precautionary Release Request

- An electronic payment receipt that has not been previously used.
- Commercial invoice stamped with the medical stamp duty, in addition to the factory or bank stamp.
- Bill of Lading.
- Registration license in the Register of Medical Device Importers issued by the Central Administration for Licensing of Pharmaceutical institutions(in the case of release under an importation plan).
- Valid registration license.
- Importation approval and the attached proforma invoice (in the case of release under an importation approval) OR a valid importation plan (in the case of release under an importation plan).

3. Essential Requirements for Receiving an Annual Importation Plan Request

- An electronic payment receipt that has not been previously used.
- Valid registration license matching the data uploaded to the platform; if expired, the registration file acceptance number during the circulation grace period must be provided.
- Quality and circulation certificates as specified in the certificates table according to the classification in the Regulatory Guide for Issuing Importation Approvals for Medical Devices of All Types.
- Registration license in the Register of Medical Device Importers issued by the Central Administration for Licensing of Pharmaceutical institutions.
- A letter of discrepancies between the expired license and the application submitted for registration (New Registration - Re-registration).

4. Essential Requirements for Amending Annual Importation Plans

- An electronic payment receipt that has not been previously used.
- The importation plan intended for amendment.
- A letter from the importing company/local manufacturer explaining the reason for the amendment.

5. Essential Requirements for Receiving/Amending a Scientific Committee Decision

- An electronic payment receipt that has not been previously used.
- Quality and circulation certificates as specified in the certificates table according to the classification in the Regulatory Guide.

6. Essential Requirements for Receiving Unified Procurement Authority (UPA) Files

- An electronic payment receipt that has not been previously used.
- Invoice in the name of the Unified Procurement Authority (mentioning the contract number is not required).
- Quality and circulation certificates according to classification.
- Authorization issued by the Unified Procurement Authority to the authorized person, mentioning the contract number, signed and stamped (Original required).
- Authorization from the Egyptian company to the Unified Procurement Authority to import the invoice contents, signed and stamped (Original required).
- Contract concluded between the Unified Procurement Authority and the foreign company, signed and stamped, matching the items in the contract's item appendix.
- Undertaking from the Unified Procurement Authority for the registered items regarding the storage location.
- Submission of an Excel sheet for the items as mentioned in the invoice, specifying the GTIN Code, to the designated email.
- For registered items: Valid registration license and all related variation letters or grace period extensions.