Central Administration Of Medical Devices
General Administration Of Medical Devices Marketing Authorization

Minimum Requirements for Receiving Applications for Import Approvals of Medical equipment and their Spare Parts, Annual Approvals, Unified Procurement Authority (UPA) Approvals and Amendments to Import Approvals Via MeDevice Electronic Platform Year 2025

Code: EDREX:NP.CAMD.14

Version No:1

Issue Date: 11/2025

Effective date: 11/2025

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1 Import Approval Requirements for Medical equipment and Their Spare Parts:

1. Submission of a valid and *unused electronic payment receipt*.
2. Submission of a *preforma invoice*.
3. Submission of a valid Quality and Free Sale Certificates in accordance with its appropriate classification as declared in the published EDA regulatory guidelines.
4. Valid *importer registration license* issued by the Central Administration for Licensing of Pharmaceutical Institutions.
5. Valid *registration notification letter* for applicable non-sterile items.
6. *Scientific Committee approval* for
    a. Class IIb non-sterile devices imported from non-reference countries.
    b. Sterile medical accessories.
7. For local manufacturers: *industrial register, industrial license*, and *Declaration of Conformity* of the final product.
8. *Approval letter* from the host entity, in case of exhibition or conference purposes, where applicable.

2 Amendment of Import Approvals:

1. Submission of a valid and *unused electronic payment receipt*.
2. Copy of the import approval subject to amendment.
3. Official letter from the applicant stating the justification for amendment.
4. The approval must be valid and within one year from the date of issuance.

3 Annual Import Approvals:

1. Submission of a valid and unused electronic payment *receipt*.
2. Submission of a valid Quality and Free Sale Certificates in accordance with its appropriate classification as declared in the published EDA regulatory guidelines.
9. Valid *importer registration license* issued by the Central Administration for Licensing of Pharmaceutical Institutions.
3. Scientific Committee approval where applicable.
4. Manufacturer declaration confirming accessories are non-sterile, non-standalone, and without separate certification.
5. Applicant declaration letter stating all accessories included within the annual approval.

4 Unified Procurement Authority (UPA) Requirements:

1. Submission of a valid and unused electronic payment *receipt*.
2. Invoice issued by the name of the Unified Procurement Authority with or without contract number.
3. Submission of a valid Quality and Free Sale Certificates in accordance with its appropriate classification as declared in the published EDA regulatory guidelines.
4. Original signed and stamped authorization letter issued by the name of the Unified Procurement Authority (UPA) with contract number to authorize the legal representative person to deal in the name of the Unified Procurement Authority (UPA).
5. Original signed and stamped authorization letter issued by the name of the Local company to authorize the Unified Procurement Authority (UPA) to deal with the importation responsibility of the invoice items.
6. Contract annex listing all items.
7. Submission of itemized data in Excel Sheet via official email md.certificate@edaegypt.gov.eg including GTIN, pricing, manufacturer details, and classification.
8. Valid registration license for amended or extended items.
9. Scientific Committee approval for applicable Class IIb devices and sterile devices.