

Minimum Requirements for Submitting Import Approval Requests for In-vitro Diagnostic medical devices and Laboratory Equipment/ Annual IVD Import Approvals/ Annual IVD Import Approval variations/ Imported IVD listing requests/ Local IVD listing requests/ Unified Procurement Authority (UPA) Files via the "MeDevice" Electronic Platform Year 2025

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First: Minimum requirements for Approval Requests of In-vitro diagnostic medical devices and laboratory equipment

- 1- Electronic payment receipt (not used before)
- 2- Proforma Invoice
- 3- International quality certificates and free sale certificates as mentioned in certificates annex as per classifications mentioned in the guidelines of IVD listing and issuance of IVD Import approvals.
- 4- Importer register license (for kits in case of importing IVD or non-IVD products- for medical devices in case of importing laboratory equipment and their consumables
- 5- For local factories:
 - ✓ Factory license (issued from industrial development authority)
 - ✓ Industrial register (issued from industrial development authority)
 - ✓ Technical license for operation of In-vitro diagnostic medical devices plant
 - ✓ Certificate of analysis of raw materials and quality certificates of the local factory.

Second: Minimum requirements of Annual IVD Import approval requests

- 1- Electronic payment receipt (not used before)
- 2- Application mentioning products submitted in the annual approval
- 3- Importer register license (for kits in case of importing IVD or non-IVD products- for medical devices in case of importing laboratory equipment and their consumables
- 4- International quality certificates and free sale certificates as mentioned in certificates annex as per classifications mentioned in the guidelines of IVD listing and issuance of IVD Import approvals.

Third: Minimum requirements of Annual IVD Import approval variation

- 1- Electronic payment receipt (not used before)
- 2- Original copy of the Annual IVD import approval requiring variation
- 3- Clarification letter from the company for the variation required

Fourth: Minimum requirements of Imported IVD listing request

- 1- Electronic payment receipt (not used before)
- 2- Application for the submitted products in the listing request
- 3- Kits Importer register license mentioning the name of the legal manufacturer of the products or the distributor company as per the relationship letter between the manufacturer and the distributor.
- 4- International quality certificates and free sale certificates as mentioned in certificates annex as per classifications mentioned in the guidelines of IVD listing and issuance of IVD Import approvals.

Fifth: Minimum requirements of Local IVD listing requests

- 1- Electronic payment receipt (not used before)
- 2- Application for the submitted products in the listing request
- 3- Factory license (issued from industrial development authority)
- 4- Industrial register (issued from industrial development authority)
- 5- International quality certificates and free sale certificates as mentioned in certificates annex as per classifications mentioned in the guidelines of IVD listing and issuance of IVD Import approvals.

Sixth: Minimum requirements of Unified Procurement Authority (UPA) Files

- 1- Electronic payment receipt (not used before)
- 2- Proforma invoice for UPA (it's not mandatory to mention the contract number in it)
- 3- International quality certificates and free sale certificates as mentioned in certificates annex as per classifications mentioned in the guidelines of IVD listing and issuance of IVD Import approvals.
- 4- Signed and stamped Delegation letter issued from UPA for the representative mentioning contract number (original copy)
- 5- Signed and stamped Delegation letter issued from the Egyptian company for UPA allowing for importing invoice contents (original copy)

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- 6- Signed and stamped Contract between UPA and foreign company, with mapping of products by numbering on products annex in the contract
- 7- Commitment from UPA for products storage site
- 8- An Excel sheet for the products as mentioned in the invoice mentioning GTIN code to be sent on the following E-mail: ivd.import@edaegypt.gov.eg as follows:

Name of the product as mentioned in the invoice	Product classification	Quantity	Unit type	Legal Manufacturer's name	COO	Actual Manufacturer's name	COO	Price	Unit Price	GTIN code
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- 9- Letter clarifying numbers of IVD listing requests for the products found in the invoice.