MED-13011/16/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices Division)

Food & Drugs Administration Bhawan,
Kotla road, New Delhi-110002

Dated: 15 SEP 2025

Circular

Subject: Separate provision for Subsequent Importer in Online System for Medical Devices- regarding.

In order to simplify the regulatory approval procedure, the CDSCO has initiated various steps to bring more transparency and accountability in the regulatory system. Several **'Tool Tips'** have been published in CDSCO website to give more clarity on the technical requirements etc., while making applications in portal for regulatory approval. The procedure for **'Brand Approval'** has been simplified with minimum requirements and separated from the routine endorsement applications with the objective to reduce processing timelines and facilitate expedited approval.

Now, a separate provision for **'Subsequent Importer'** has been made functional w.e.f 11.09.2025 in the CDSCO online portal (https://cdscomdonline.gov.in) for import of already approved Medical Devices and In-vitro diagnostics (IVD) by the Central Licensing Authority under Medical Devices Rules, 2017.

In view of the above, the applicant who intend to import Medical Devices & IVDs which are already approved by the Central Licensing Authority for marketing in the country may submit their application for import of such devices as subsequent importer as per checklist provided for the said purpose.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

All stakeholders through CDSCO Website

Copy for information to:

1. State/UTs Licensing Authorities.
2. CDSCO, Zonal/Sub-Zonal/Port offices
3. IT cell and CDAC Team