File No.: MED-16035/14/2025-eoffice
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standards Control Organization
(Medical Devices Division)

FDA Bhawan, New Delhi
Dated: 04 DEC 2025

Circular

Sub: New provision for Risk Classification of Medical Devices on the CDSCO Online System for Medical Devices – Reg.

In order to simplify the regulatory approval procedures and easing the process of risk classification of medical devices other than In-vitro Diagnostic (IVD) medical devices, a new Risk Classification Module has been made functional on the CDSCO Online System for Medical Devices (http://cdscomdonline.gov.in) for all stakeholders w.e.f. 27.11.2025.

In view of the above, the applicant seeking risk classification for the device which is not listed in the CDSCO published classification list, may submit application through the said portal to obtain risk classification of device under Medical Device Rules, 2017.

(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