F. No. IVD-19011(11)/32/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(In-Vitro Diagnostic Division)

FDA Bhawan, New Delhi

Dated: 06 FEB 2026

Circular

Sub: New provision for Risk Classification of In-Vitro Diagnostic 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 In-Vitro Diagnostic 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. 02.02.2026.

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 In-Vitro Diagnostics 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

IVD-19011(11)/32/2024-eoffice
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

FDA Bhawan, New Delhi
Dated:
06 FEB 2026

To,

Sh. Rishi Prakash,
Senior Director,
Centre for Development of Advanced Computing (CDAC),
C-56/1, Anusandhan Bhawan, Institutional Area,
Sector-62, Noida, 201307, U.P.

Sub: User Acceptance Letter for Medical Device Portal 3.0 Enhancement — Reg.

With reference to the Medical Device Portal Enhancements, CDAC team has studied the new requirements for the new modules, as per the Gazette of India dated 20 September 2022, with designated CDSCO officials in the said In-Vitro Diagnostics division. The online processes for the below modules have also been developed & demonstrated to the In-Vitro Diagnostics division officials of CDSCO. Feedback from In-Vitro Diagnostics officials have been incorporated.

After various iterations of meetings and discussions, the said application with the following modules is accepted for making it operational at www.cdscomdonline.gov.in.

New Module Development (additional activity) in regard to:

1. ***Risk Classification Module for IVD for both applicants and officials.***
2. ***Risk Classification module for IVD for OTP based registered users.***

The user acceptance is for the processes mentioned above only.

The above mentioned system modules shall be made operational by hosting at CDAC Noida Data Center using the URL: www.cdscomdonline.gov.in post verification by the In-Vitro Diagnostics division officials on the UAT Test link.

Further, it may also be noted that application has been / shall be regularly updated/maintained as per maintenance/ enhancement requirement of In-Vitro Diagnostics division of CDSCO.

Thanking You,

Yours Faithfully,

Dr. Rajeev Singh Raghuvanshi
Drug Controller General(I)

Copy to:
PS to DCG(I) for information
DDC(I), In-Vitro Diagnostics Division.

NEW MODULE FOR RISK BASED CLASSIFICATION

Pre-Screening Checkpoint

1. Whether the proposed product qualifies the definition of In-vitro Diagnostic Medical Device under the Medical Device Rules, 2017.

   ☐ YES ☐ NO

2. Whether you have verified that the proposed IVD is NOT listed in the CDSCO risk classification lists published on the CDSCO website?

   ☐ YES ☐ NO

- *If Yes-Yes then the application shall proceed
- **If No to either the questions, then the following response is to be sent

The proposed product is either not an In-Vitro Diagnostic Medical Device or is already listed in the CDSCO risk classification lists published on the CDSCO website. You may again verify the same.

Document Checklist for Risk Classification of In-vitro Diagnostic Medical device (to be uploaded by the applicant)

S.No.	Checklist
1.0	Application
2.0	Product Details:
2.1	Technical device details including Intended use, Indication, Device principle, technology, composition/components/accessories etc.
2.2	Catalogue of products/IFU/User manual/Package insert
2.3	Product Labels/product design
2.4	Regulatory status of the proposed device/similar device registered in other countries viz. USA, UK, EU, Australia, Canada or Japan etc.
2.5	Any other information, if available