STEPS TO BE FOLLOWED BY THE MANUFACTURERS/ IMPORTERS FOR REGISTRATION OF NON-NOTIFIED MEDICAL DEVICES

Step-1-> Follow the URL https://cdscomdonline.gov.in/NewMedDev/Homepage

Step-2-> Applicant has to click on the registration link from the portal.

Step-3-> Applicant has to register with a valid Email-id and Mobile No.

Step-4->The applicants has to upload the following documents for registering on the portal:-

- Id Proof Details
- Undertaking
- Corporate Address Proof Details (Certificate of Incorporation)
- Copy of Manufacturing License and the Wholesale Licenses (If not then upload the justification for the same)

Step- 5->The applicant has to verify the registration through the OTP (4 digits) received on the mobile.

Step-6->After self-verification, the applicants can login and proceed further.

Guidance Document for Manufacturers / Importers for voluntary/ mandatory registration of Medical Devices

Documents required for Registration of medical devices by the Manufactures: -

1. Name & address of the company or firm or any other entity manufacturing the medical device along with name and address of manufacturing site of medical device
2. Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension	Shelf Life	Sterile or Non Sterile	Brand Name

3. Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device
4. undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic

Documents required for Registration of Medical Devices by the Importers: -

1. Name of the company or firm or any other entity importing the medical device
2. Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension	Shelf Life	Sterile or Non Sterile	Brand Name

3. Specification and standards of that medical device
4. certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device
5. Free sale certificate from country of origin

6. undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

- The registration of Class A, B, C & D devices has been kept voluntary for a period of 18 months w.e.f. 1st April 2020 i.e till 30.09.2021,
- Voluntary Registration of Class A & B devices shall be followed by Mandatory Registration for 12 months after 18 months of Voluntary registration period is over i.e. up to 30.9.2022,
- From 01.10.2022 Class A & B devices will fall under licensing regime.
- Voluntary Registration of Class C & D devices shall be followed by mandatory registration for 24 months after 18 months' Voluntary registration period is over i.e. 01.10.2021 to 30.9.2023
- From 01.10.2023 Class C & D devices will fall under licensing regime.