



VOLUNTARY REGISTRATION OF MEDICAL DEVICES WITH CDSCO PROCESS ROADMAP - How to Register Your Products



Exclusively for SMTA Members

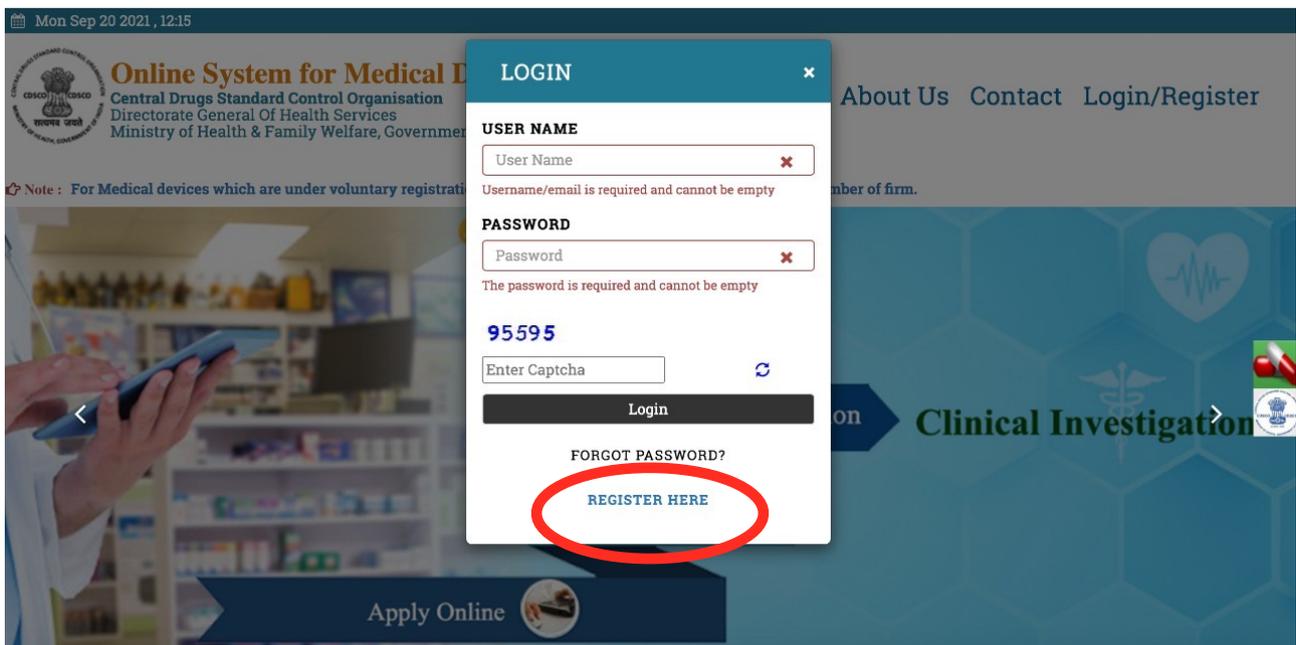
1. Visit - <https://cdscomonline.gov.in/NewMedDev/Homepage> - Click on 'Login/Register'



Note : For Medical devices which are under voluntary registrations , the file number generated is the registration number of firm.



2. Click on 'Register Here'



3. This page will appear — From the drop down menu for ‘Registration Purpose’ — Select ‘For Voluntary registration/Compulsory registration of applicable Medical Devices vide GSR 102’ and Click on ‘Submit’

Home / Registration Purpose

Registration Purpose

Registration Purpose:* For Voluntary registration/Compulsory registration of applicable Medical Devices vide GSR 102

4. Online Registration form for ACCOUNT CREATION will appear -

- (a) Create Username (use company email id) and Password
- (b) Fill in Company and Personnel Details
- (c) Documents to be uploaded with form - ID PROOF, UNDERTAKING (format provided), ADDRESS PROOF (Certificate of Incorporation/GST)
- (d) Check details and click on ‘Submit’
- (e) ID will be verified through OTP - once OTP is confirmed, Company Account will be created

Applicant Details

Applicant Type:* Non Regulatory Device
Multiple Roles can be selected

User-Name:*

Password:*
Only Best Passwords are accepted

Confirm Password:*
Only Best Passwords are accepted

Name:* Mr.

Mobile Number:* +91

Gender:* Male Female

Nationality:* Indian

ID Proof Details:* Select One No file chosen
(Single PDF < 10 MB)

Undertaking:* No file chosen
(Single PDF < 10 MB) (Undertaking) - Available in Enterable PDF Format

Designation:*

Alternate Email ID:

Registering for Division:* Choose Division
Multiple Divisions can be selected

Registered Indian Address (This address will be referred in all the forms submitted to CDSCO office)

Organization Name*:

Organization Type*:

CIN (Corporate Identification Number):

Address Line *

Country* State* District*

City/Taluka/Mandal/Tehsil* Pin Code*

Contact No.* (Please include STD Code - Phone Number)
Multiple Contact Numbers can be added with comma separation

Fax No.* (Please include STD Code - Fax Number)
Multiple Fax Numbers can be added with comma separation

Upload Your Corporate Address Proof Details (Certificate of Incorporation)*
(Single PDF < 10 MB) No file chosen

Please tick (✓) this option if you want to receive SMS alerts.

59637

I agree to the [terms, conditions and privacy policy](#) laid down by Central Drugs Standard Control Organisation, DGHS, Ministry of Health & Family Welfare for availing the online services provided under this portal. *

5. **HOW TO REGISTER YOUR PRODUCTS** - Once account is created, go back to - <https://cdscomonline.gov.in/NewMedDev/Homepage> - Click on 'Login/Register' to log into your account



Online System for Medical Devices
 Central Drugs Standard Control Organisation
 Directorate General Of Health Services
 Ministry of Health & Family Welfare, Government of India

Home About Us Contact **Login/Register**

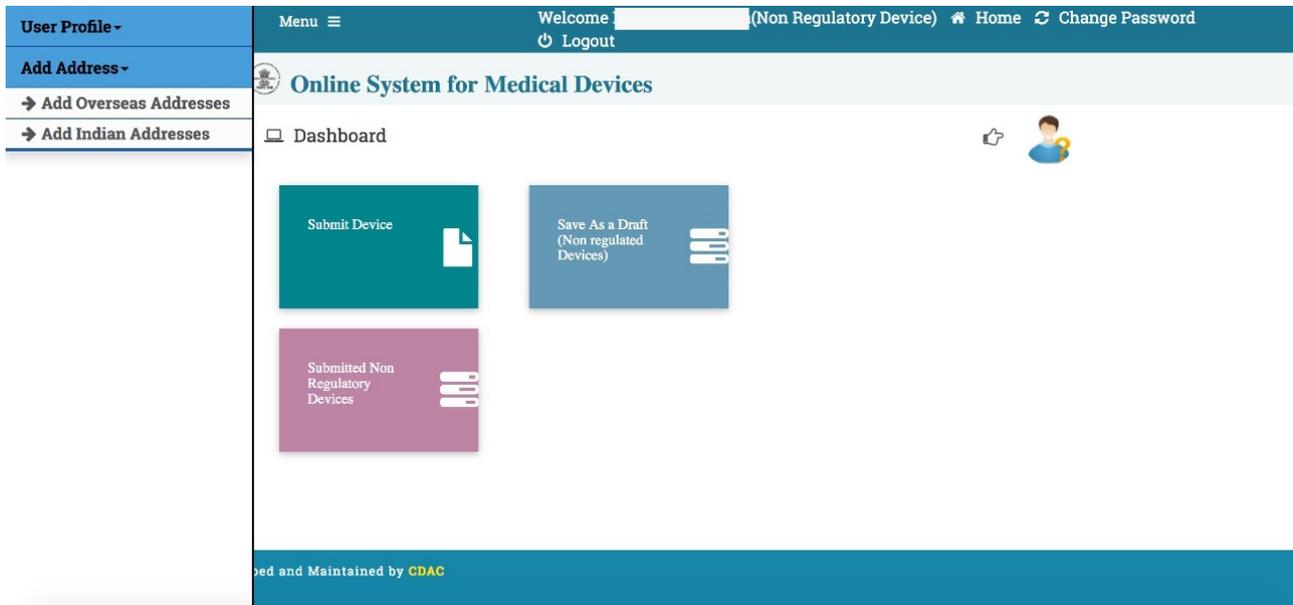
Note : For Medical devices which are under voluntary registrations , the file number generated is the registration number of firm.



**Online System
for
Regulation of Medical Devices**

- ✓ Application Submission
- ✓ Track Status of Application
- ✓ Grant of Permission/Approval/
License/NOC

6. Once logged in with your username and password - **This dashboard will appear.**
- Click on **'Menu'**
 - Click on **'Add Address'**
 - Add Indian or Overseas Address depending on location of Manufacturer



7. Fill up Details of the Manufacturer, click on **'Save'**

Manufacturer Address Details

Premises Type:

Organisation Name :

Address:

Country: **State**

District **Pin Code**

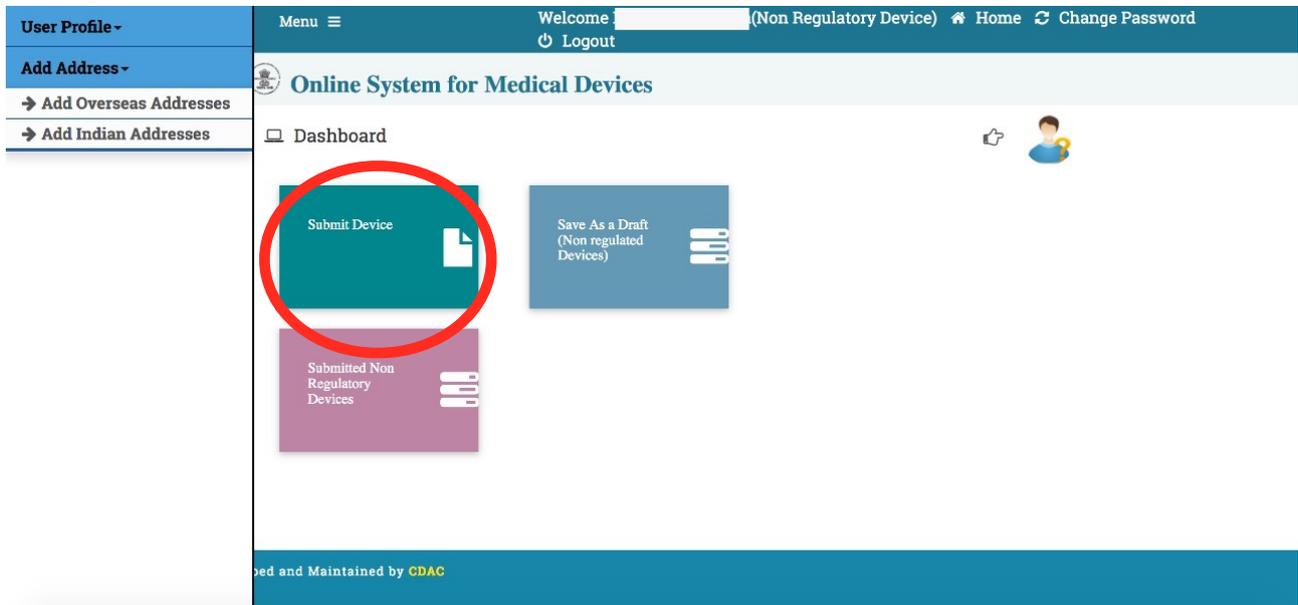
Fax No. (Please include STD Code - Fax Number)

Multiple Fax Numbers can be added with comma separation

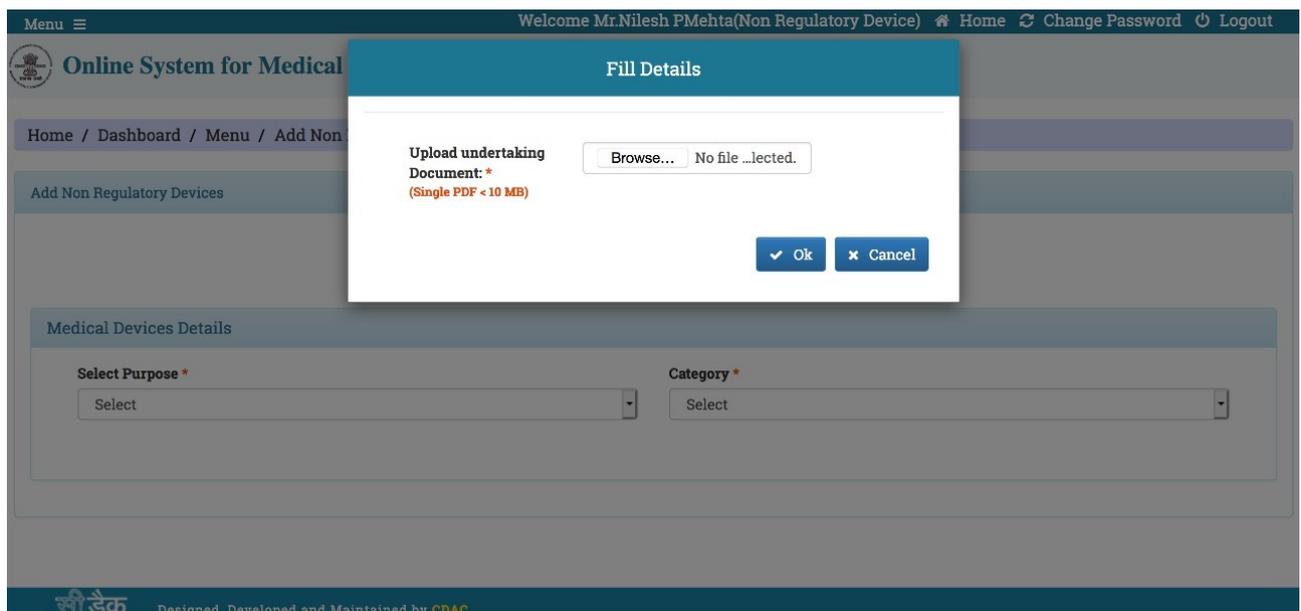
Contact No. (Please include STD Code - Phone Number)

Multiple Contact Numbers can be added with comma separation

8. After Submitting Manufacturer Details, come back to your Dashboard. Click on ‘Submit Device’



9. This screen will appear, Upload undertaking on Company Letterhead Stating that all information submitted is true.



10. After submitting undertaking, this form will appear - Fill in Device details. Documents required to be uploaded at the time of Product Registration –

*For Manufacturers - ISO 13485 Certificate

*For Importers - (a) ISO 13485 Certificate and (b) Free Sale Certificate from overseas Manufacturer

 **Online System for Medical Devices**

Home / Dashboard / Menu / Add Non Regulatory Device / Add Device Detail

Add Non Regulatory Devices

Add Device Details

Medical Devices Details

Select Purpose *
Manufacturing ✓

Category *
MD ✓

Select Manufacturing Site Details:*
Select

Premises in this section are fetched from Manufacturing Site Details added under User Profile

ISO Document: *
(Single PDF < 10 MB)

Choose File No file chosen

Generic Name of Device: *
Enter Name

Brand Name (optional)

Medical Device Category: *
Select

Grouping Description: *

Notified Category of Medical Device: *
Select

Class of Device: *
Select

Device Dimension:

Sterilization: *
Select

Material of construction: *

Shelf Life: *
Shelf Life
(In case of Non-Sterilized products, kindly write NIL for shelflife)

Storage Condition: *

Package Size
(Enter Comma Separated Package Size)

Intended Use *

Product Description *

Accessories/Components +

Models +

Shelf Life * **Storage Condition: *** **Package Size**
(In case of Non-Sterilized products, kindly write NIL for shelflife) (Enter Comma Seperated Package Size)

Intended Use * **Product Description ***

Accessories/Components +
 Models +

Whether Device contains/coated with drugs/polymers :

[Save and Continue](#)

11. After Clicking 'Save and Continue' - Come back to your dashboard.
 Click on **'Save As a Draft (Non regulated Devices)'**

User Profile v	Menu ☰	Welcome [User Name] (Non Regulatory Device) Home Change Password Logout
Add Address v	Online System for Medical Devices	
→ Add Overseas Addresses → Add Indian Addresses	Dashboard 👤	
	<div style="display: flex; justify-content: space-around;"> <div style="background-color: #00728f; color: white; padding: 10px; width: 150px; text-align: center;"> Submit Device </div> <div style="background-color: #00728f; color: white; padding: 10px; width: 150px; text-align: center; border: 2px solid red;"> Save As a Draft (Non regulated Devices) </div> </div> <div style="background-color: #8e44ad; color: white; padding: 10px; width: 150px; margin-top: 10px; text-align: center;"> Submitted Non Regulatory Devices </div>	
Designed and Maintained by CDAC		

12. This screen will appear - Your saved application will be shown here. From the 'Action' menu, select 'Submit'

The screenshot shows the 'Online System for Medical Devices' interface. At the top, there is a header with the system name and a breadcrumb trail: 'Home / Dashboards / Non regulatory Devices'. Below this, there is a search bar and a table. The table has columns for 'S.No', 'File No', 'Devices (Brand Name)', 'Certificates', and 'Action'. The table is currently empty, displaying 'No data available in table'. The 'Action' column is circled in red. Below the table, there are 'Previous' and 'Next' buttons. The footer of the page includes the CDAC logo and the text 'Designed, Developed and Maintained by CDAC'.

13. After submitting, click on 'Submitted Non Regulatory Devices' - You will be able to view the issued registration number under the 'File No.' Tab

The screenshot shows the 'Online System for Medical Devices' dashboard. The top navigation bar includes a user profile section, a menu icon, and a welcome message. The main content area features a dashboard with several cards: 'Submit Device', 'Save As a Draft (Non regulated Devices)', and 'Submitted Non Regulatory Devices'. The 'Submitted Non Regulatory Devices' card is circled in red. The sidebar on the left contains a 'User Profile' section and an 'Add Address' section with options for 'Add Overseas Addresses' and 'Add Indian Addresses'. The footer of the page includes the CDAC logo and the text 'Designed, Developed and Maintained by CDAC'.