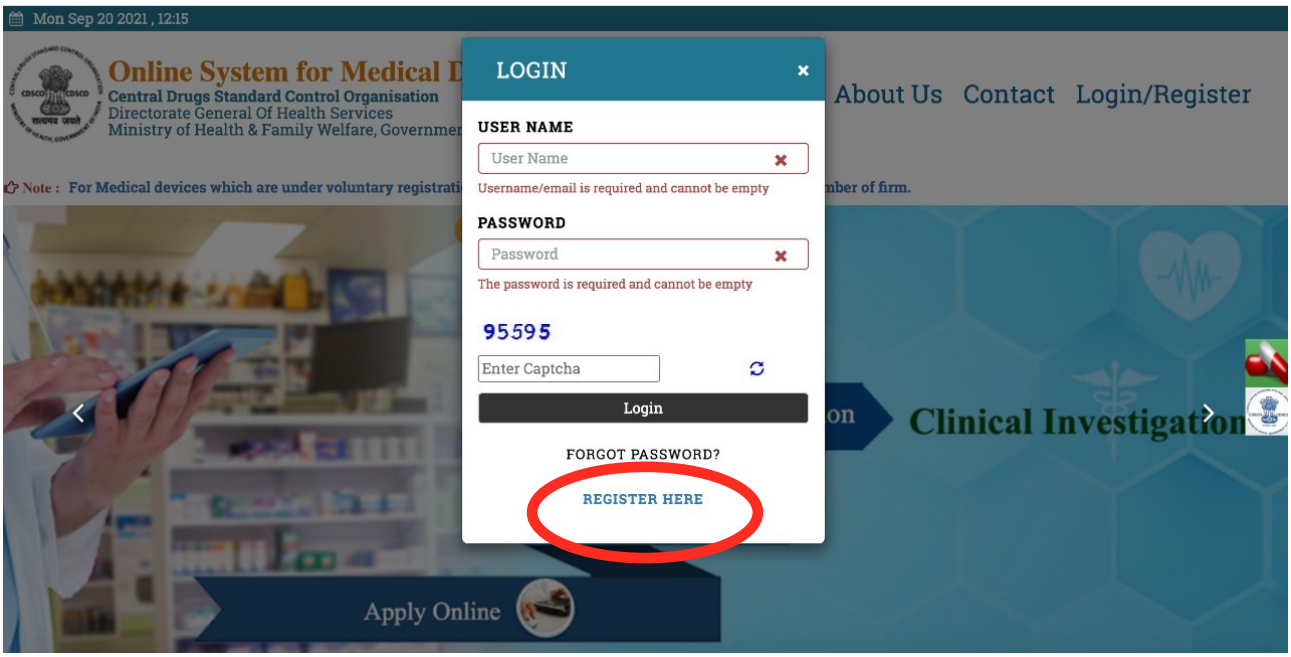
VOLUNTARY REGISTRATION OF MEDICAL DEVICES WITH CDSCO

PROCESS ROADMAP - How to Register Your Products

Exclusively for SMTA Members

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

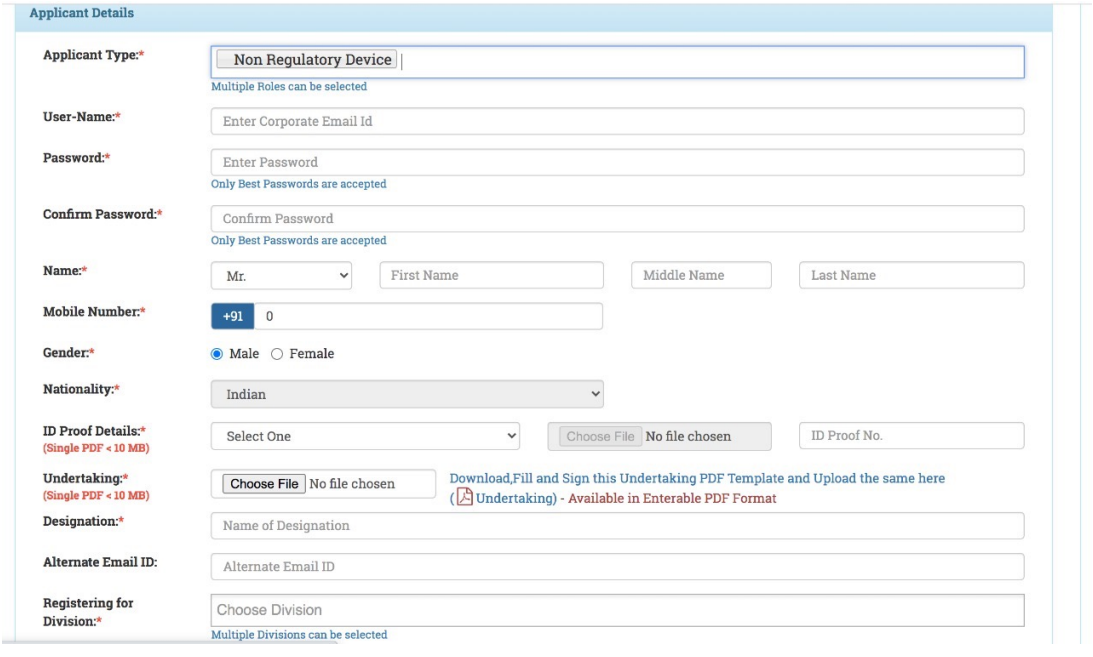
2. Click on '**Register Here**'

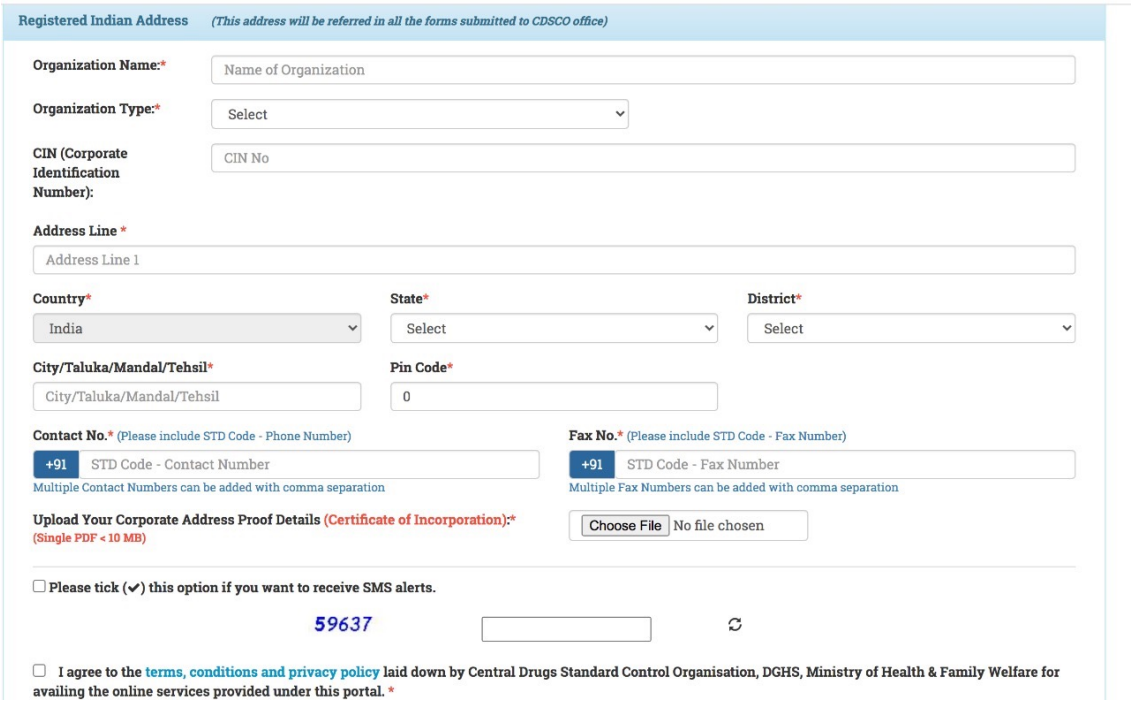


3. This page will appear — From the drop down menu for **'Registration Purpose'** — Select '**For Voluntary registration/Compulsory registration of applicable Medical Devices vide GSR 102'** and Click on **'Submit'**

4. Online Registration form for ACCOUNT CREATION will appear -

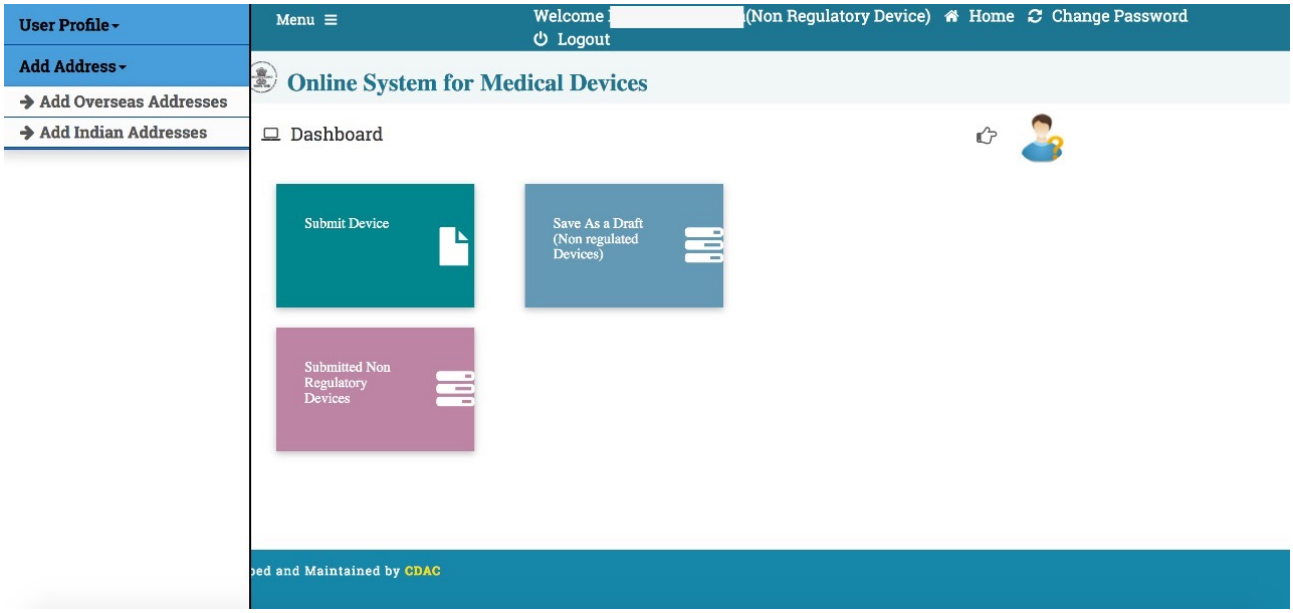
(a) Create Username (use company email id) and Password
(b) Fill in Company and Personnel Details
(c) Documents to be uploaded with form - ID PROOF, UNDERTAKING (format provided), ADDRESS PROOF (Certificate of Incorporation/GST)
(d) Check details and click on 'Submit'
(e) ID will be verified through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



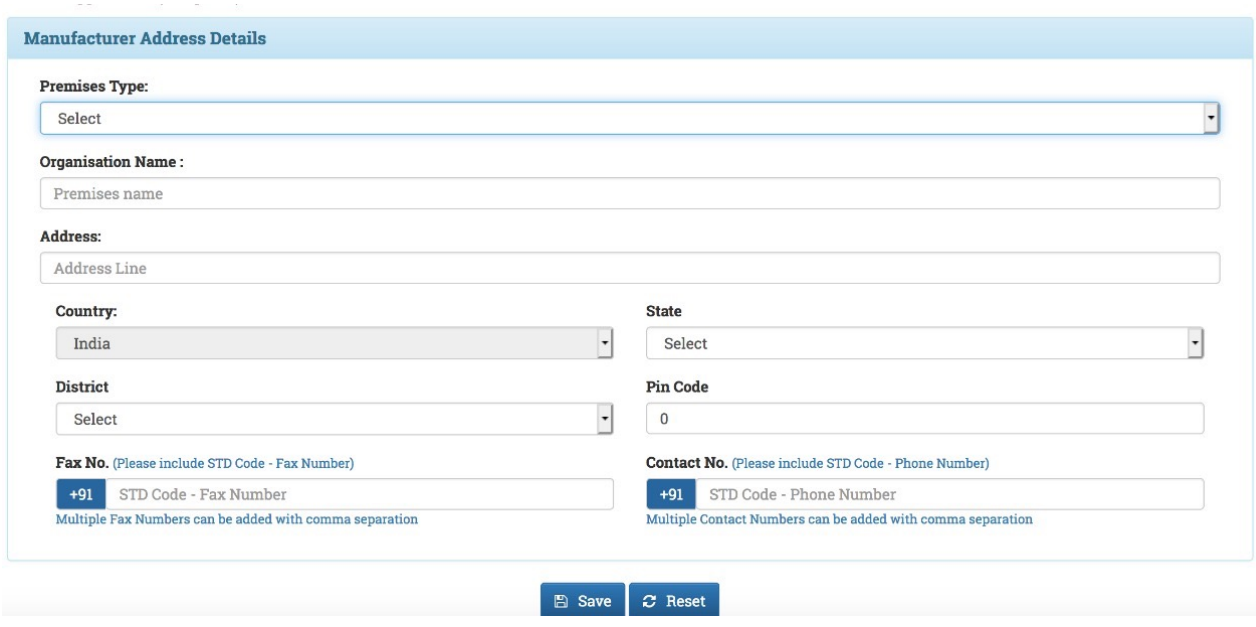


5. **HOW TO REGISTER YOUR PRODUCTS** - Once account is created, go back to - https://cdscomdonline.gov.in/NewMedDev/Homepage - Click on **'Login/Register' to log into your account**

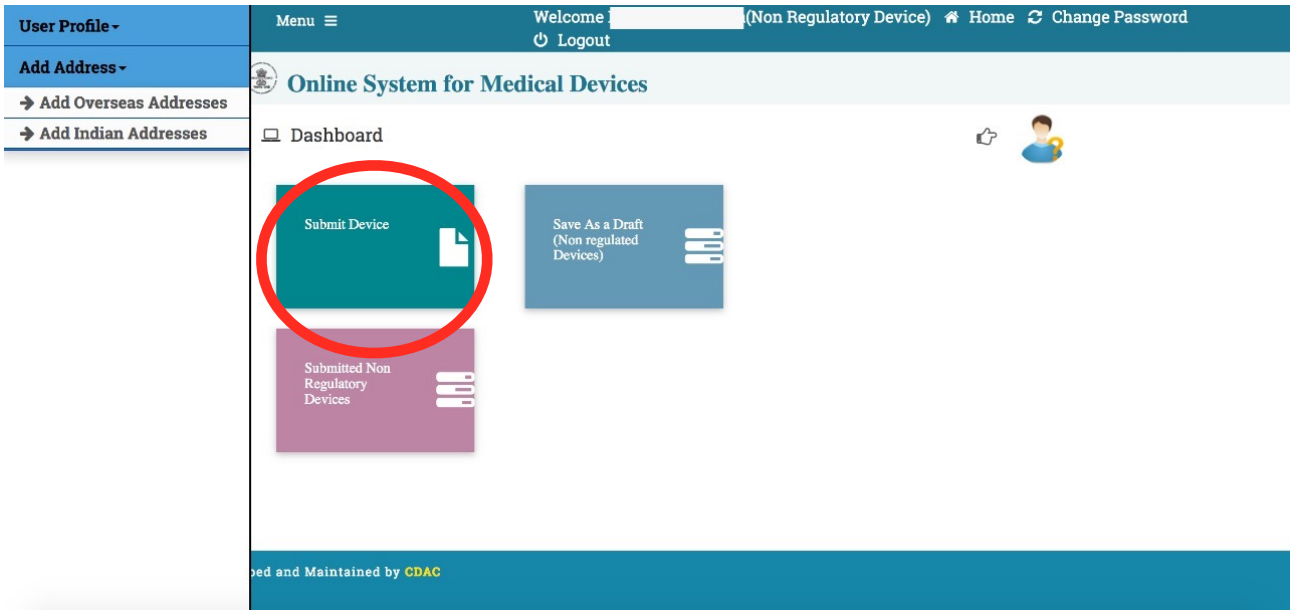
6. Once logged in with your username and password **- This dashboard will appear.**
(a) Click on **'Menu'**
(b) Click on **'Add Address'**
(c) Add Indian or Overseas Address depending on location of Manufacturer



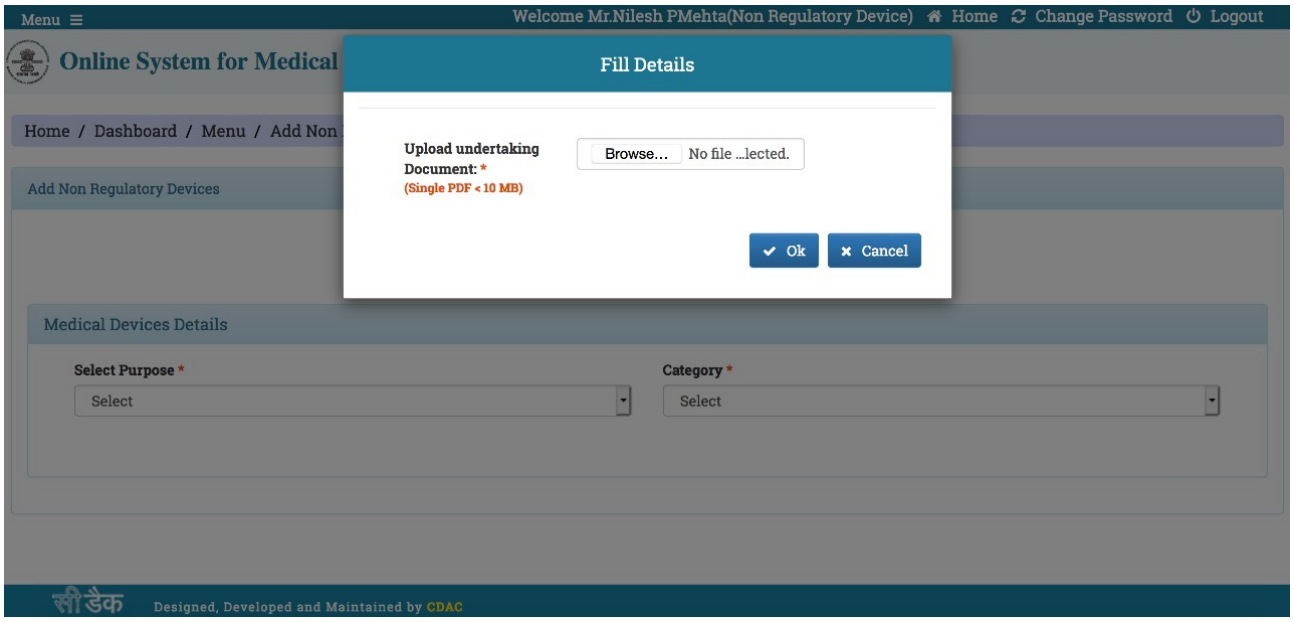
7. Fill up Details of the Manufacturer, click on **'Save'**



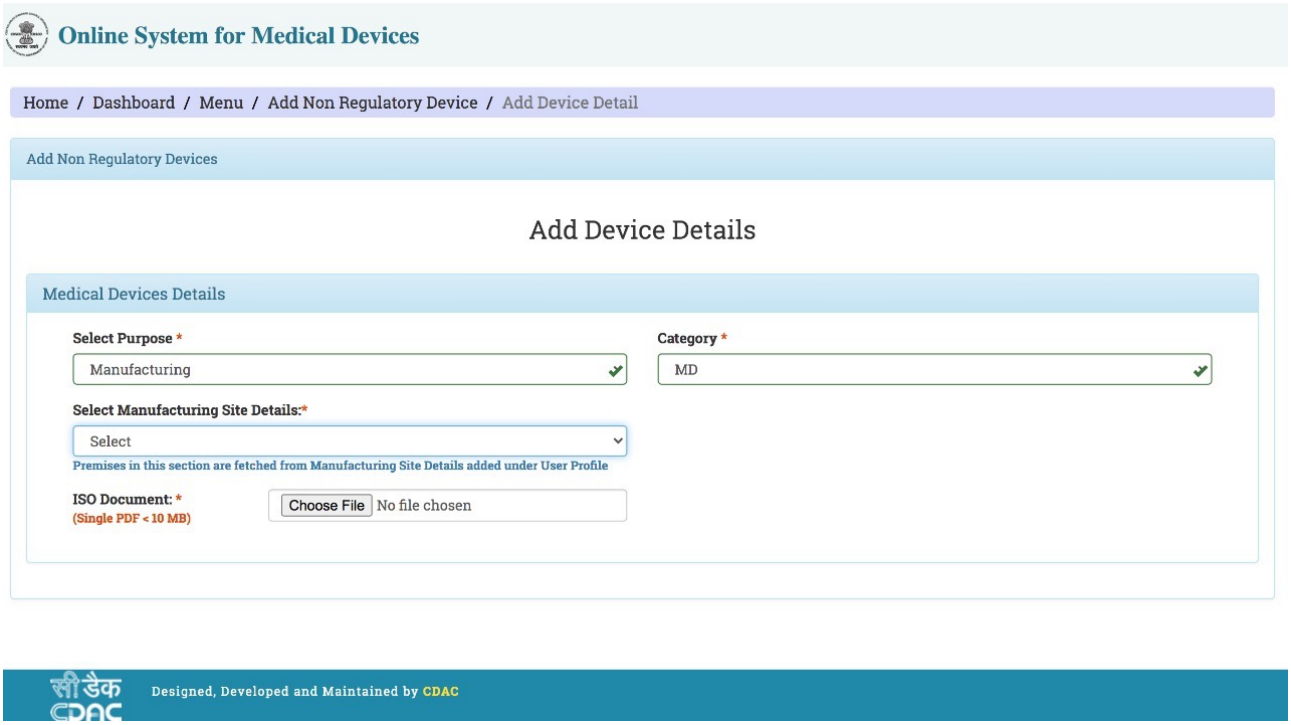
8. After Submitting Manufacturer Details, come back to your Dashboard. Click on '**Submit Device**'

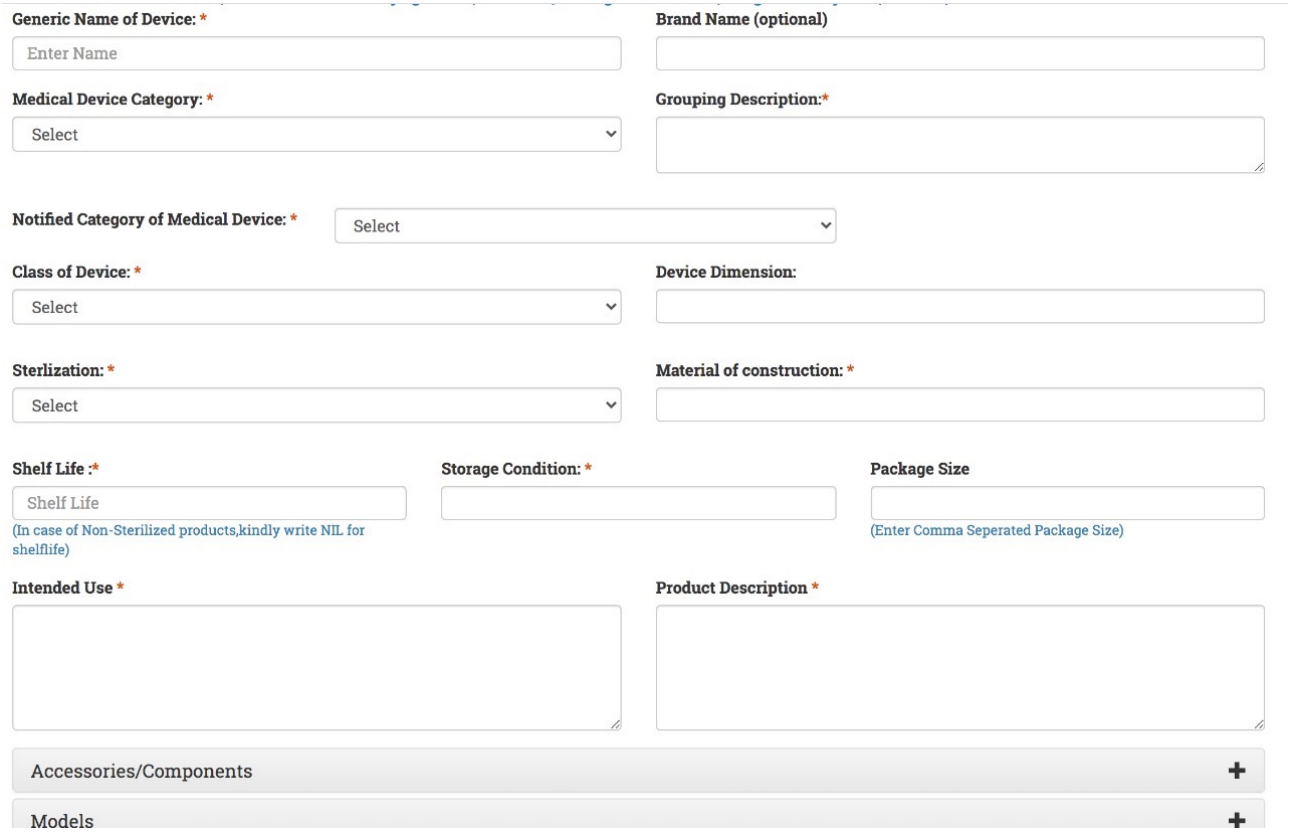


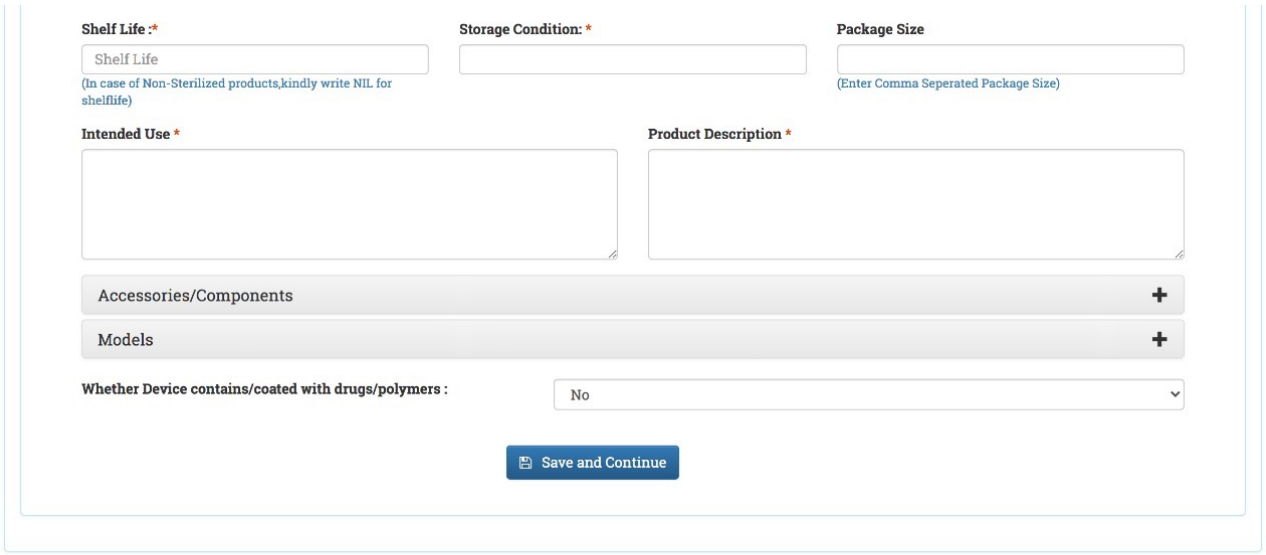
9. This screen will appear, Upload undertaking on Company Letterhead Stating that all information submitted is true.



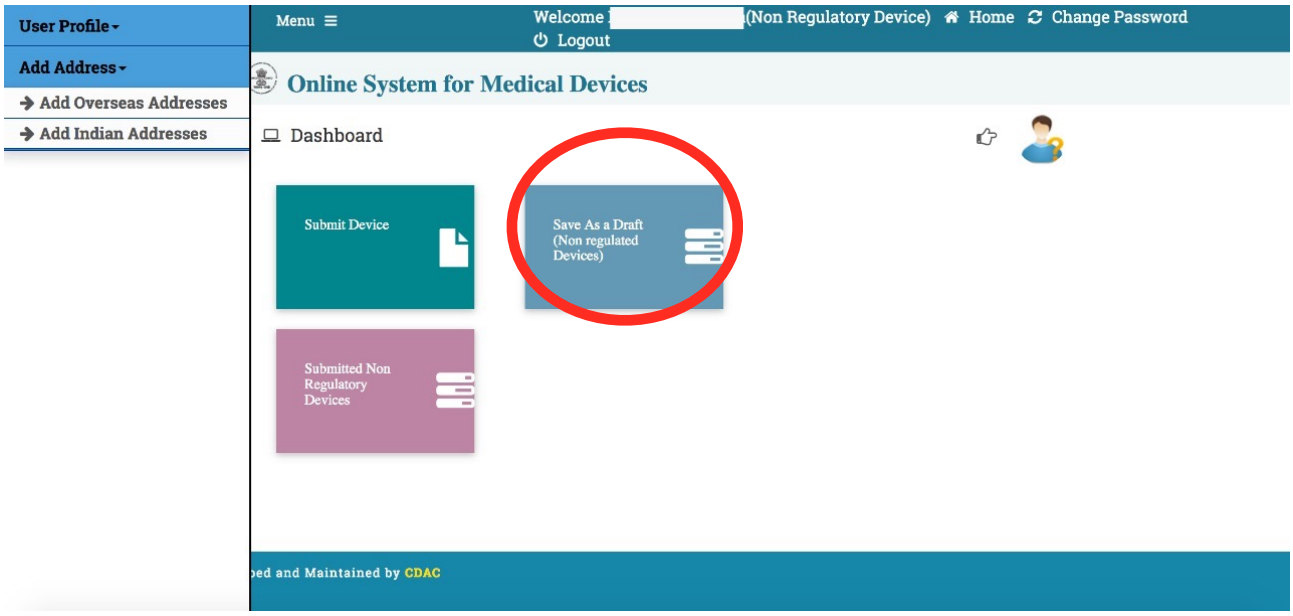
10. After submitting undertaking, this form will appear - **Fill in Device details.**
Documents required to be uploaded at the time of Product Registration —
*For Manufacturers - ISO 13485 Certificate
*For Importers - (a) ISO 13485 Certificate and (b) Free Sale Certificate from overseas Manufacturer



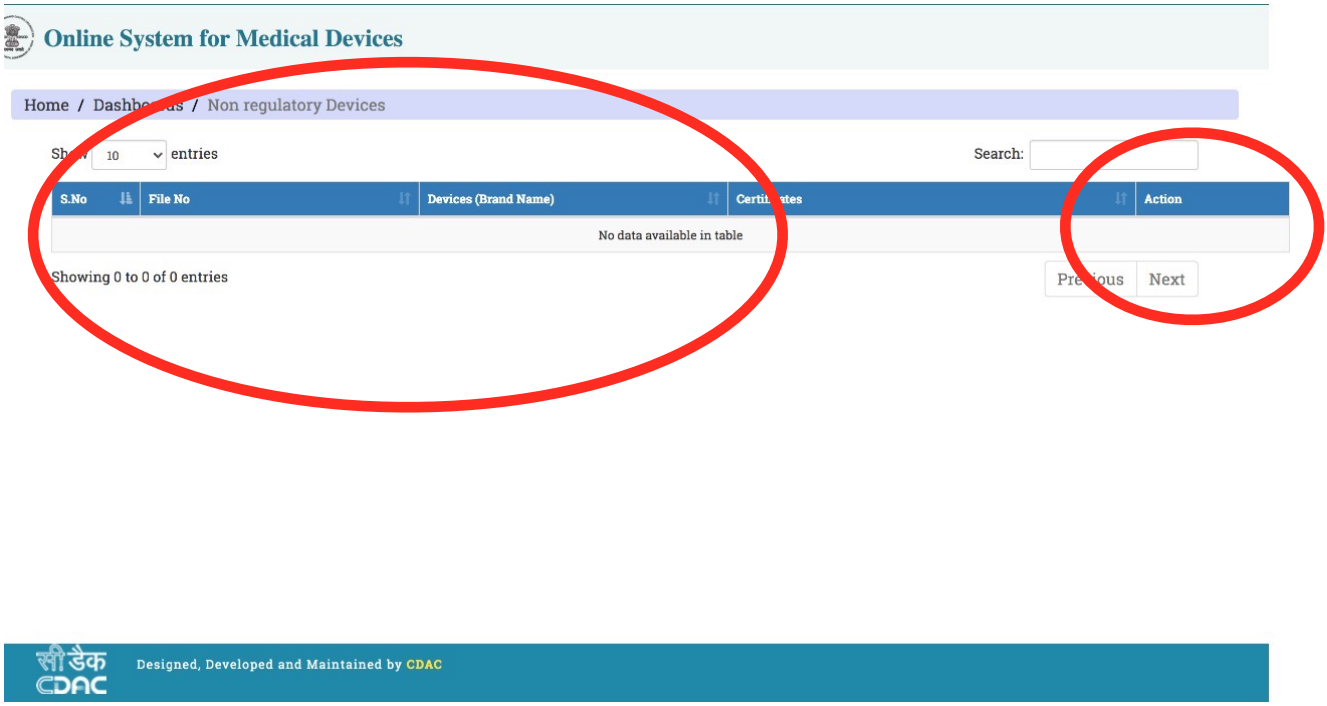




11. After Clicking 'Save and Continue' - Come back to your dashboard.
Click on '**Save As a Draft (Non regulated Devices)**'



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



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