



Central Drug Standard Control Organization (CDSCO)

Applicant User Manual

For

Medical Device Portal

Version: 1.0

Release Date: 28/12/2017

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1. Introduction

Online Portal for Medical devices enables applicant to submit online applications for Medical Devices regulatory process to CDSCO. It will also enable upload of supporting documents, respond to queries from CDSCO officials and track their application status. The user account lists out all the applications submitted and licenses/permissions held by them and provides the statistical analysis of the applications for various processes & licenses issued, suspended /cancelled, withdrawn.

The following sections details about the various steps

1.1. User Login

- How to login into the system?
- User can login the system with the correct User Name and Password credentials,as shown in **Figure 1**.

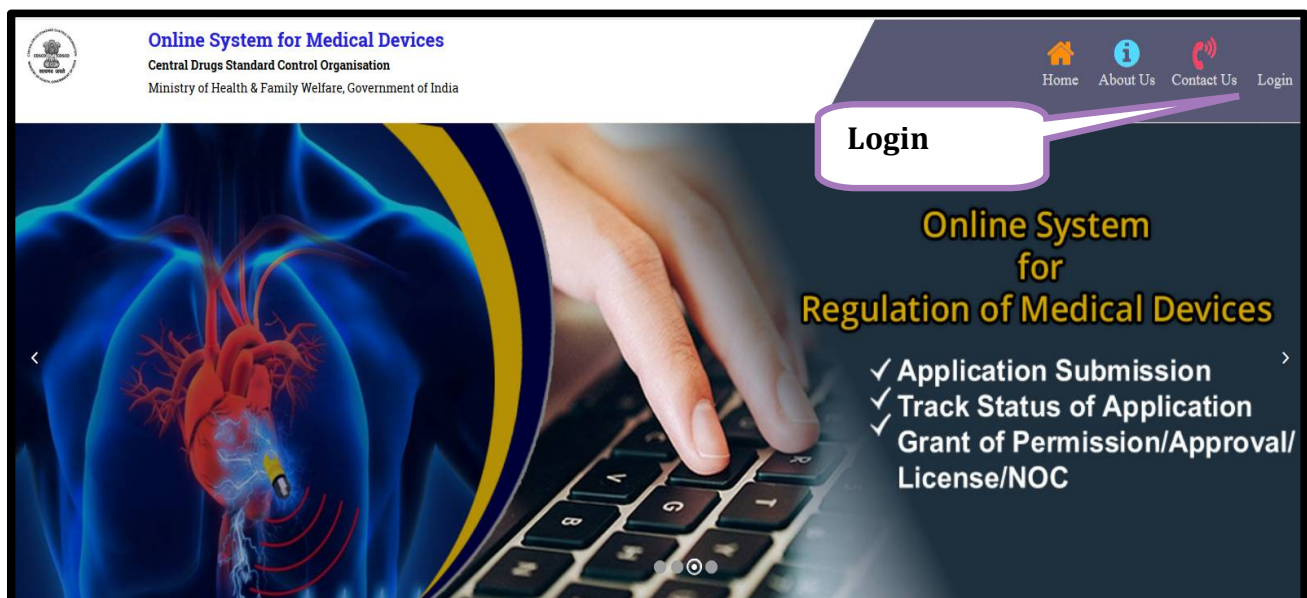


Figure 1: Login Screen

1.2. Dashboard

- **Dash Board Screen** : After successful login to the application the system will show a Dashboard there you can see the multiple informations,as shown in **Figure 2**.

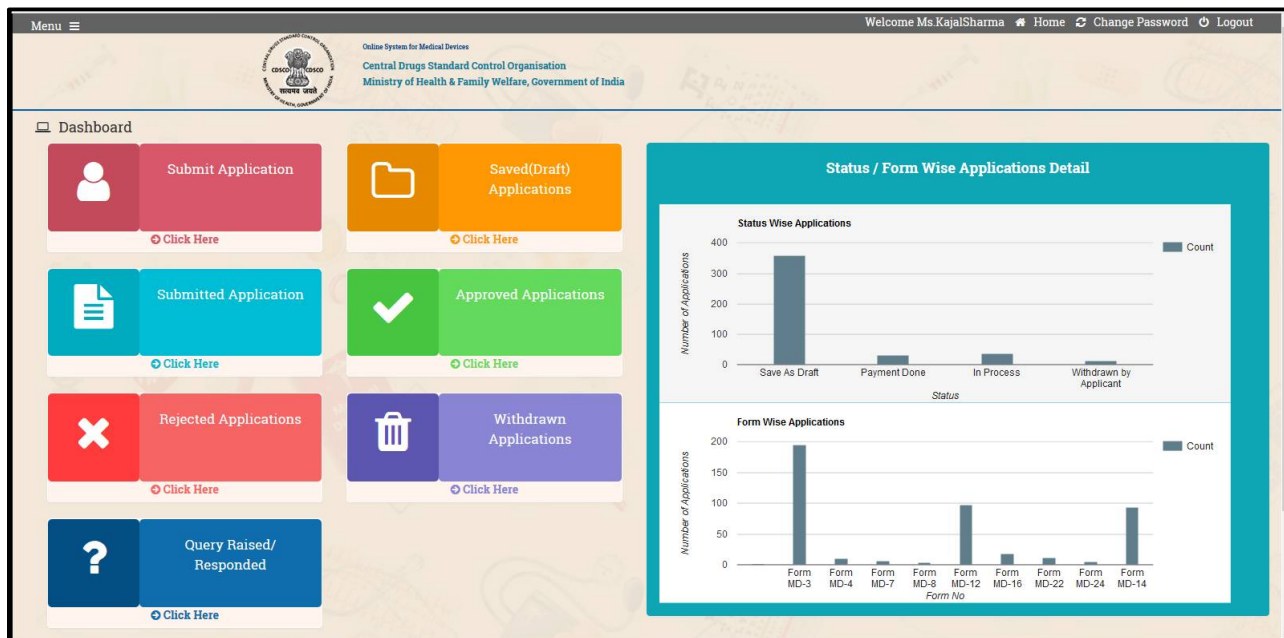




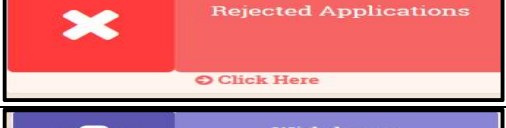
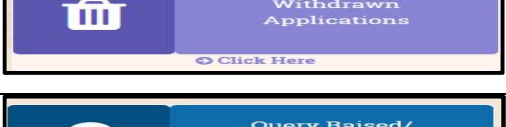



Figure 2 : Dashboard Screen

➤ Various options are available on the dashboard as described below :-

Table 1 : Dashboard Option

	<p>Submit application - For Fresh Application Click on Submit Application Button.</p>
	<p>Saved (Draft) Applications - To view the pending/incomplete applications click on Saved (Draft) Applications.</p>
	<p>Submitted Application:To view the status of submitted applications click on “Submitted Application” link.</p>
	<p>Approved Application: This session used to store the Approved Application.</p>
	<p>Rejected Application : This interface is reserved for Rejected Applications</p>
	<p>Withdrawn Application :This link is to view all Withdrawn Applications</p>
	<p>Query Raised/ Responded:This link is to help query raised by CDSCO.</p>

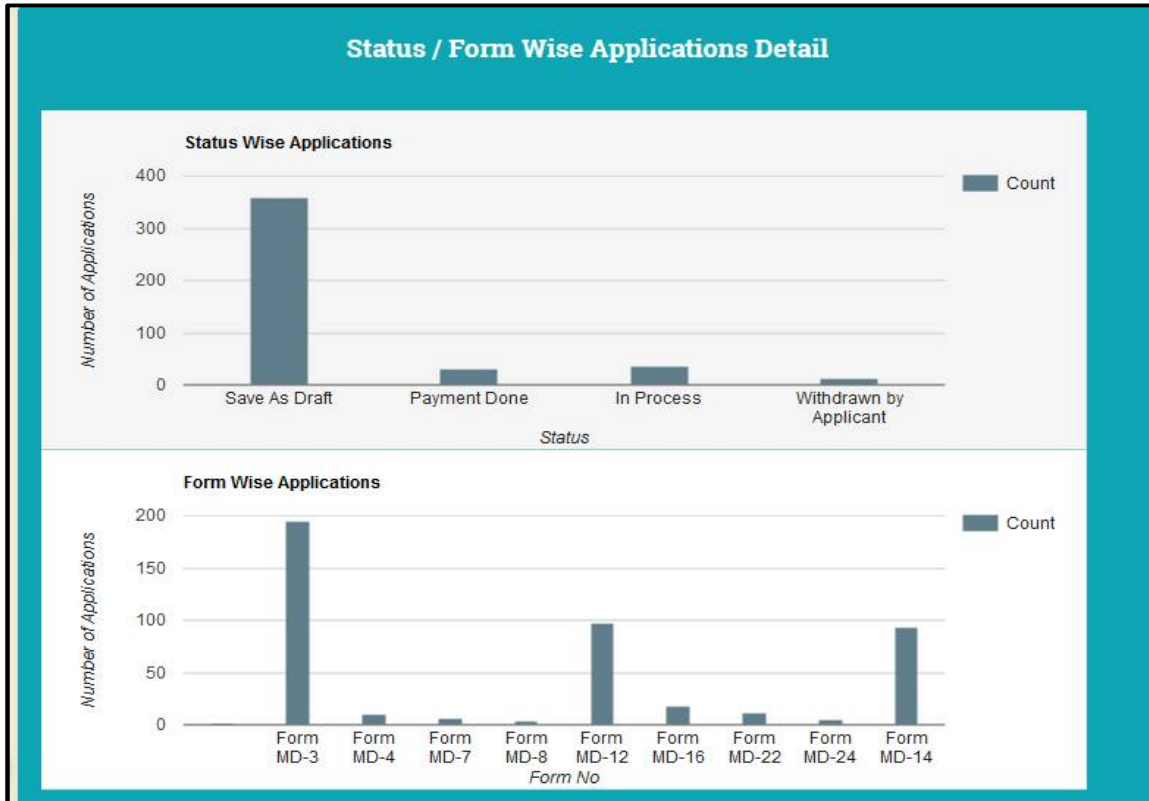


Figure 3 : Status / form Wise Application Detail

1.3. Change Password

- If the user want to change their password then they can click on ‘Change Password’ link, as shown in **Figure 4**.

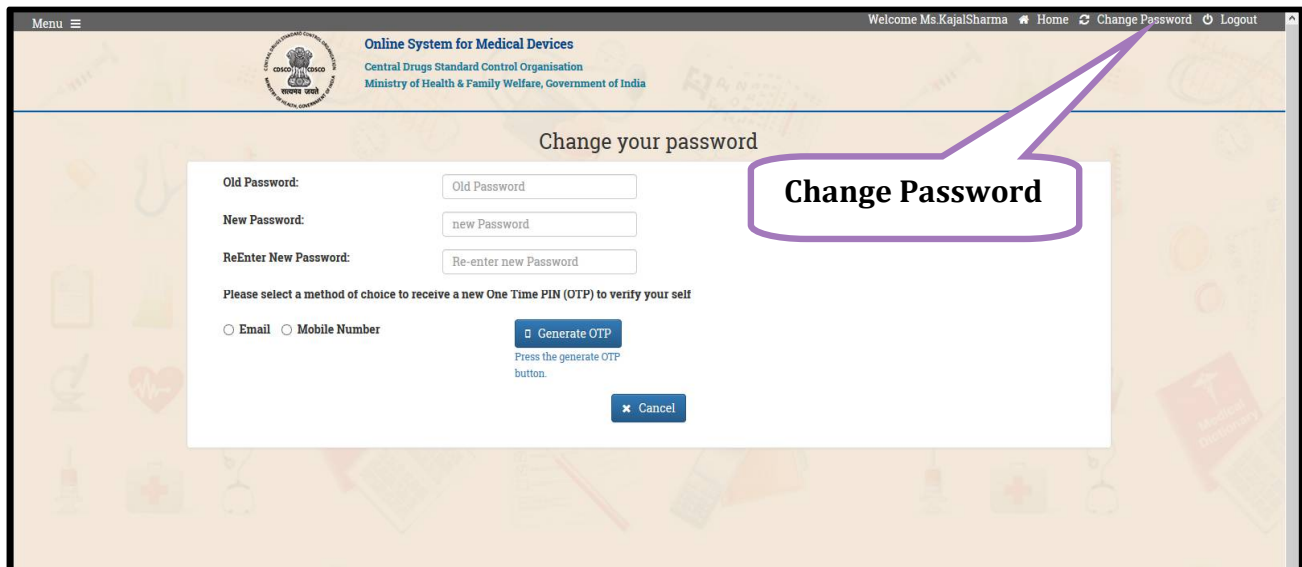


Figure 4 : Screen of Change Password Option

- After clicking the “Change Password” link you can see a new screen as shown in **Figure 5** where you can change the old password with the new one.

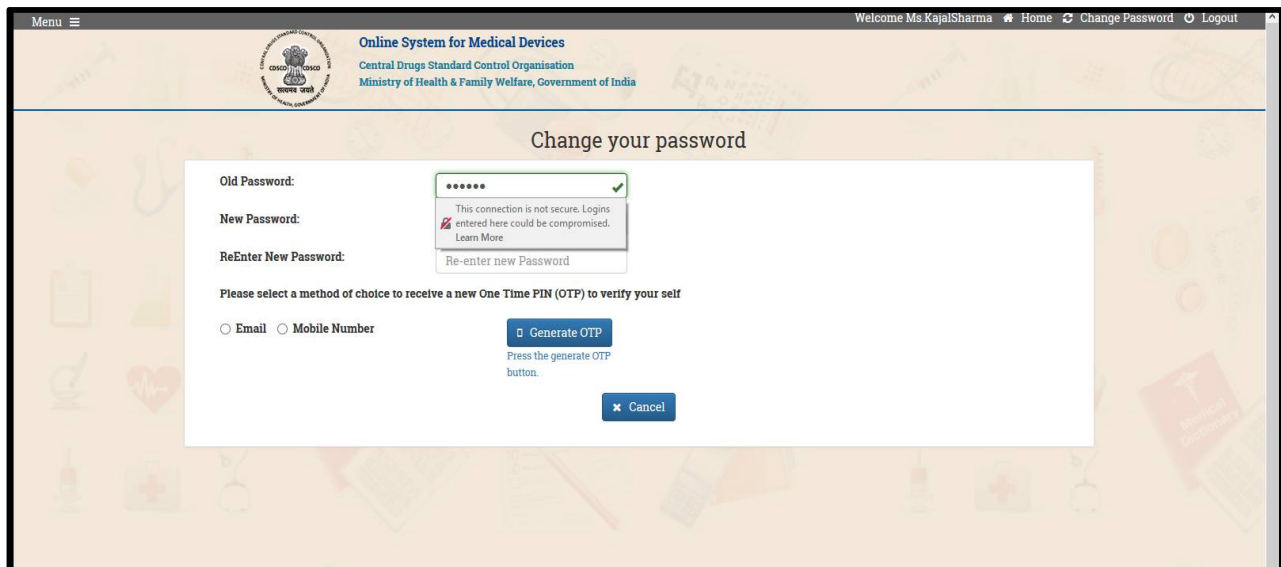


Figure 5 : Screen of change password (Continue)

Note

- After enter the new password click on “save” button and the password will be saved with the new one.

1.4. User Profile

- Click on Menu as Shown in the **figure 6**. After click on Menu Button it shows “User Profile”, “Add Address”, and “Online Payment”.

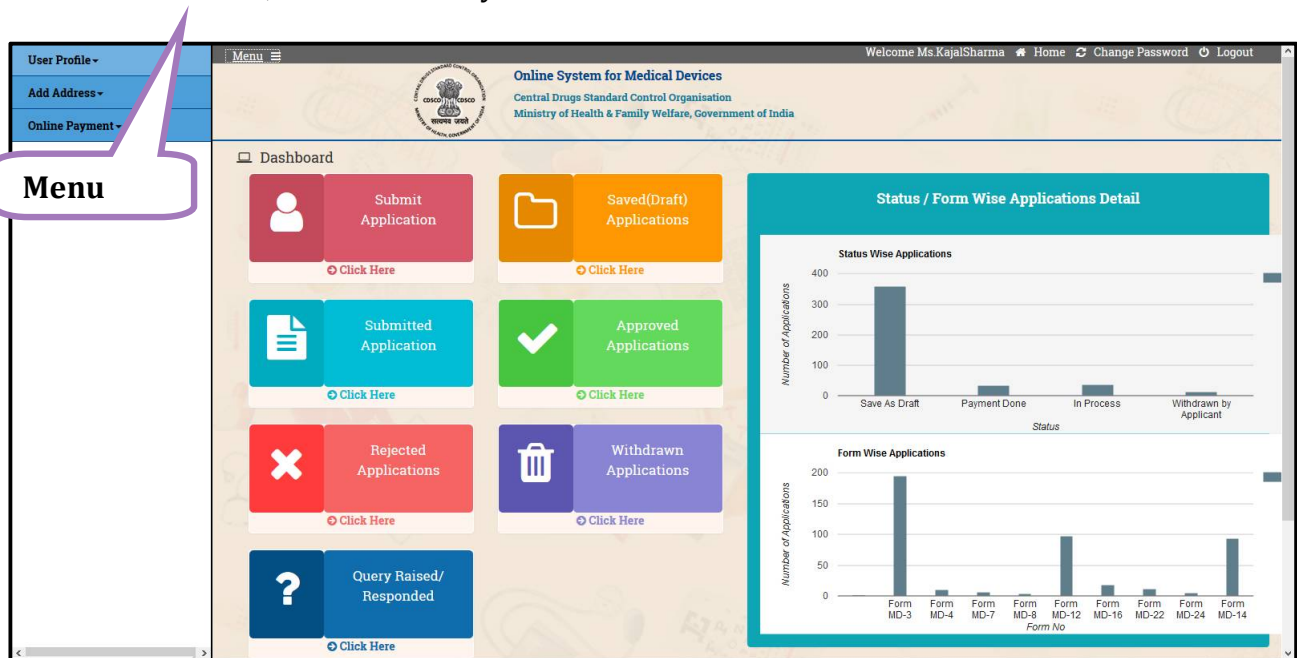


Figure 6 : Menu Button

➤ Click on User Profile as shown in **Figure 7**.

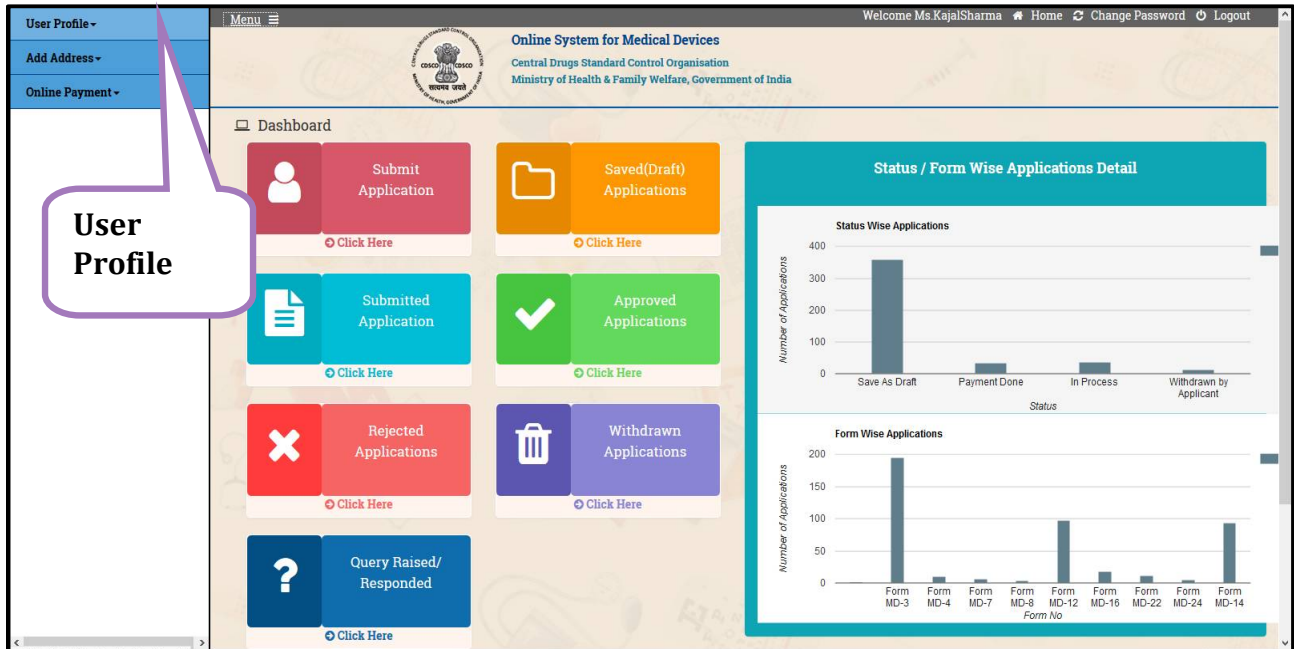


Figure 7 : User Profile

➤ After clicking the User Profile, click on “View Profile” Option. Then you will get below the mention screen i.e as shown in the **figure 8**.

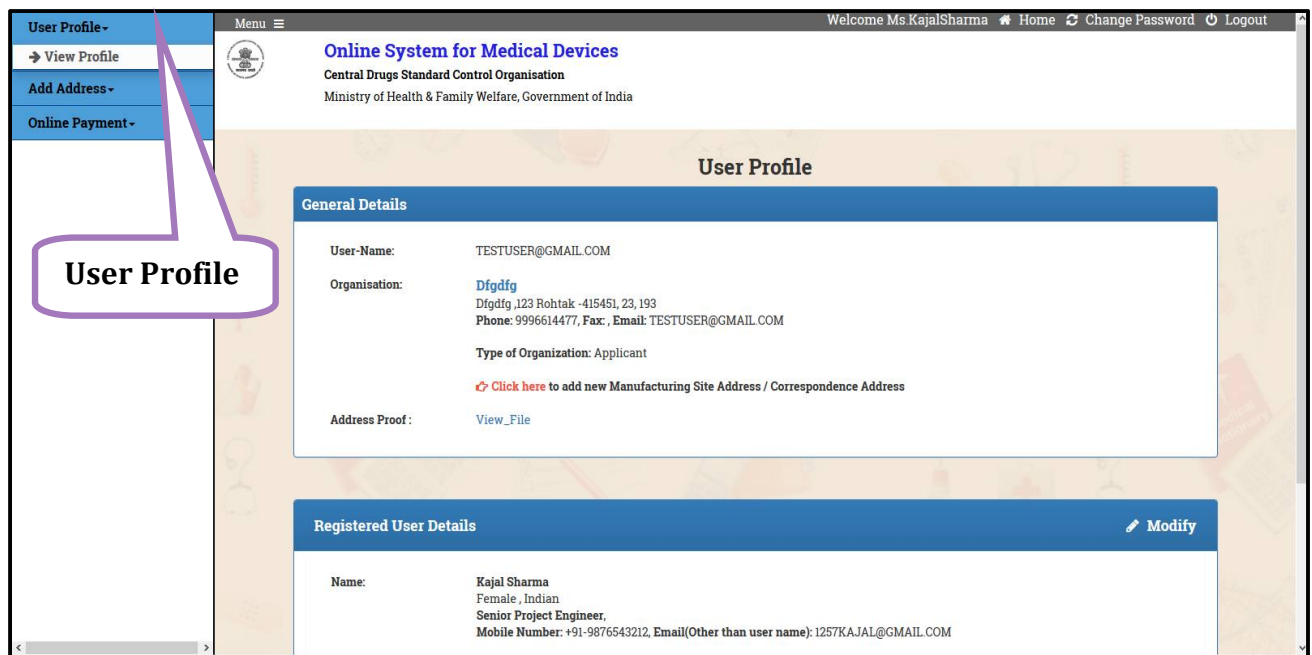


Figure 8 : Click on View Profile

1.5. Add Address

- There is two Option in Add Address (a) Add Correspondence and Site Address (b) Foreign Manufacturer address as shown in **figure 9**.

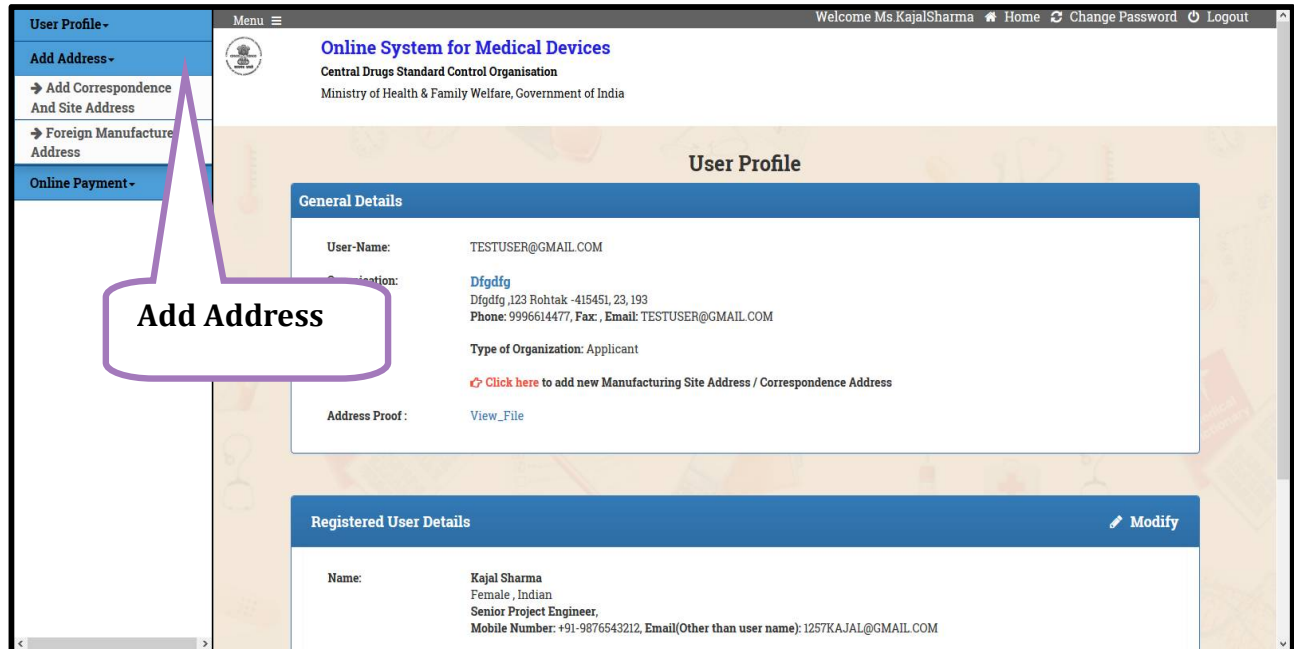


Figure 9 : Add Address

- Click on Add Correspondence and Site Address the screen will show as mention in **figure 10**.

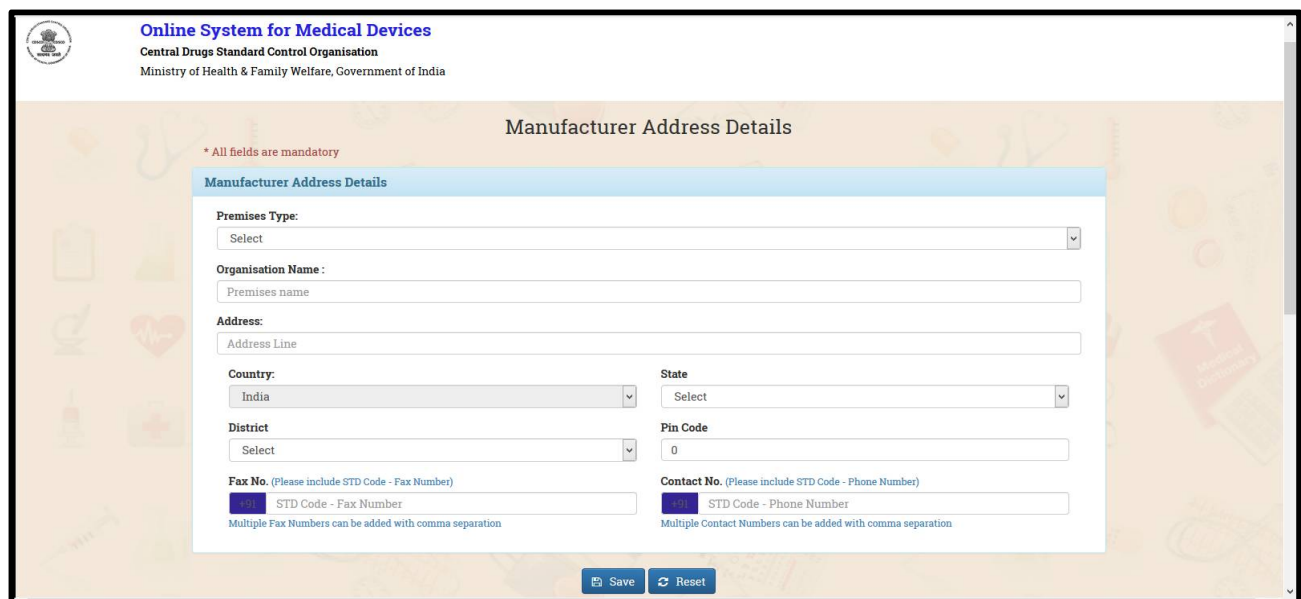
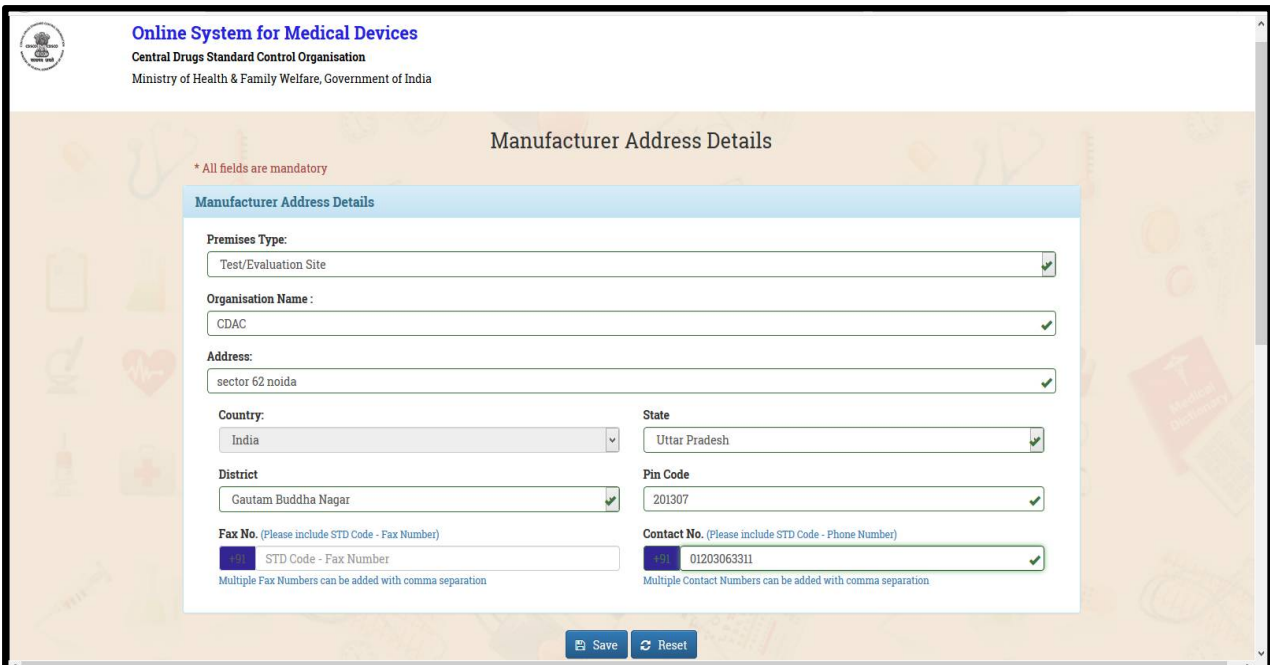


Figure 10 : Manufacturer Address Details

- Fill all the mandatory details (*) as shown in **figure 11**, and then after click on Save button.



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

Manufacturer Address Details

* All fields are mandatory

Manufacturer Address Details

Premises Type:
Test/Evaluation Site

Organisation Name :
CDAC

Address:
sector 62 noida

Country: India | **State:** Uttar Pradesh

District: Gautam Buddha Nagar | **Pin Code:** 201307


Fax No. (Please include STD Code - Fax Number)
+91 STD Code - Fax Number

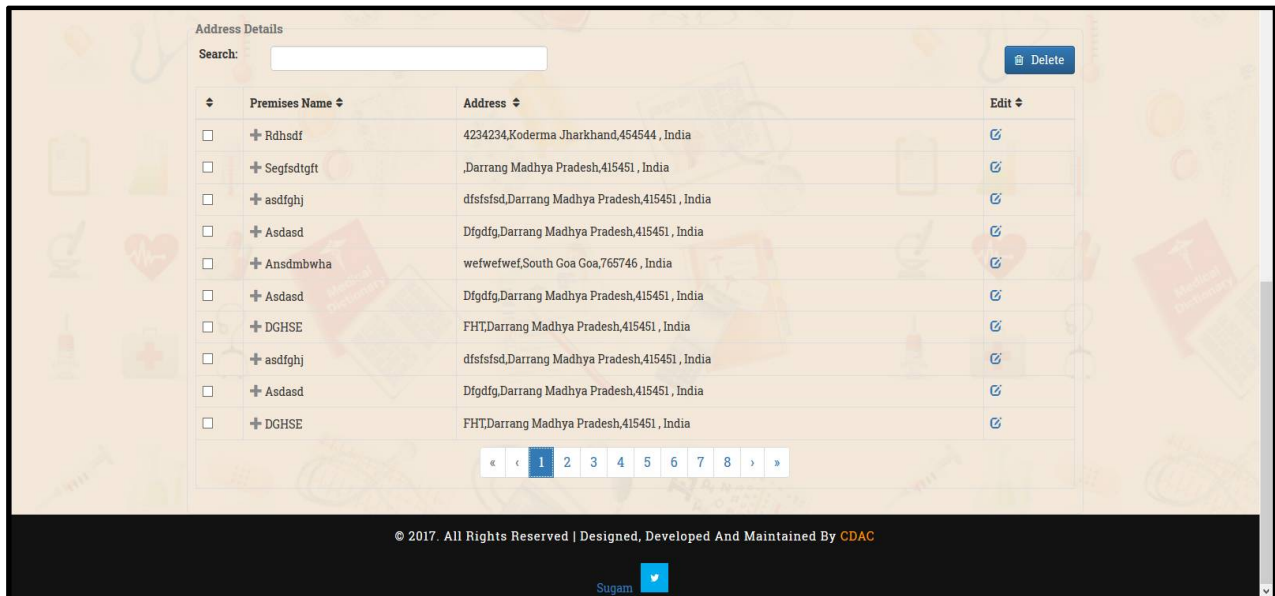
Contact No. (Please include STD Code - Phone Number)
+91 01203063311

Multiple Fax Numbers can be added with comma separation
Multiple Contact Numbers can be added with comma separation

[Save](#) [Reset](#)

Figure 11 : Click on Save Button

- After click on save button, the list will shown as below the mention **Figure 12**. User can Edit with Edit Button  or Delete the Address.



Address Details

Search:

[Delete](#)

Pre	Premises Name	Address	Edit
<input type="checkbox"/>	+ Rdhsdf	4234234,Koderma Jharkhand,454544 , India	
<input type="checkbox"/>	+ Segfsdtgft	.Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ asdfghj	dfsfsfsd,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ Ansdmbwha	wefwefwef,South Goa Goa,765746 , India	
<input type="checkbox"/>	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ DGHSE	FHT,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ asdfghj	dfsfsfsd,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	
<input type="checkbox"/>	+ DGHSE	FHT,Darrang Madhya Pradesh,415451 , India	

« 1 2 3 4 5 6 7 8 »

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Figure 12 : Address Details

- After click on edit button user can modify or Reset the details.As shown in **figure 13**.

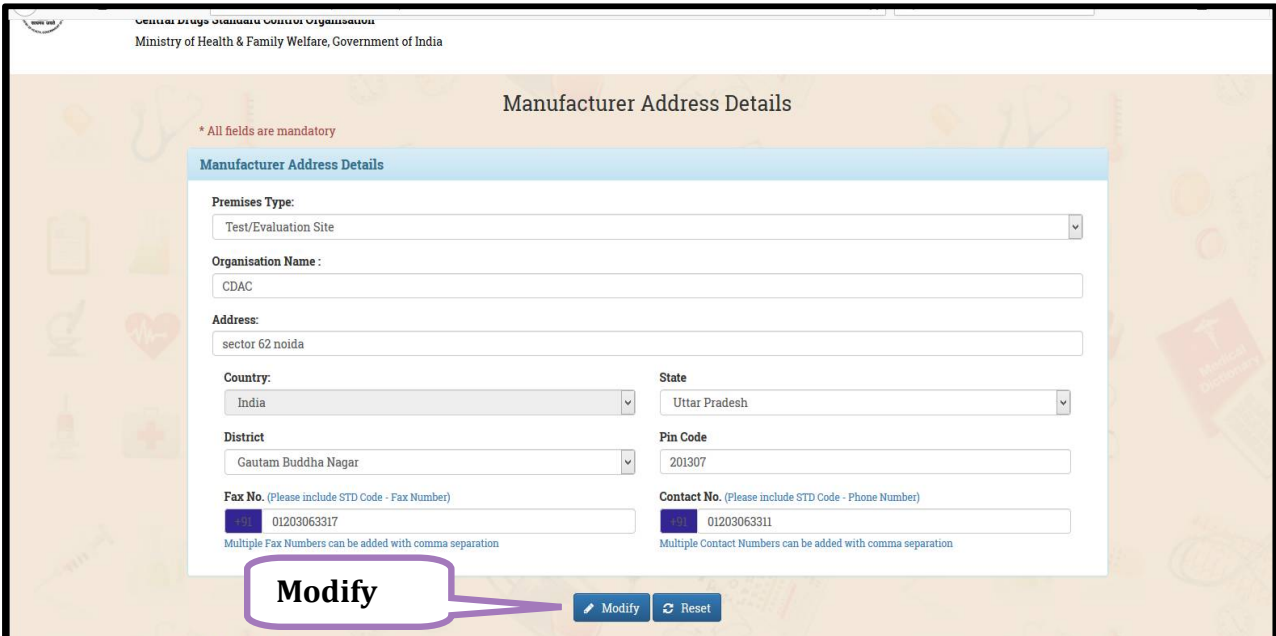
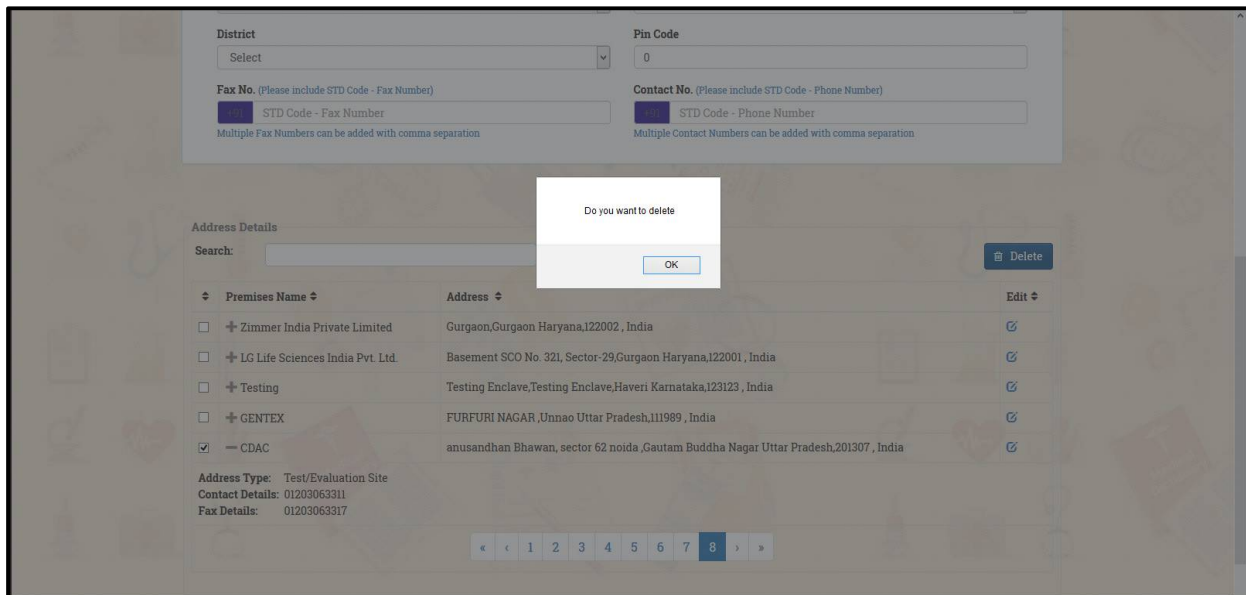


Figure 13 : Modify or Reset the Details

- If User wants to delete any address details, Select by Checklist button, and then click on Delete Button, After you clicked Delete Button, you can get Popup Message i.e “Do you Want to Delete” then click on OK button.



Address Details	Search:	Delete																		
<table border="1"> <thead> <tr> <th>Premines Name</th> <th>Address</th> <th>Edit</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> + Zimmer India Private Limited</td> <td>Gurgaon,Gurgaon Haryana,122002 , India</td> <td></td> </tr> <tr> <td><input type="checkbox"/> + LG Life Sciences India Pvt. Ltd.</td> <td>Basement SCO No. 321, Sector- 29,Gurgaon Haryana,122001 , India</td> <td></td> </tr> <tr> <td><input type="checkbox"/> + Testing</td> <td>Testing Enclave,Testing Enclave,Haveri Karnataka,123123 , India</td> <td></td> </tr> <tr> <td><input type="checkbox"/> + GENTEX</td> <td>FURFURI NAGAR Unnao Uttar Pradesh,11989 , India</td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> - CDAC</td> <td>anusandhan Bhawan, sector 62 noida ,Gautam Buddha Nagar Uttar Pradesh,201307 , India</td> <td></td> </tr> </tbody> </table>	Premines Name	Address	Edit	<input type="checkbox"/> + Zimmer India Private Limited	Gurgaon,Gurgaon Haryana,122002 , India		<input type="checkbox"/> + LG Life Sciences India Pvt. Ltd.	Basement SCO No. 321, Sector- 29,Gurgaon Haryana,122001 , India		<input type="checkbox"/> + Testing	Testing Enclave,Testing Enclave,Haveri Karnataka,123123 , India		<input type="checkbox"/> + GENTEX	FURFURI NAGAR Unnao Uttar Pradesh,11989 , India		<input checked="" type="checkbox"/> - CDAC	anusandhan Bhawan, sector 62 noida ,Gautam Buddha Nagar Uttar Pradesh,201307 , India			
Premines Name	Address	Edit																		
<input type="checkbox"/> + Zimmer India Private Limited	Gurgaon,Gurgaon Haryana,122002 , India																			
<input type="checkbox"/> + LG Life Sciences India Pvt. Ltd.	Basement SCO No. 321, Sector- 29,Gurgaon Haryana,122001 , India																			
<input type="checkbox"/> + Testing	Testing Enclave,Testing Enclave,Haveri Karnataka,123123 , India																			
<input type="checkbox"/> + GENTEX	FURFURI NAGAR Unnao Uttar Pradesh,11989 , India																			
<input checked="" type="checkbox"/> - CDAC	anusandhan Bhawan, sector 62 noida ,Gautam Buddha Nagar Uttar Pradesh,201307 , India																			

Figure 14 : Popup Message: Delete

- Now click on Foreign Manufacturer address Details, the screen will shown as figure 13. Fill all the required field as shown in **figure 15**.

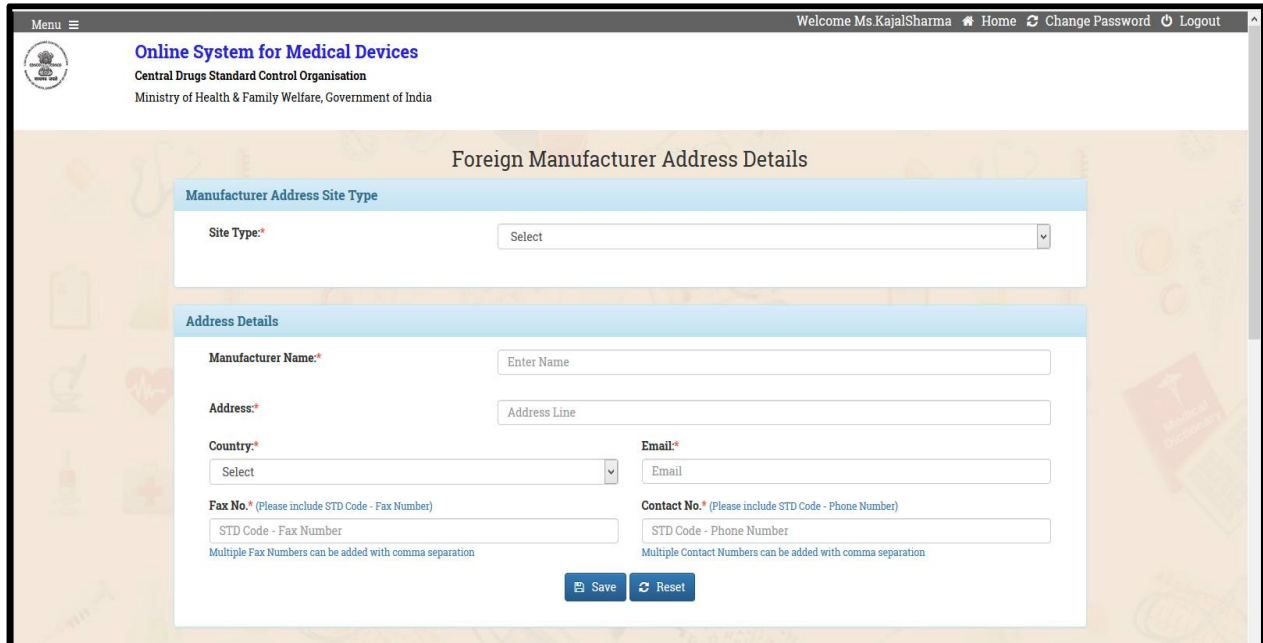


Figure 15 : Screen of Foreign Manufacturer address Details

- After fill all the details you can save information by clicking the Save Button. As shown in **figure 16**.

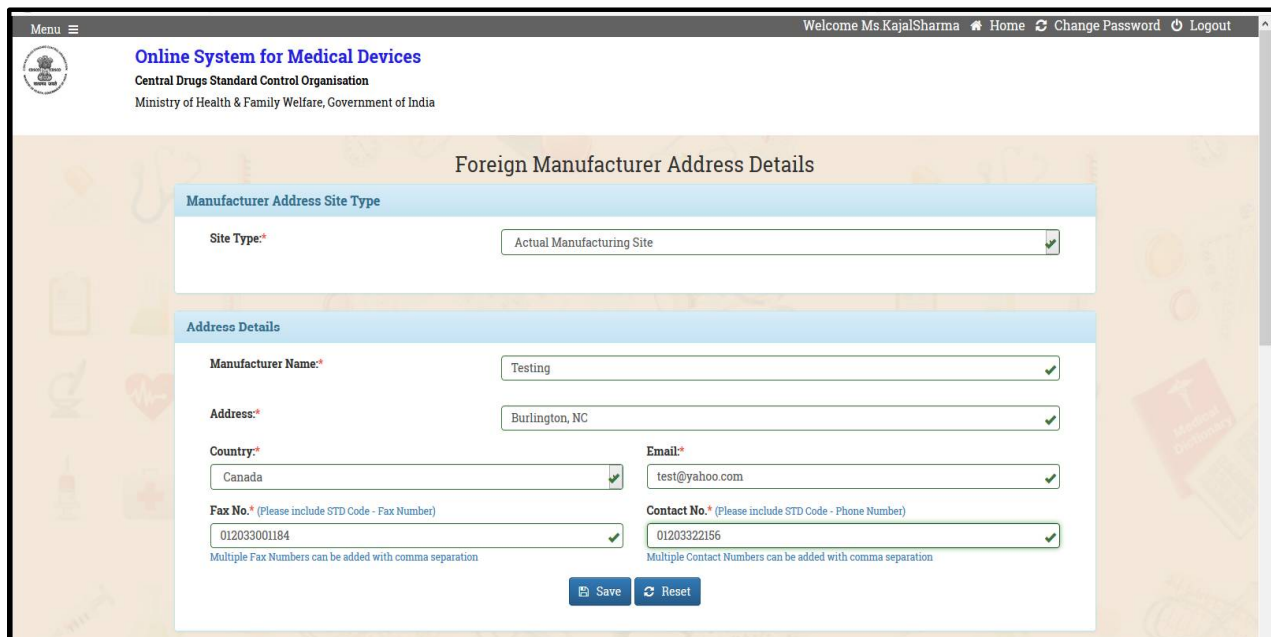
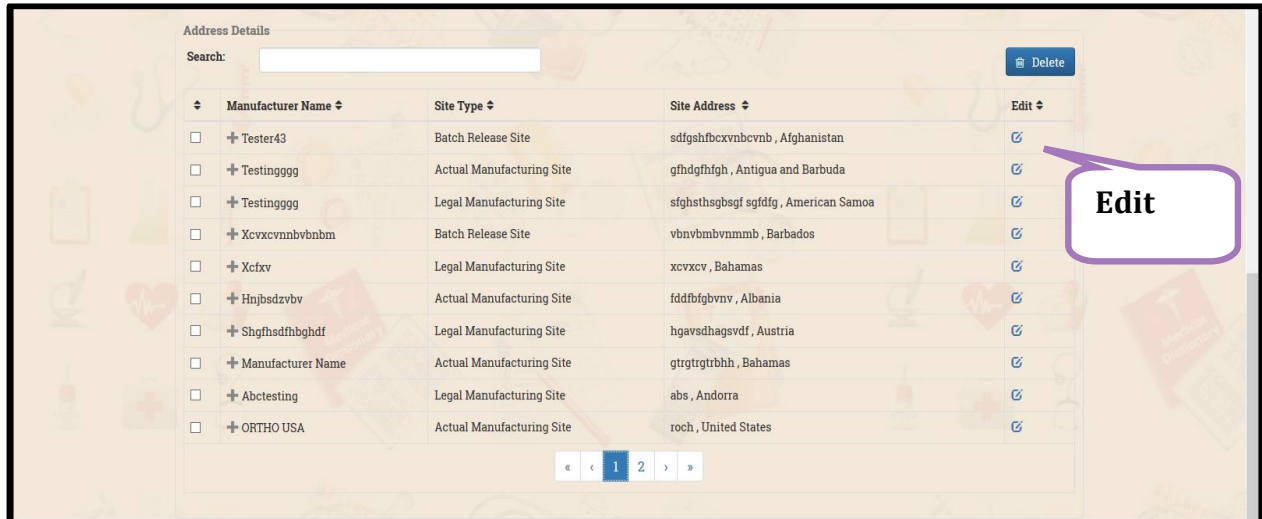


Figure 16 : Filled all Required Field


- After click on Save Button Address Details list will show, **figure 17**, user can Edit or Delete the address.

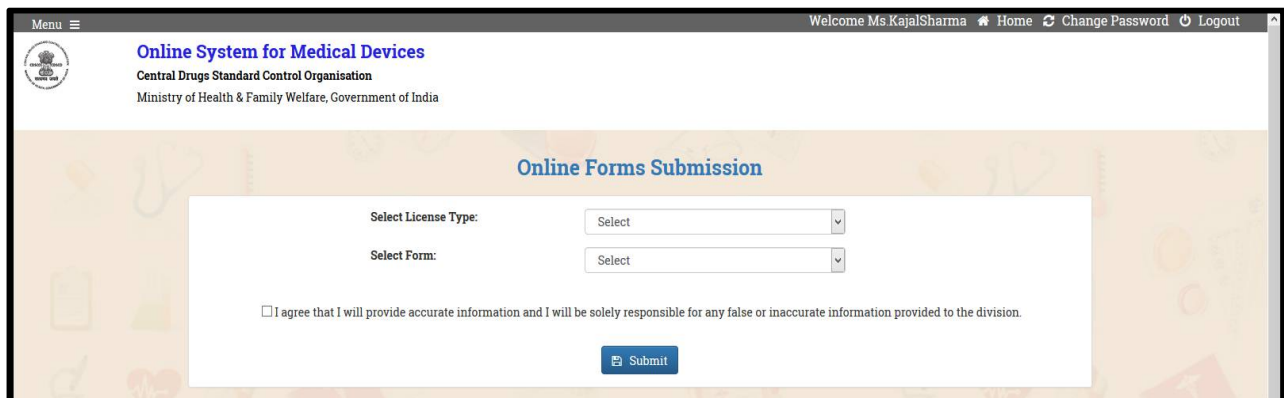


Address Details				Delete
Search: <input type="text"/>				
Manufacturer Name	Site Type	Site Address	Edit	
<input type="checkbox"/> + Tester43	Batch Release Site	sdfgshfbcxvnbvnb, Afghanistan		
<input type="checkbox"/> + Testingggg	Actual Manufacturing Site	ghdghfgh, Antigua and Barbuda		
<input type="checkbox"/> + Testingggg	Legal Manufacturing Site	sfgshsthsbgsf sgfdgf, American Samoa		
<input type="checkbox"/> + Xcvxcvnbvnbm	Batch Release Site	vbnvbnvbnmb, Barbados		
<input type="checkbox"/> + Xcfzv	Legal Manufacturing Site	xcvxcv, Bahamas		
<input type="checkbox"/> + Hnjbsdzvbv	Actual Manufacturing Site	fdffgfbvvnv, Albania		
<input type="checkbox"/> + Shghsfhbgbhd	Legal Manufacturing Site	hgavsthsagsvdf, Austria		
<input type="checkbox"/> + Manufacturer Name	Actual Manufacturing Site	gtrgrtrrbhh, Bahamas		
<input type="checkbox"/> + Abctestng	Legal Manufacturing Site	abs, Andorra		
<input type="checkbox"/> + ORTHO USA	Actual Manufacturing Site	roch, United States		

Figure 17 : List of address Details

1.6. Submit Application

- Click on  Submit Application then below the mention screen will show, **Figure 18.**



Menu Welcome Ms KajalSharma Home Change Password Logout

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

Online Forms Submission

Select License Type:

Select Form:

I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.

Figure 18 : Screen of after Click on Submit application

- Fill all the details using Dropdown Menu List like Selet License Type, Select Forms then after click on Submit Button for Online Form Submission. As shown in **figure 19, 20, 21, 22.**

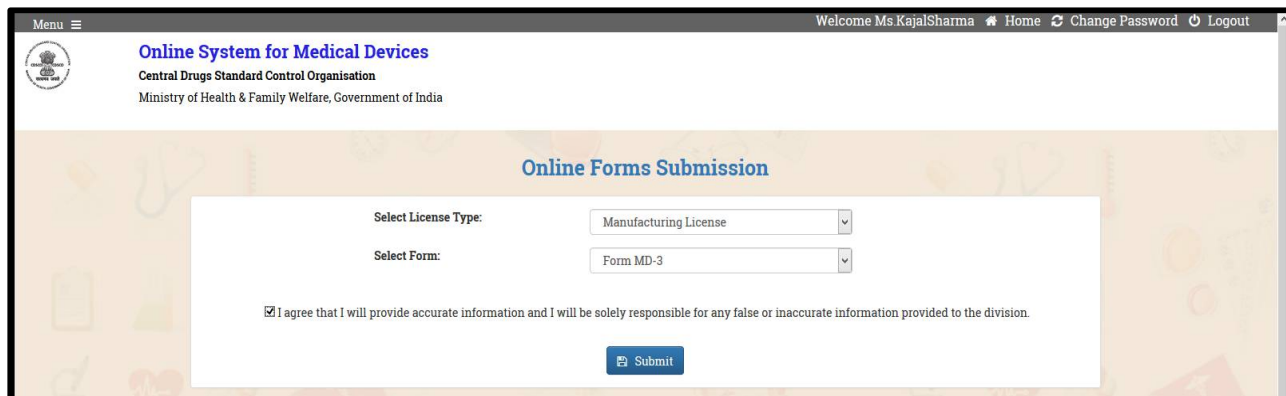


Figure 19 : Submit application (Continue)

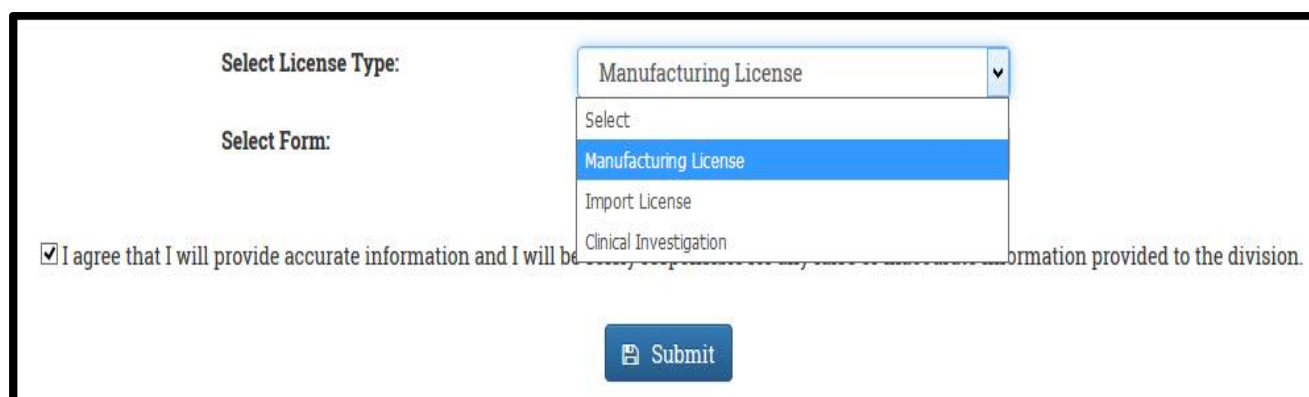


Figure 20 : Three Options - Manufacturing License, Import License, Clinical Investigation

- Select any Form from Dropdown List like – (a) Form MD- 3 (b) Form MD- 4 (c) Form MD- 7 (d) Form MD- 8. As shown in **figure 19**.

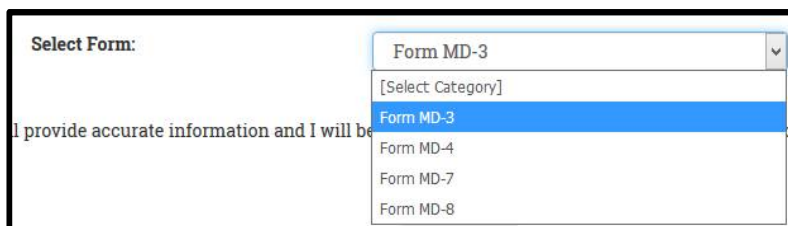


Figure 21 : Form Type

- Read carefully General Instructions then after Proceed. As Shown in **Figure 20**.

GENERAL INSTRUCTIONS

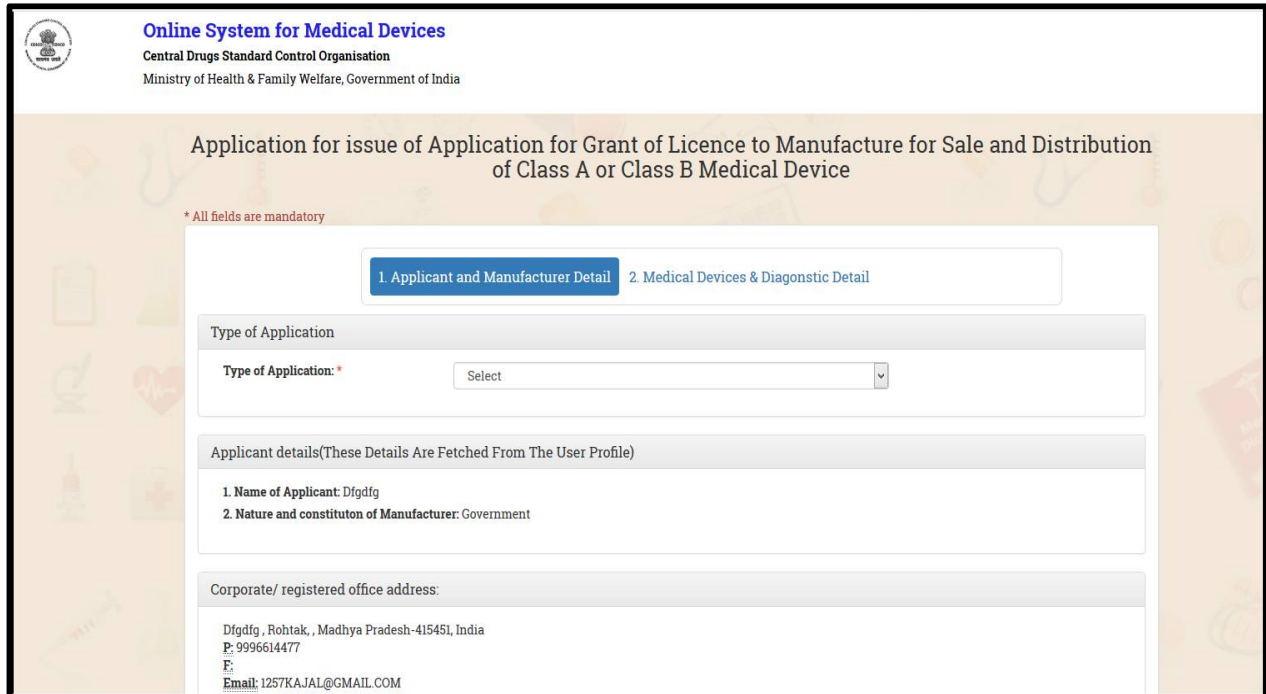
** User can proceed to Online Form Submission only if the User Profile is complete.*

Please read the below instructions carefully before proceeding to Online Form Submission

1. *Online Form Submission* is divided into few simple steps like:
 - Filling of Form
 - Uploading Essential Documents in checklist
 - Payment (if applicable) and
 - Final Form Upload.
2. User is required to download  pdf in *Full Preview step*. After downloading, perform the following steps:
 - Sign and Stamp the form
 - Scan the Signed and Stamped Form
 - Upload this form in the *Upload Form step*
3. Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

Figure 22 : General Instructions

- After click on Submit Button screen will show in **figure 23& figure 24**.



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

Application for issue of Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B Medical Device

* All fields are mandatory

1. Applicant and Manufacturer Detail 2. Medical Devices & Diagnostic Detail

Type of Application

Type of Application: *

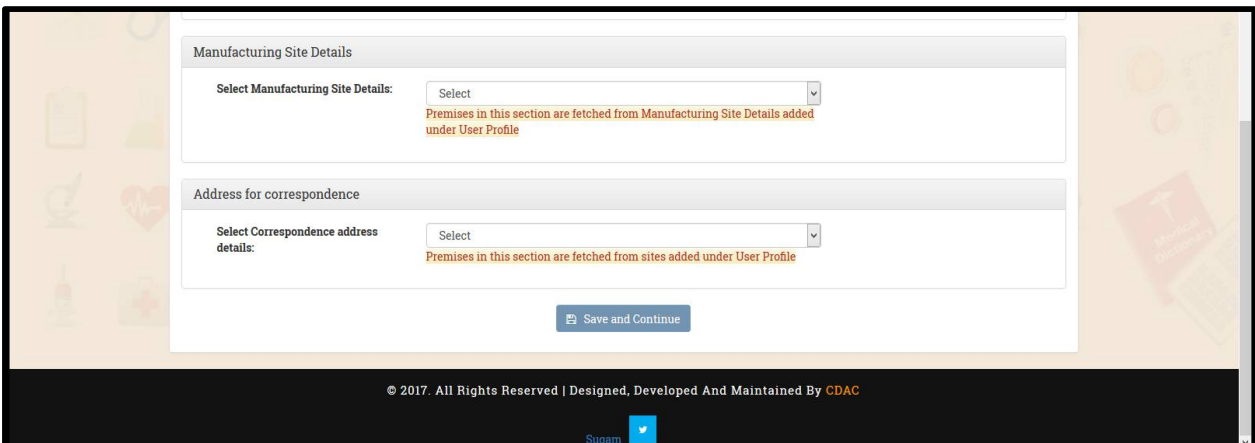
Applicant details(These Details Are Fetched From The User Profile)

1. Name of Applicant: Dfgdfg
2. Nature and constitution of Manufacturer: Government

Corporate/ registered office address:

Dfgdfg, Rohtak, Madhya Pradesh-415451, India
P: 9996614477
E:
Email: 1257KAJAL@GMAIL.COM

Figure 23 : Screen of After Click on Submit Button



Manufacturing Site Details

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

Address for correspondence

Select Correspondence address details:
Premises in this section are fetched from sites added under User Profile

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Figure 24 : Screen of After Click on Submit Button (Continue)

- Select Type of Application, Select Manufacturing Site Details and Select Correspondence address details then click on Save and Continue. As shown in the figure

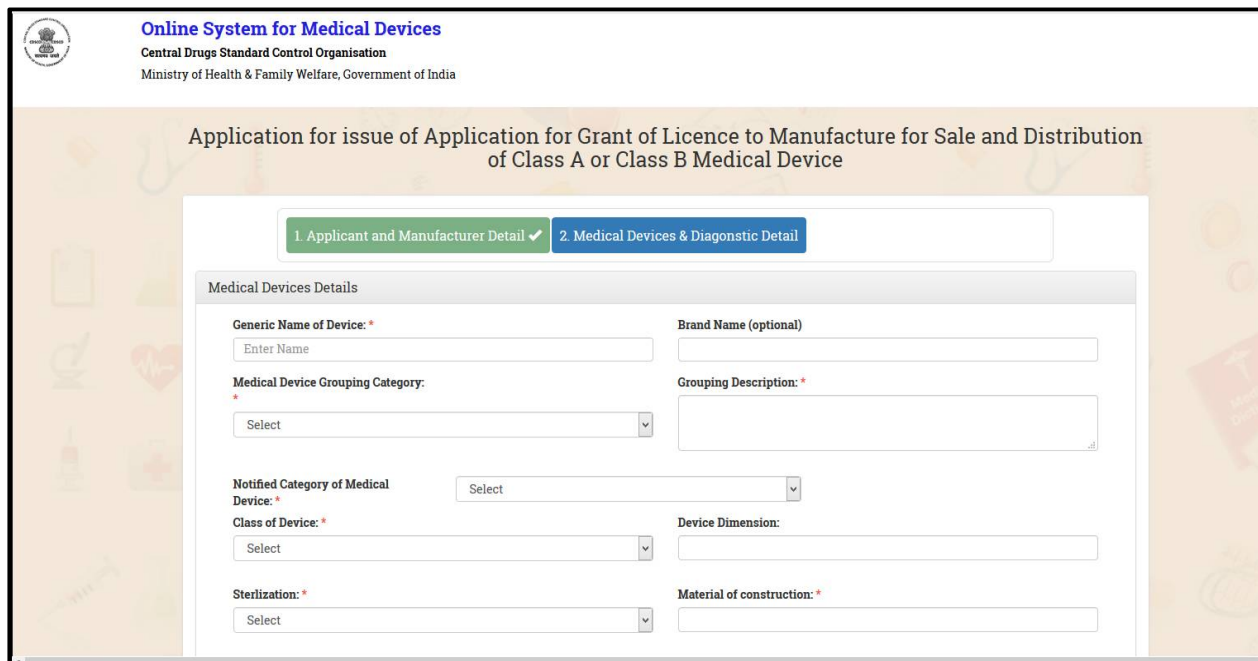


Figure 25 : Screen of after click on Save and Continue

- **Medical Device Details** : After click on save button then fill Medical Device Details like Generic Name of Device, Medical Device Grouping Category, Grouping Description, Notified Category of Medical Device, Class of Device, Sterilization, Product Description etc. as shown in the **figure 24**.

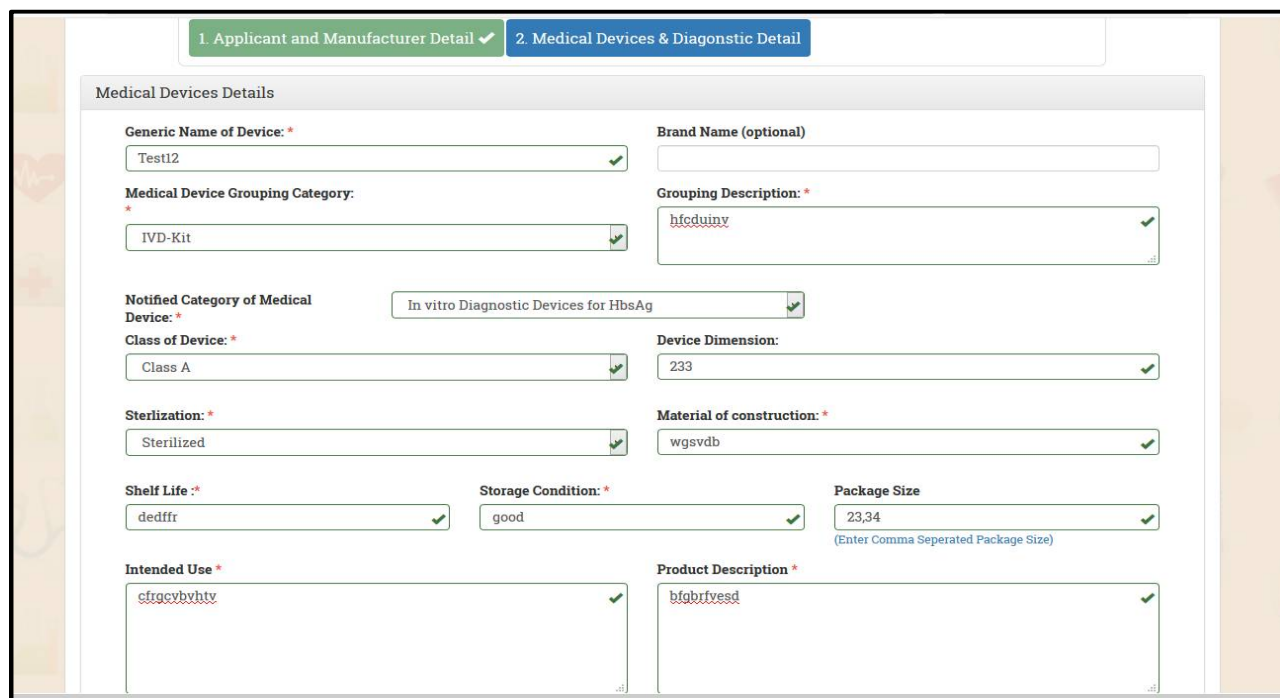
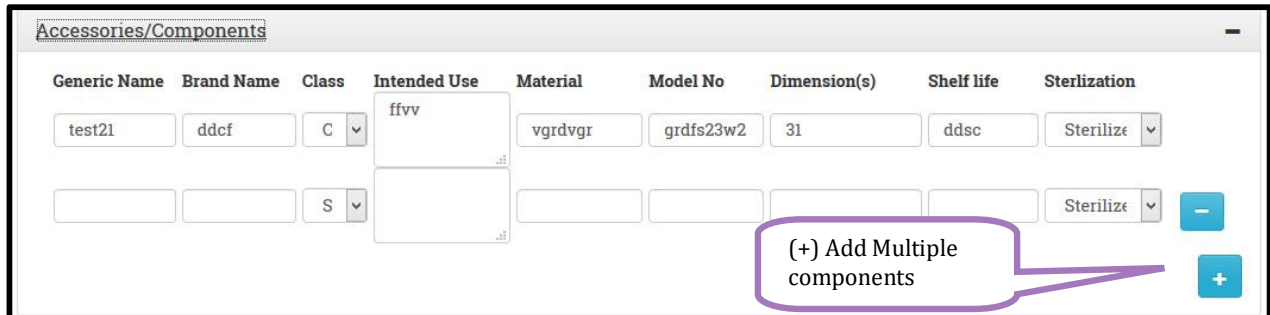


Figure 26 : Screen of Medical device Details

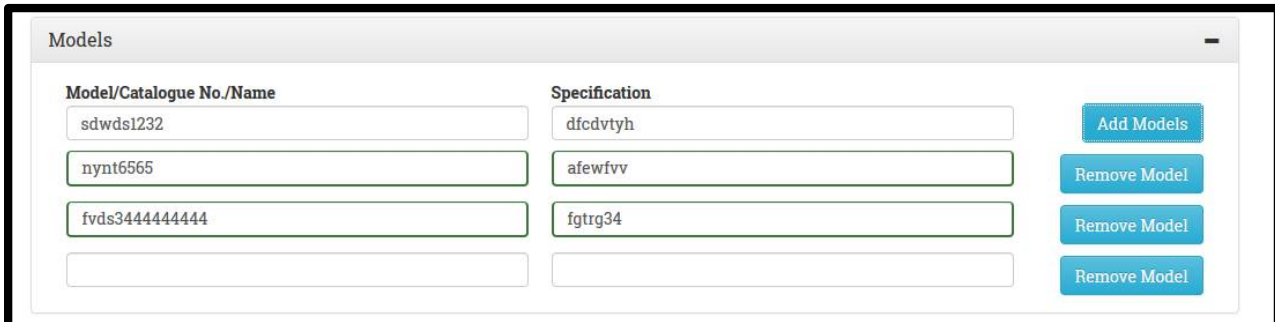
- **Accessories/Components** :User can Add(+) or Remove (-) the field. Refer **figure 25**.



Generic Name	Brand Name	Class	Intended Use	Material	Model No	Dimension(s)	Shelf life	Sterilization
test21	ddcf	C	ffvv	vgrdvgr	grdfs23w2	31	ddsc	Sterilize
		S						Sterilize

Figure 27 : Accessories/Components

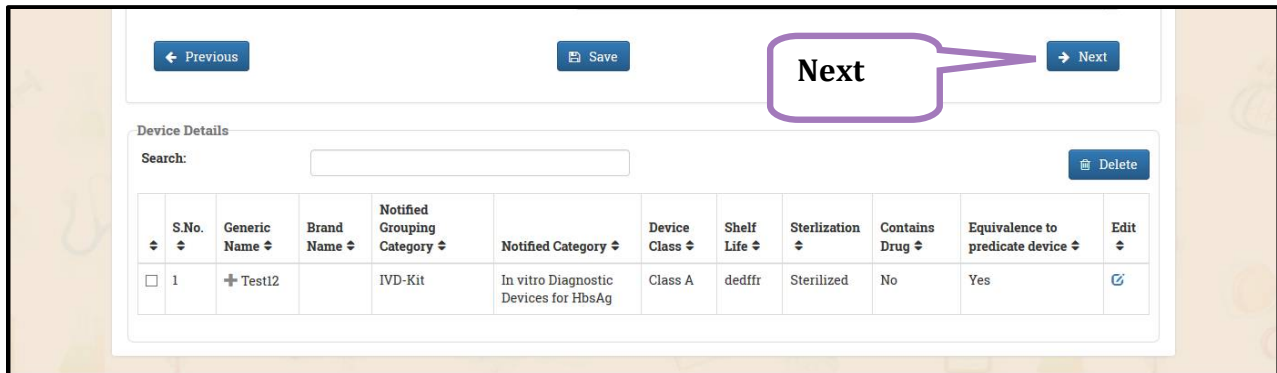
- **Models** : User can “Add Model ” or “Remove Model” with the help of Buttons. As shown in figure 26



Model/Catalogue No./Name	Specification
sdwds1232	dfcdvtyh
nynt6565	afewfvv
fvds3444444444	fgtrg34

Figure 28 : Fill Model Details

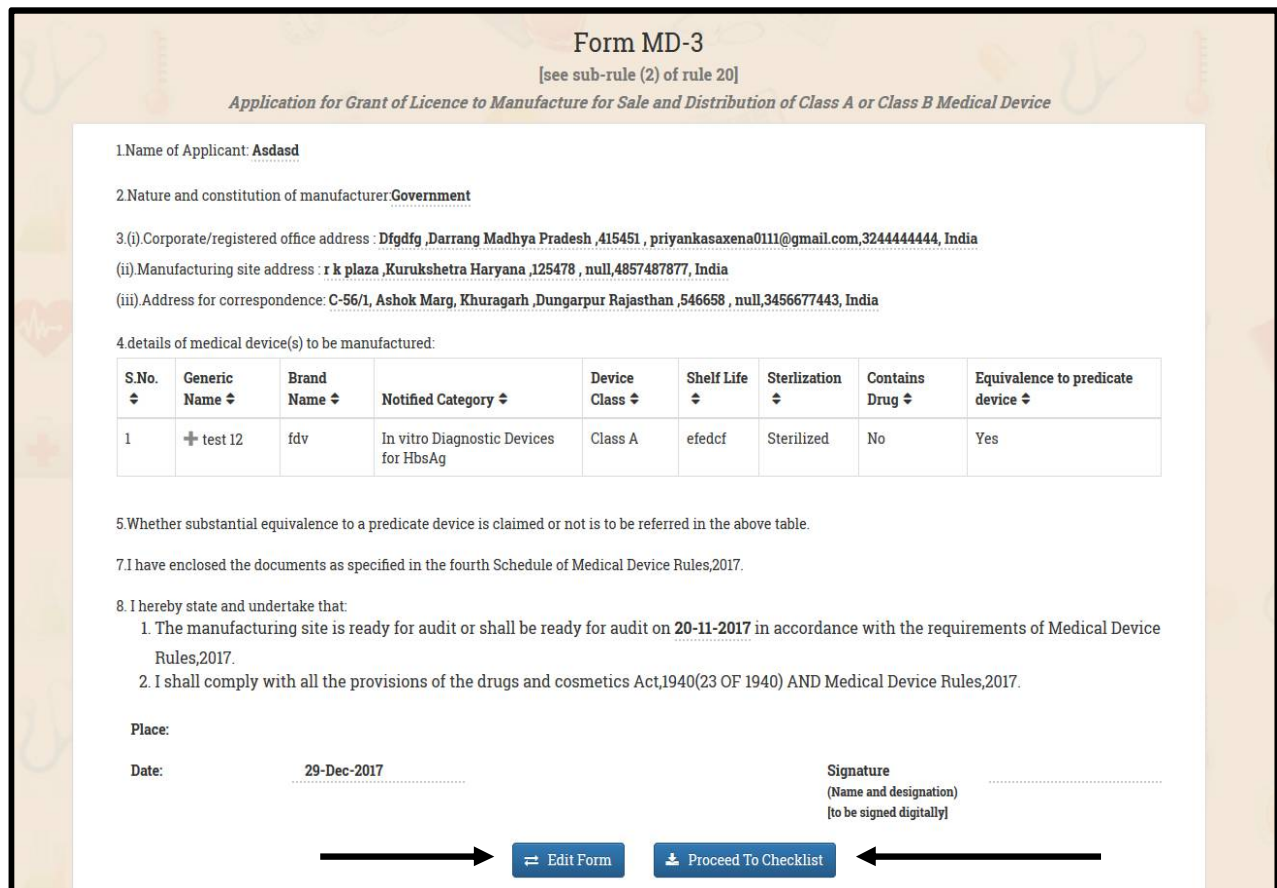
- Fill all the details click on Save Button, After Save the information screen will show in this **figure 27**. Shows device details, user can Edit or delete the device details.



S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterilization	Contains Drug	Equivalence to predicate device	Edit
1	Test12		IVD-Kit	In vitro Diagnostic Devices for HbsAg	Class A	dedffr	Sterilized	No	Yes	

Figure 29 : List of Device Details

- Then click on NEXT Button, screen will show in **figure 28**.User can Edit Form or Proceed to Checklist.



Form MD-3
[see sub-rule (2) of rule 20]
Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B Medical Device

1.Name of Applicant: Asdasd

2.Nature and constitution of manufacturer: Government

3.(i).Corporate/registered office address : Dfgdfg ,Darrang Madhya Pradesh ,415451 , priyankasaxena0111@gmail.com,3244444444, India
 (ii).Manufacturing site address : r k plaza ,Kurukshetra Haryana ,125478 , null,4857487877, India
 (iii).Address for correspondence: C-56/1, Ashok Marg, Khuragarh ,Dungarpur Rajasthan ,546658 , null,3456677443, India

4.details of medical device(s) to be manufactured:

S.No.	Generic Name	Brand Name	Notified Category	Device Class	Shelf Life	Sterilization	Contains Drug	Equivalence to predicate device
1	+ test 12	fdv	In vitro Diagnostic Devices for HbsAg	Class A	efedcf	Sterilized	No	Yes

5.Whether substantial equivalence to a predicate device is claimed or not is to be referred in the above table.

7.I have enclosed the documents as specified in the fourth Schedule of Medical Device Rules,2017.

8. I hereby state and undertake that:
 1. The manufacturing site is ready for audit or shall be ready for audit on 20-11-2017 in accordance with the requirements of Medical Device Rules,2017.
 2. I shall comply with all the provisions of the drugs and cosmetics Act,1940(23 OF 1940) AND Medical Device Rules,2017.

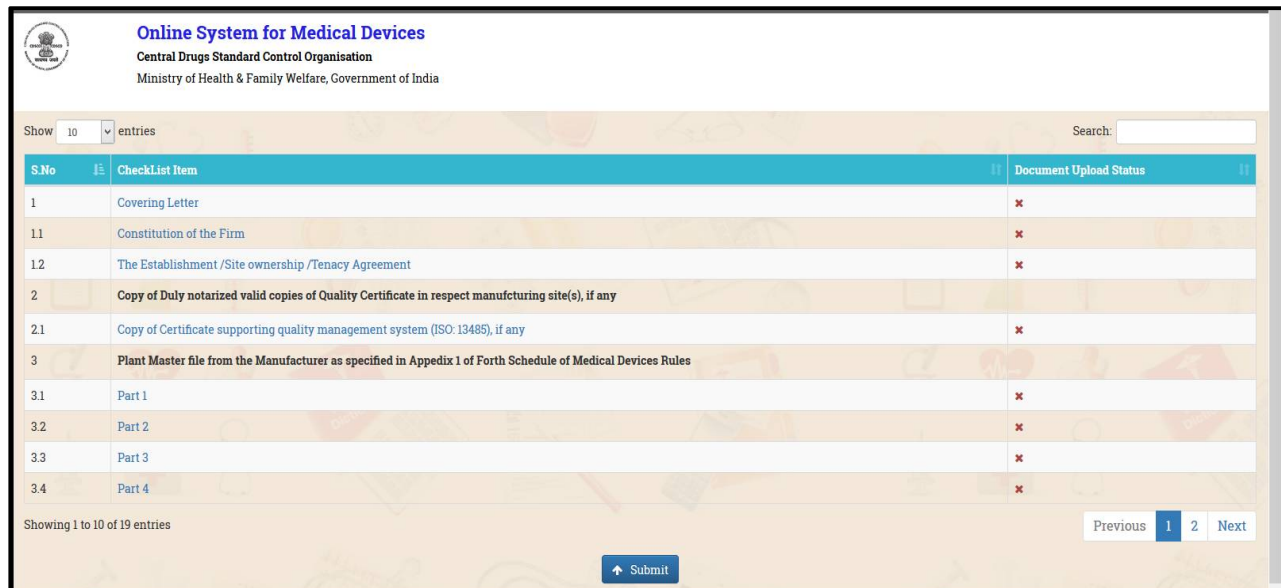
Place: _____
 Date: 29-Dec-2017

Signature
(Name and designation)
(to be signed digitally) _____

→ [Edit Form](#) [Proceed To Checklist](#) ←

Figure 30 : Form MD - 3

- After Click on Proceed to Checklist, screen will show like **figure 29**.



S.No	CheckList Item	Document Upload Status
1	Covering Letter	x
11	Constitution of the Firm	x
12	The Establishment /Site ownership /Tenacy Agreement	x
2	Copy of Duly notarized valid copies of Quality Certificate in respect manufacturing site(s), if any	
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	x
3	Plant Master file from the Manufacturer as specified in Appedix 1 of Forth Schedule of Medical Devices Rules	
3.1	Part 1	x
3.2	Part 2	x
3.3	Part 3	x
3.4	Part 4	x

Figure 31 : Checklist Item

- Then User can upload the Documents, View the documents and Reset the Document.
- **For Upload the document** : User can click any “Cheklist Items” like – Covering Letter, Constitution of the firm, The Establishment /Site ownership /Tenacy Agreement etc.
- After click on Covering Letter or The Establishment /Site ownership /Tenacy Agreement. The screen will show like **figure 30**.

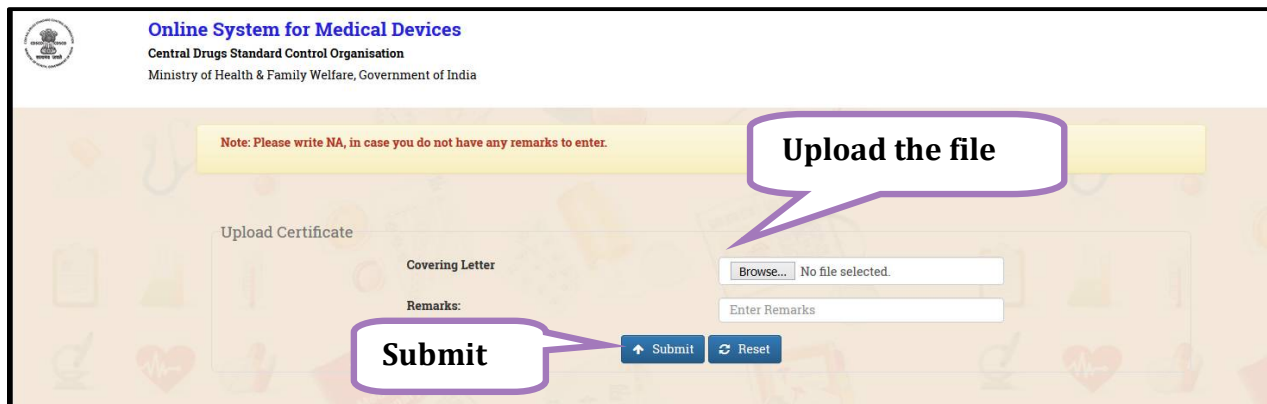


Figure 32 : Upload document for Covering Letter

- Then Submit the Upload Documents, If user wants to view the document or can change the upload document, he can do so. As shown in the **figure 31**.



Figure 33: View Upload Document or change file

- After upload, all the documents, “documents Upload status” will show as figure 33. Uploaded documents will show, Mark as Green colour.

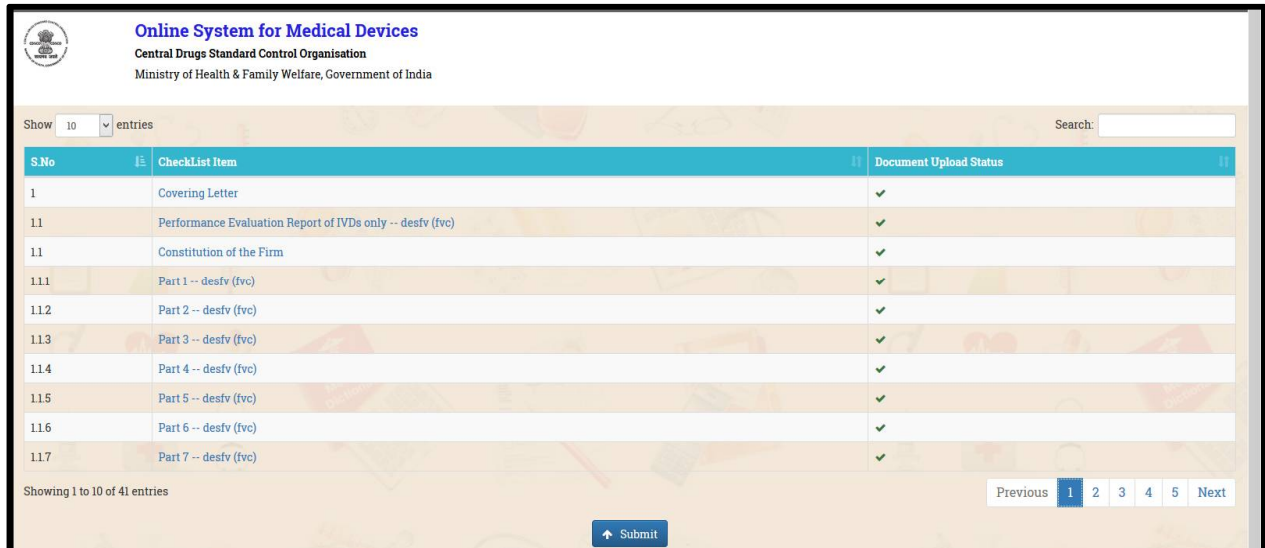


Figure 34 : Screen of “Documents Upload Status”

- After Click on Submit Button the screen will show in this figure 33.

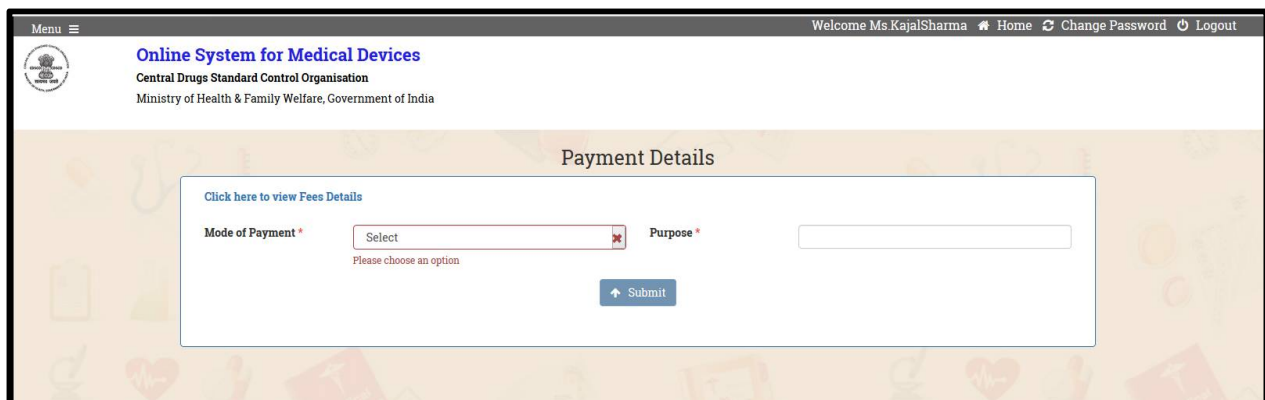
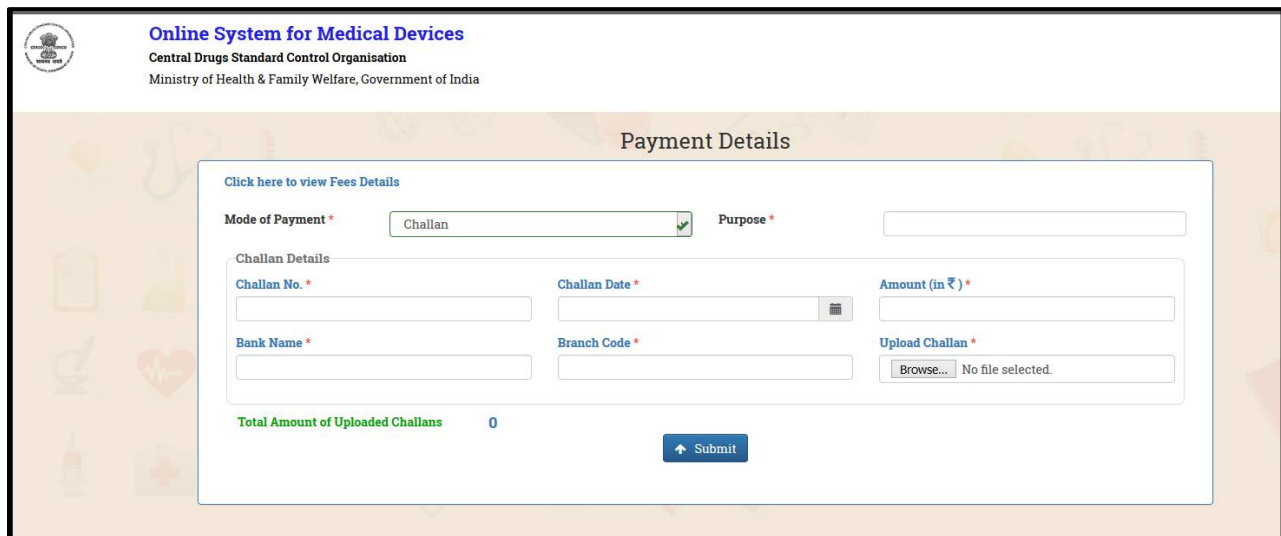


Figure 35 : Payment Detail Screen

- Select Mode of Payment Challan, Fill Challan Details Like Challan No., Date, Amount, Bank Name, Branch Code, and Upload Challan.



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Payment Details

[Click here to view Fees Details](#)

Mode of Payment * ✓ Purpose *

Challan Details

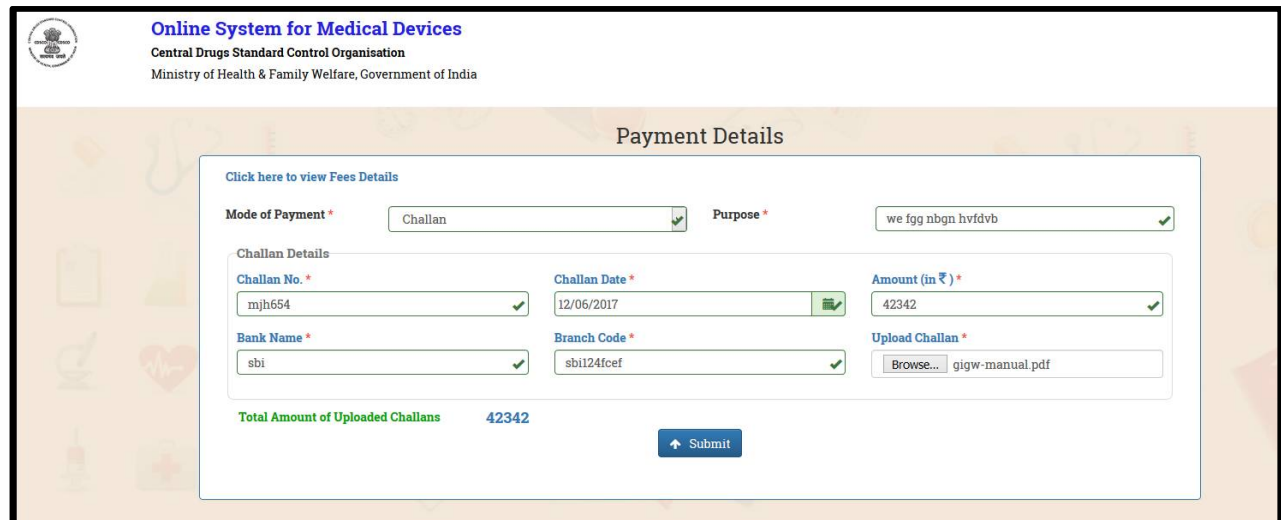
Challan No. * ✓ Challan Date * ✓ Amount (in ₹) *

Bank Name * ✓ Branch Code * ✓ Upload Challan *

Total Amount of Uploaded Challans 0

Figure 36 : Payment Details (Continue)

- After Fill all the details, then Click on Submit Button.



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Payment Details

[Click here to view Fees Details](#)

Mode of Payment * ✓ Purpose * ✓

Challan Details

Challan No. * ✓ Challan Date * ✓ Amount (in ₹) * ✓

Bank Name * ✓ Branch Code * ✓ Upload Challan *

Total Amount of Uploaded Challans 42342

Figure 37 : Payment Details (Continue)

- After click on Submit the screen will show as **figure 36**. In this shows **Download PDF** or click on **Next** Button for Continue.

Form MD-3

[see sub-rule (2) of rule 20]

Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B Medical Device

1.Name of Applicant: Asdasd

2.Nature and constitution of manufacturer: Government

3.(i).Corporate/registered office address : Dfgdfg ,Darrang Madhya Pradesh ,415451 , priyankasaxena0111@gmail.com,3244444444, India
 (ii).Manufacturing site address : FURFURI NAGAR ,Unnao Uttar Pradesh ,111989 , null,98109201289, India
 (iii).Address for correspondence: aaaaaaaaaaaaaaaaa ,Shimla Himachal Pradesh ,757887 , null,1222222390, India

4.details of medical device(s) to be manufactured:

S.No. ↕	Generic Name ↕	Brand Name ↕	Notified Category ↕	Device Class ↕	Shelf Life ↕	Sterlization ↕	Contains Drug ↕	Equivalence to predicate device ↕
1	+ desfv	fvv	In vitro Diagnostic Devices for HbsAg	Class A	gbdseveg	Sterilized	No	Yes

5.Whether substantial equivalence to a predicate device is claimed or not is to be referred in the above table.

6.Fee paid on 06/Dec/2017 Rs. 42343 receipt/challan/transaction id 34r3b t54.

7.I have enclosed the documents as specified in the fourth Schedule of Medical Device Rules,2017.

8.I hereby state and undertake that:

- The manufacturing site is ready for audit or shall be ready for audit on 20-11-2017 in accordance with the requirements of Medical Device Rules,2017.
- I shall comply with all the provisions of the drugs and cosmetics Act,1940(23 OF 1940) AND Medical Device Rules,2017.

Place: _____


Date: 29-Dec-2017 _____

Signature
(Name and designation)
[to be signed digitally] _____

Download PDF Next

Figure 38 : Preview of Form MD-3

➤ After Click on Next Button the screen will show as **figure 37**.



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Upload Form

Browse... | gigw-manual.pdf ✓

Figure 39 : Upload Form

➤ After Click on Submit Button, below the mention screen will show, **figure 38** and Message will show i.e “ Your Application has been submitted Successfully”, note your File no. **MFG/MD/2017/915**.



Figure 40 : Screen of Application Successfully Submitted

1.7. Save as Draft

1.8. Submitted Application



- Click on Submitted Application under the dashboard screen,
- To view the status of submitted applications. In this you can Withdraw the application as shown in the **figure 39**.

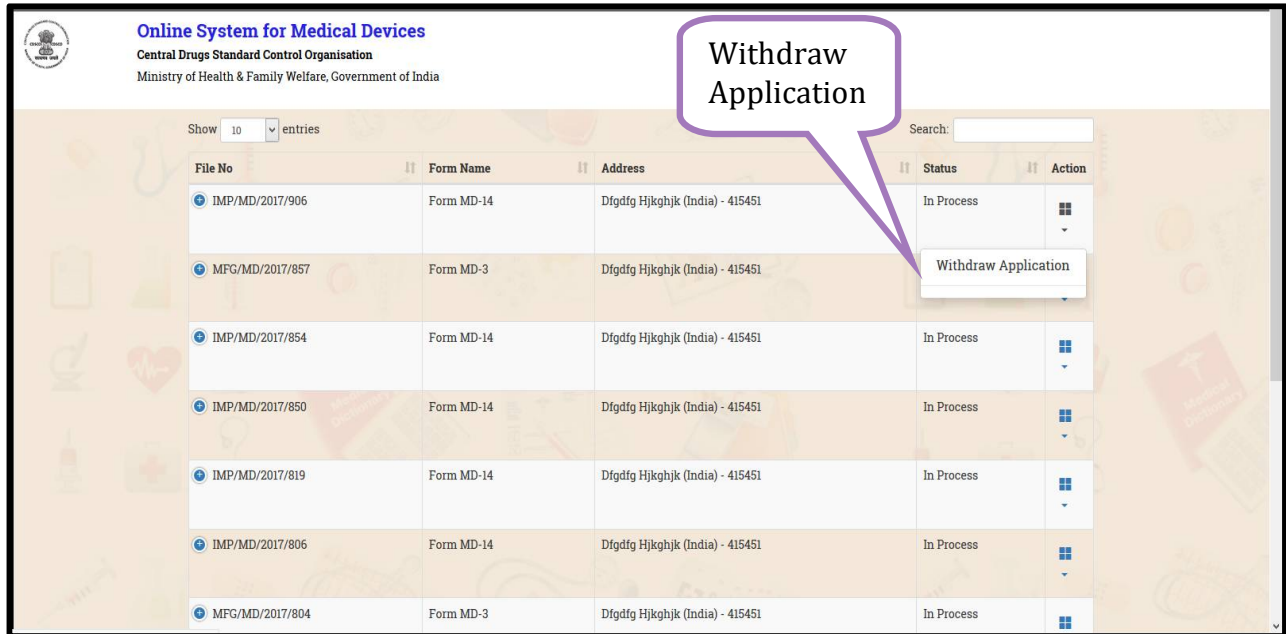


Figure 41 : Screen of after click on Submitted Application

- After Click on Withdraw Application Confirmation message will show. As shown in the figure 42.

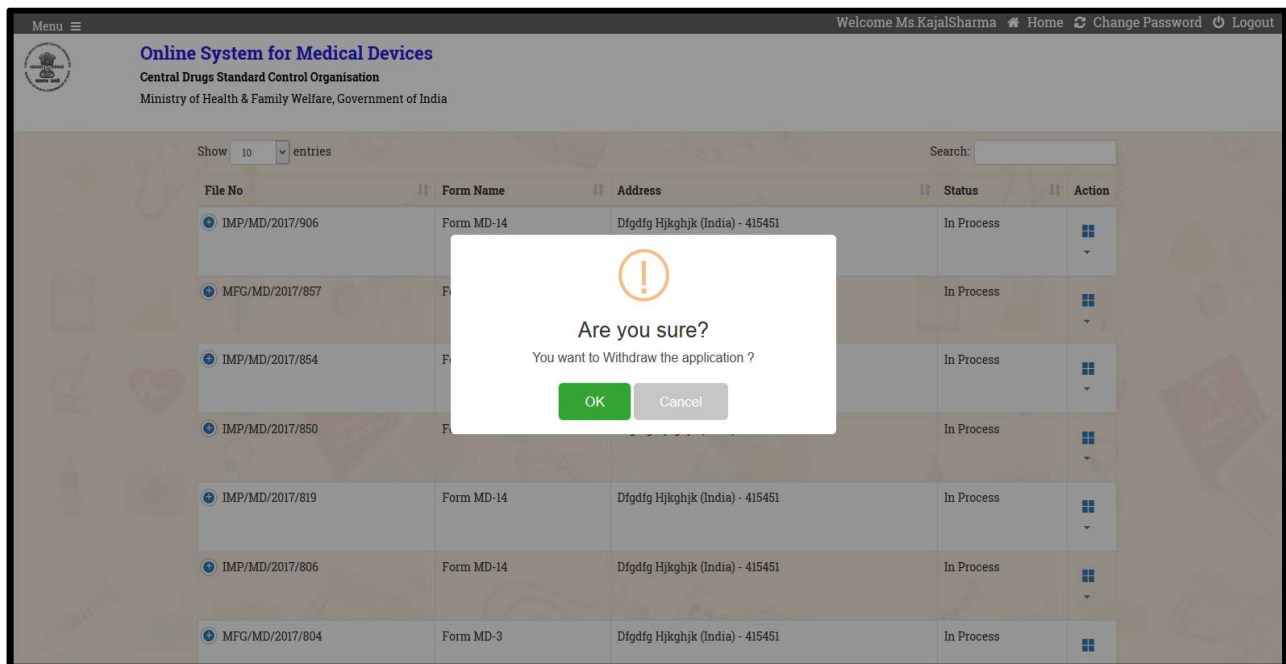


Figure 42 : Popup Message: "You want to withdraw the Application."

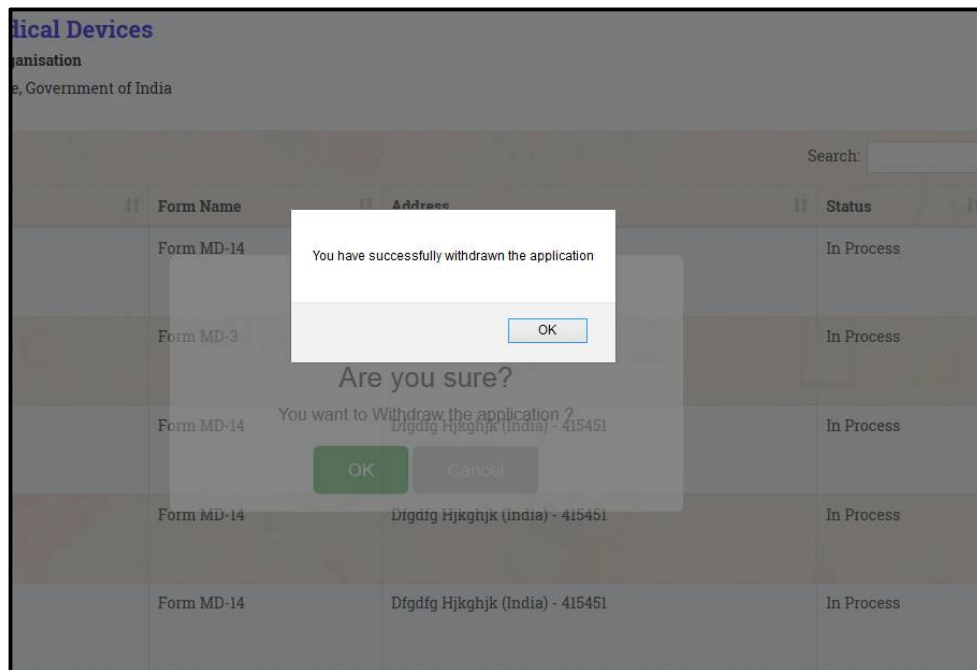


Figure 43 : Popup Message- Successfully Withdraw the application