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Table 1 : Dashboard Option ........................................................................................................5
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and provides the statistical analysis of the applications for various processes & licenses issued, suspended/cancelled, withdrawn.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](image)

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.
Various options are available on the dashboard as described below:

**Table 1: Dashboard Option**

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit Application</td>
<td>For Fresh Application Click on Submit Application Button.</td>
</tr>
<tr>
<td>Saved (Draft) Applications</td>
<td>To view the pending/incomplete applications click on Saved (Draft) Applications.</td>
</tr>
<tr>
<td>Submitted Application</td>
<td>To view the status of submitted applications click on “Submitted Application” link.</td>
</tr>
<tr>
<td>Approved Application</td>
<td>This session used to store the Approved Application.</td>
</tr>
<tr>
<td>Rejected Application</td>
<td>This interface is reserved for Rejected Applications</td>
</tr>
<tr>
<td>Withdrawn Application</td>
<td>This link is to view all Withdrawn Applications</td>
</tr>
<tr>
<td>Query Raised/Responded</td>
<td>This link is to help query raised by CDSCO.</td>
</tr>
</tbody>
</table>
1.3. **Change Password**

- If the user wants to change their password, they can click on the 'Change Password' link, as shown in Figure 4.
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)](image)

**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](image)
- Click on User Profile as shown in **Figure 7**.

- 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**.
1.5. **Add Address**

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

- Click on Add Correspondence and Site Address, the screen will show as mentioned in figure 10.
- Fill all the mandatory details (*) as shown in figure 11, and then after click on Save button.

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.

Figure 12: Address Details

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

Now click on Foreign Manufacturer address Details, the screen will shown as figure 13. Fill all the required field as shown in figure 15.
After fill all the details you can save information by clicking the Save Button. As shown in figure 16.

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

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

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

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

*Users 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** the 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**.
Select Type of Application, Select Manufacturing Site Details and Select Correspondence address details then click on Save and Continue. As shown in the figure.
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.
- **Accessories/Components**: User can Add(+) or Remove (-) the field. Refer figure 25.

![Figure 27: Accessories/Components](image)

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

![Figure 28: Fill Model Details](image)
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.

Figure 29 : List of Device Details

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

Figure 30 : Form MD - 3
➢ After Click on Proceed to Checklist, screen will show like figure 29.

![Checklist Item]

➢ Then User can upload the Documents, View the documents and Reset the Document.

➢ **For Upload the document**: User can click any “Checklist Items” like – Covering Letter, Constitution of the firm, The Establishment /Site ownership /Tenancy Agreement etc.

➢ After click on Covering Letter or The Establishment /Site ownership /Tenancy Agreement. The screen will show like figure 30.

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

After Click on Submit Button the screen will show in this figure 33.
- Select Mode of Payment Challan, Fill Challan Details Like Challan No., Date, Amount, Bank Name, Branch Code, and Upload Challan.

![Payment Details](image1)

**Figure 36:** Payment Details (Continue)

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

![Payment Details](image2)

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

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.
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.
➢ After Click on Withdraw Application Confirmation message will show. As shown in the figure 42.
Figure 43: Popup Message - Successfully Withdraw the application