



Central Drug Standard Control Organization (CDSCO)

Applicant User Manual

For

Medical Device Portal

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Centre for Development of Advanced Computing

(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India) Anusandhan Bhawan, C-56/1, Institutional Area, Sector-62, Noida-201307 Phone: 91-120-3063311-14 Website:<u>http://www.cdac.in</u>

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Table 1 : Dashboard Option



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provides the statistical analysis of the applications for various processes & licenses issued, suspended /cancelled, withdrawn.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

-	Submit Application	Submit application - For Fresh Application Click on Submit Application Button.
O C	Click Here	
	Saved(Draft) Applications Click Here	Saved (Draft) Applications - To view the pending/incomplete applications click on Saved (Draft) Applications.
	abmitted Application	Submitted Application: To view the status of submitted applications click on "Submitted Application" link.
	pproved Applications	Approved Application: This session used to store the Approved Application.
	Rejected Applications	Rejected Application : This interface is reserved for Rejected Applications
Ð	Click Here	
	Withdrawn Applications Click Here	Withdrawn Application : This link is to view all Withdrawn Applications
?	Query Raised/ Responded	Query Raised/ Responded: This link is to help query raised by CDSCO.





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.*

Menu =			Welcome Ms.KajalSharma 🛛 🖨 Hom	e 😂 Change Password 🙂 Logout 🔷
ament		Online System for Medical Devices Central Drugs Standard Control Organisation Ministry of Health & Family Welfare, Government of India	Ranging and	10
		Change your	password	
27	Old Password:	Old Password	Change Password	
	New Password:	new Password		
-	ReEnter New Password:	Re-enter new Password		
	Please select a method o	f choice to receive a new One Time PIN (OTP) to verify you	ır self	
	🔿 Email 🔿 Mobile Nur	a ocherate ori		
do		Press the generate OTP button.		
× Y		× Cano	cel	
1				
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.

Menu ≡				Welcome Ms.KajalShar	ma 希 Home 😂 Cha	ange Password 🙂 Logout 🔥
min	cosco Jin cosco Central D	System for Medical Devices Drugs Standard Control Organisation of Health & Family Welfare, Government of India	MANING	munit		
		Change your	password			
	Old Password:	••••••				
	New Password:	This connection is not secure. Logins for entered here could be compromised. Learn More				
and the second	ReEnter New Password:	Re-enter new Password				
	Please select a method of choice to	o receive a new One Time PIN (OTP) to verify you	r self			
	🔿 Email 🔿 Mobile Number	Generate OTP Press the generate OTP				
d		button.	_			
<u>~</u>		× Cano	cel			
1.						
4						

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**.

User Profile -	Menu ≡			Welcome Ms.KajalSharma	🕈 Home 🏾 🕄 Change Password	🛈 Logout
→ View Profile Add Address - Online Payment -		Central Drugs Standard Co	r Medical Devices ntrol Organisation y Welfare, Government of India			
		19-10	User Profile	6	9D2 1	12
	6	General Details				
User Prof	ile	User-Name: Organisation: Address Proof :	TESTUSER@GMAIL.COM Dfgdfg Dfgdfg,123 Rohtak -415451, 23, 193 Phone: 9996614477, Fax: , Email: TESTUSER@GMAIL.COM Type of Organization: Applicant Click here to add new Manufacturing Site Address / Correspon View_File	dence Address		
	č	Registered User Detail	s	6		
<	,	Name:	Kajal Sharma Female , Indian Senior Project Engineer, Mobile Number: +91-9876543212, Email(Other than user name): 12	157KAJAL@GMAIL.COM		5%





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.

User Profile+	Menu ≡			Welcome Ms KajalSharma	🕷 Home 🏾 Change Password	<mark></mark> Logout
Add Address- Add Correspondence And Site Address		Central Drugs Standard	for Medical Devices Control Organisation nily Welfare, Government of India			
 → Foreign Manufacture Address Online Payment - 		Q - C	User Profile	2	121	191
Add	Addre	General Details User-Name: SS Address Proof :	TESTUSER@GMAIL.COM Dfgdfg Dfgdfg, 123 Rohtak -415451, 23, 193 Phone: 9996614477, Fax: , Email: TESTUSER@GMAIL.COM Type of Organization: Applicant C Click here to add new Manufacturing Site Address / Correst View_File	pondence Address		
	6	Registered User Deta	ails		🖋 Modify	
< >>	-10	Name:	Kajal Sharma Female , Indian Senior Project Engineer, Mobile Number: +91-9876543212, Email(Other than user name)): 1257KAJAL@GMAIL.COM		

Figure 9 : Add Address

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

	Online System for Medical Devices Central Drugs Standard Control Organisation Ministry of Health & Family Welfare, Government of India	
	* All fields are mandatory	Address Details
	Manufacturer Address Details	
	Premises Type:	
6	Select	·
	Organisation Name :	
	Premises name	
1	Address:	I B
1	Address Line	
	Country:	State
1	India	Select
THE A	District	Pin Code
	Select	Ū
	Fax No. (Please include STD Code - Fax Number)	Contact No. (Please include STD Code - Phone Number)
1.00	(9) STD Code - Fax Number	STD Code - Phone Number
	Multiple Fax Numbers can be added with comma separation	Multiple Contact Numbers can be added with comma separation
1000	and the second s	The state of the s
	🖽 Save	C Reset

Figure 10 : Manufacturer Address Details

Fill all the mandotory 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	
	* All fields are mandatory	Address Details
	Manufacturer Address Details	
	Premises Type:	
Te 1	Test/Evaluation Site	· · · · · · · · · · · · · · · · · · ·
	Organisation Name :	
	CDAC	✓
d	Address:	
1	sector 62 noida	✓
	Country:	State
1	India	Uttar Pradesh 🖌
	District	Pin Code
ing the second	Gautam Buddha Nagar 🖌	201307
	Fax No. (Please include STD Code - Fax Number)	Contact No. (Please include STD Code - Phone Number)
	+9) STD Code - Fax Number	91 01203063311
110	Multiple Fax Numbers can be added with comma separation	Multiple Contact Numbers can be added with comma separation

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.

¢	Premises Name 🗢	Address 🗢	Edit \$	
	+ Rdhsdf	4234234,Koderma Jharkhand,454544 , India	Ø	
	+ Segfsdtgft	,Darrang Madhya Pradesh,415451 , India	G	
	🕂 asdfghj	dfsfsfsd,Darrang Madhya Pradesh,415451 , India	Ø	
	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	Ø	
	+ Ansdmbwha	wefwefwef,South Goa Goa,765746 , India	Ø	
	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	Ø	
	+ DGHSE	FHT,Darrang Madhya Pradesh,415451 , India	Ø	
	+ asdfghj	dfsfsfsd,Darrang Madhya Pradesh,415451 , India	Ø	
	+ Asdasd	Dfgdfg,Darrang Madhya Pradesh,415451 , India	Ø	
	+ DGHSE	FHT,Darrang Madhya Pradesh,415451 , India	Ø	
		« < 1 2 3 4 5 6 7 8 > »		
	© 2	2017. All Rights Reserved Designed, Developed And Maintained By CDAC		

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



* All fields are mandatory	Address Details
Manufacturer Address Details	
Premises Type:	
Test/Evaluation Site	v
Organisation Name :	
CDAC	
Address:	
sector 62 noida	
Country:	State
India	Uttar Pradesh 🗸
District	Pin Code
Gautam Buddha Nagar	201307
Fax No. (Please include STD Code - Fax Number) 01203063317	Contact No. (Please include STD Code - Phone Number) 01203063311
Multiple Fax Numbers can be added with comma separation	Multiple Contact Numbers can be added with comma separation

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.

	Fax No. (Please include STD Code - Fax Number		Contact No. (Please include STD Code - Phone Number)	
	STD Code - Fax Number		en STD Code - Phone Number	
	Multiple Fax Numbers can be added with comm	na separation	Multiple Contact Numbers can be added with comma separation	
	idress Details Harch:	Do you t	vant to delete	音 Delete
Y.	¢ Premises Name ≎	Address \$	ок	Edit \$
] 🕂 Zimmer India Private Limited	Gurgaon,Gurgaon Haryana,122002	, India	Ø
	+ LG Life Sciences India Pvt. Ltd.	Basement SCO No. 321, Sector-29,	Surgaon Haryana,122001 , India	Ø
] 🕂 Testing	Testing Enclave, Testing Enclave, F	laveri Karnataka,123123 , India	Ø
	GENTEX	FURFURI NAGAR ,Unnao Uttar Pr	adesh,111989 , India	Ø
V	g — CDAC	anusandhan Bhawan, sector 62 n	oida ,Gautam Buddha Nagar Uttar Pradesh,201307 , India	Ø
	ddress Type: Test/Evaluation Site ontact Details: 01203063311 ax Details: 01203063317			

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.**



Cer	nline System for Medical Device atral Drugs Standard Control Organisation aistry of Health & Family Welfare, Government of		welcome A	fs.KajalSharma 🏾 🖶 Hoi	ne 🥃 Change Pass	
		Foreign Manufactu	ırer Address Details			
	Manufacturer Address Site Type					
	Site Type:*	Select			*	
	Address Details					
	Manufacturer Name:*	Enter Name				
	Address:*	Address Line				
	Country:*		Email:*			
	Select	~	Email			
	Fax No.* (Please include STD Code - Fax Nu	mber)	Contact No.* (Please include STD Code - Phone	Number)		
	STD Code - Fax Number		STD Code - Phone Number			
	Multiple Fax Numbers can be added with cor		Multiple Contact Numbers can be added with com	ma separation		
		🖺 Save	2 Reset			

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.

Menu ≡			Welcome Ms.KajalSharma	希 Home 🏾 Change Pa	ssword 😃 Logout 🥤
	Online System for Medical Devices Central Drugs Standard Control Organisation Ministry of Health & Family Welfare, Government of India				
-	101	Foreign Manufactu	rer Address Details		
	Manufacturer Address Site Type				
	Site Type:*	Actual Manufacturing	Site	*	
1					
	Address Details				
	Manufacturer Name:*	Testing		~	
¥	Address:*	Burlington, NC		~	
	Country:*		Email:*		
	Canada	- 1 2	test@yahoo.com	~	
륲	Fax No.* (Please include STD Code - Fax Number)		Contact No.* (Please include STD Code - Phone Number)		
	012033001184	1	01203322156	~	
	Multiple Fax Numbers can be added with comma separa	tion	Multiple Contact Numbers can be added with comma separation		
min		🖺 Save	2 Reset		

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.



Sea	earch:			🗎 Delete	
÷	Manufacturer Name 🗢	Site Type 🗢	Site Address 🗢	Edit \$	
	+ Tester43	Batch Release Site	sdfgshfbcxvnbcvnb , Afghanistan	ø	
	+ Testingggg	Actual Manufacturing Site	gfhdgfhfgh , Antigua and Barbuda	Ø	
	+ Testingggg	Legal Manufacturing Site	sfghsthsgbsgf sgfdfg , American Samoa	G	Edit
	+ Xcvxcvnnbvbnbm	Batch Release Site	vbnvbmbvnmmb , Barbados	G	
	+ Xcfxv	Legal Manufacturing Site	xcvxcv, Bahamas	Ø	
	Hnjbsdzvbv	Actual Manufacturing Site	fddfbfgbvnv , Albania	Ø	
	+ Shgfhsdfhbghdf	Legal Manufacturing Site	hgavsdhagsvdf, Austria	Ø	
	Hanufacturer Name	Actual Manufacturing Site	gtrgtrgtrbhh , Bahamas	ø (
	+ Abctesting	Legal Manufacturing Site	abs , Andorra	Ø	
	+ ORTHO USA	Actual Manufacturing Site	roch , United States	Ø	

Figure 17 : List of address Details

1.6. Submit Application

Click on show,

 Submit Application
 Submit Application
 Submit Application

 Show,
 Submit Application
 Figure 18.

Menu =	Central Dru	System for Medical Devices gs Standard Control Organisation Health & Family Welfare, Government of India		Welcome Ms.KajalSharma 🕷 Home 🏾 C	nange Password ウ Logout 🛛 ^
-			Online Forms Submission		
		Select License Type: Select Form:	Select Select	v v	
		□ I agree that I will provide accurate informa	ation and I will be solely responsible for any false or inac	ccurate information provided to the division.	
d			🖺 Submit		

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.



Menu =	Central Drugs S	stem for Medical Devices Standard Control Organisation Alth & Family Welfare, Government of India		Welcome Ms KajalSharma 🐐 Home 🥱 Ch	ange Password 🗢 Logout 🗠
-		Onl	ine Forms Submission		
		Select License Type:	Manufacturing License	~	
-		Select Form:	Form MD-3	¥	
		☑ I agree that I will provide accurate information and I	will be solely responsible for any false or in	accurate information provided to the division.	
d			🖺 Submit		

Figure 19 : Submit application (Continue)

Select License Type:	Manufacturing License	~
Calast Former	Select	
Select Form:	Manufacturing License	
	Import License	
☑ I agree that I will provide accurate information and I will be	Clinical Investigation	ormation provided to the division.
<i>.</i>		•
	🖺 Submit	

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.

Select Form:	Form MD-3	~
	[Select Category]	
l provide accurate information and I will b	Form MD-3	
i provide accurate information and I will be	Form MD-4	
	Form MD-7	
	Form MD-8	



> 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 **1** 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**.



	Central I	e System for Medical Dev Drugs Standard Control Organisation of Health & Family Welfare, Governmen		
		Application for issue of All fields are mandatory	of Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B Medical Device	
		1. Ap	plicant and Manufacturer Detail 2. Medical Devices & Diagonstic Detail	
d		Type of Application: *	Select	
k		Applicant details(These Details 1. Name of Applicant: Dfgdfg 2. Nature and constituton of Manu	Are Fetched From The User Profile)	
		2. Nature and constitution of Manu Corporate/ registered office add		
Laur		Dfgdfg , Rohtak, , Madhya Pradesh <u>P:</u> 9996614477 <u>F:</u> <u>Email:</u> 1257KAJAL@GMAIL.COM	415451, India	

Figure 23 : Screen of After Click on Submit Button

	Manufacturing Site Details		n al
02	Select Manufacturing Site Details:	Select Premises in this section are fetched from Manufacturing Site Details added under User Profile	0
de	Address for correspondence		
	Select Correspondence address details:	Select Premises in this section are fetched from sites added under User Profile	
르 🗷		Save and Continue	
	© 20	D17. All Rights Reserved Designed, Developed And Maintained By CDAC	
		Sugan	

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



	Central Dr	System for Medical Device ugs Standard Control Organisation f Health & Family Welfare, Government of I			
		Application for issue of <i>I</i>	Application for Grant of of Class A or Class	Licence to Manufacture for Sale and Distribution s B Medical Device	
		1. Applicant and Manu Medical Devices Details	Ifacturer Detail 🖌 2. Medical Devic	es & Diagonstic Detail	
		Generic Name of Device: *		Brand Name (optional)	
<u>S</u> .		Medical Device Grouping Category:		Grouping Description: *	
		Select	~		
		Notified Category of Medical Device: *	Select	Y	
		Class of Device: *		Device Dimension:	
		Select	~		
		Sterlization: *		Material of construction: *	
and the second s					

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, Sterlization, Product Description etc. as shown in the figure 24.

Generic Name of Device: *		Brand Name (optional)		
Testi2	-			
Medical Device Grouping Category:		Grouping Description: *		
* IVD-Kit	*	hfcduiny		-
Notified Category of Medical In vitro	o Diagnostic Devices for Hbs.	Ag		
Class of Device: *		Device Dimension:		
Class A	-ye	233		*
Sterlization: *		Material of construction:	*	
Sterilized	-ve	wgsvdb		-
Shelf Life :*	Storage Condition: *		Package Size	
dedffr 🗸	good	~	23,34	-
Intended Use *		Product Description *	(Enter Comma Seperated Package	Size)
cfrgcybyhty	-	bfgbrfvesd		-

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	Sterlization
test21	ddcf	C -) ffvv	vgrdvgr	grdfs23w2	31	ddsc	Sterilize 🗸
		S ¥		1				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	Add Models
nynt6565	afewfvv	Remove Model
fvds344444444	fgtrg34	Remove Model

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.

	← Prev	Todo			🖺 Save			Next	<u>г</u>	→ Ne	
Des	rice Deta	aile									
	arch:									a	Delete
				Notified							
•	S.No.	Generic Name 🗢	Brand Name 🗢	Grouping Category \$	Notified Category \$	Device Class 🗢	Shelf Life ≎	Sterlization	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 Cheklist.

	App	lication for G	rant of Licence to Manufactu	re for Sale a	nd Distribut	ion of Class A	or Class B N	ledical Device
Name	of Applicant: A	sdasd						
Natur	e and constitut	ion of manufac	urer:Government					
(i).Cor	porate/register	ed office addres	ss : Dfgdfg ,Darrang Madhya Prad	esh ,415451 , p	riyankasaxena	0111@gmail.com	n,3244444444,1	india
	-		aza ,Kurukshetra Haryana ,12547					
ii).Add	lress for corres	pondence: C-56	/1, Ashok Marg, Khuragarh ,Dung	arpur Rajastha	an ,546658 , nul	11,3456677443, I	ndia	
	s of medical de		nufactured:					
\$.No.	Generic Name 🖨	Brand Name 🗢	Notified Category 🗢	Device Class 🖨	Shelf Life	Sterlization \$	Contains Drug 🗢	Equivalence to predicate device 🗢
l	+ test 12	fdv	In vitro Diagnostic Devices for HbsAg	Class A	efedcf	Sterilized	No	Yes
I have. I here 1. T R	enclosed the d eby state and ur he manufactu ules,2017. shall comply	ocuments as sp ndertake that: nring site is re	a predicate device is claimed or r secified in the fourth Schedule of eady for audit or shall be read rovisions of the drugs and co	Medical Devic	e Rules,2017. n 20-11-2017	in accordanc		



> After Click on Proceed to Cheklist, screen will show like **figure 29**.

	Online System for Medical Devices Central Druge Standard Control Organisation Ministry of Health & Family Welfare, Government of India	
Show 10 ~	entries	Search:
S.No 🗦	CheckList Item	Document Upload Status
1	Covering Letter	×
11	Constitution of the Firm	×
1.2	The Establishment /Site ownership /Tenacy Agreement	x
2	Copy of Duly notarized valid copies of Quality Certificate in respect manufcturing site(s), if any	
2.1	Copy of Certificate supporting quality management system (ISO: 13485), if any	×
3	Plant Master file from the Manufacturer as specified in Appedix 1 of Forth Schedule of Medical Devices Rules	
3.1	Parti	×
3.2	Part 2	×
3.3	Part 3	×
3.4	Part 4	×
Showing 1 to 10 o	of 19 entries	Previous 1 2 Next
	★ Submit	the case of the second

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**.

(Internet internet in	Online System for Medica Central Drugs Standard Control Organis: Ministry of Health & Family Welfare, Gov	ation			
-	Note: Please write NA, in ca	se you do not have any remarks to	enter.	Upload the file	
6.1	Upload Certificate	Covering Letter			
	4 1 9	Remarks:		wse No file selected. er Remarks	
d	24	Submit	★ Submit 2 Re	set	

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**.



Covering Letter	
Remarks	gvrdvgr
Uploaded Certificate	View_File
Click to change File	View File
	Update 🕃 Reset

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.

now 10 🗸	entries	Search:
S.No	L CheckList Item	Document Upload Status
L	Covering Letter	*
.1	Performance Evaluation Report of IVDs only desfv (fvc)	* (C)
.1	Constitution of the Firm	*
.1.1	Part 1 desfv (fvc)	·
1.1.2	Part 2 desfv (fvc)	*
1.1.3	Part 3 desfv (fvc)	· / no 3
1.1.4	Part 4 desfv (fvc)	*
1.1.5	Part 5 desfv (fvc)	*
1.1.6	Part 6 desfv (fvc)	*
1.1.7	Part 7 desfv (fvc)	-

Figure 34 : Screen of "Documents Upload Status"

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

Menu =	Central D	e System for Medic rugs Standard Control Organ of Health & Family Welfare, G	isation			Welcome Ms.KajalSharma	♣ Home 2 Cha	ange Password 🖒 Logout
	U	Click here to view Fees D Mode of Payment *	etails Select Flease choose an option	Paymo	ent Details			
Ľ d		3	3		Submit	d (V d	

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.

	Online System for Medical De Central Drugs Standard Control Organisation Ministry of Health & Family Welfare, Governm			
	962 1 3	Payment Det	ails	2
		allan 🖉 Purpe	ose *	
	Challan Details Challan No. *	Challan Date *	Amount (in ₹) *	
d	Bank Name *	Branch Code *	Upload Challan * Browse No file selected.	
6	Total Amount of Uploaded Cha	lans 0		

Figure 36 : Payment Details (Continue)

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

)	Online System for Medical Central Drugs Standard Control Organisati Ministry of Health & Family Welfare, Gover	on				
			Payment Details			
	Click here to view Fees Detail Mode of Payment *	s Challan	✓ Purpose *		we fgg nbgn hvfdvb	•
	Challan Details Challan No. * mjh654	~	Challan Date * 12/06/2017	ii /	Amount (in₹)* 42342]
	Bank Name * sbi	~	Branch Code * sbi124fcef	•	Upload Challan * Browse gigw-manual.pdf	Ĵ.
	Total Amount of Uploaded	Challans 42342	▲ Submit			2

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.



		Appl	lication for G	rant of Licence to Manufactu	sub-rule (2) <i>ure for Sale a</i>		ion of Class A	or Class B M	edical Device	
1	1 Name of Applicant: Asdasd									
	2.Nature and constitution of manufacturer Government									
1	3.(i).Corpo	orate/register	ed office addres	ss : Dfgdfg ,Darrang Madhya Prad	esh <mark>,415451</mark> , p	riyankasaxena(0111@gmail.con	n,3244444444, Ir	dia	
	(ii).Manufacturing site address : FURFURI NAGAR ,Unnao Uttar Pradesh ,111989 , null,98109201289, India									
	iii).Addre	ess for corresp	pondence: aaaa	aaaaaaaaaaaaa ,Shimla Himacha	l Pradesh ,757	887 , null,12222	22390, India			
	4.details o	of medical de	vice(s) to be ma	nufactured:						
	S.No.	Generic Name ≎	Brand Name 🗢	Notified Category 🗢	Device Class \$	Shelf Life \$	Sterlization	Contains Drug 🗢	Equivalence to predicate device 🗢	
	1	🕂 desfv	fvc	In vitro Diagnostic Devices for HbsAg	Class A	gbdseveg	Sterilized	No	Yes	
	5.Whether			a predicate device is claimed or r eceipt/challan/transaction id 34r		erred in the abo	ve table.			
		nclosed the d	ocuments as sp	ecified in the fourth Schedule of	Medical Devic	ce Rules,2017.				
	7.I have ei 8. I hereby	y state and un	ndertake that:	pecified in the fourth Schedule of eady for audit or shall be read			in accordance	e with the requ	irements of Medical Device	
	7.I have en 8. I hereby 1. The Rul	y state and un e manufactu les,2017.	ndertake that: uring site is re		dy for audit o	n 20-11-2017 i				
	7.I have en 8. I hereby 1. The Rul	y state and un e manufactu les,2017.	ndertake that: uring site is re	eady for audit or shall be read	dy for audit o	n 20-11-2017 i				

Figure 38 : Preview of Form MD- 3

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

	Central D	rugs Standard Co	DT Medical Devices ontrol Organisation ly Welfare, Government of India					
*			Upload Form	Browse gigw-manual.pdf]			
								0
d	29	2	A.		d	29	14	X

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**.



Centra	ne System for Medical Device I Drugs Standard Control Organisation ry of Health & Family Welfare, Government of		Withdraw Application			
	Show 10 v entries		Search:			
	File No 1	Form Name	Address	It Status It	Action	
	IMP/MD/2017/906	Form MD-14	Dfgdfg Hjkghijk (India) - 415451	In Process		
	MFG/MD/2017/857	Form MD-3	Dfgdfg Hjkghjk (India) - 415451	Withdraw Applica	ation	
	IMP/MD/2017/854	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process	: 1	
	IMP/MD/2017/850	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process		
	IMP/MD/2017/819	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process	•	
	IMP/MD/2017/806	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process	•	
	Implementation (1997) (19977) (19977) (19977) (1997) (1997) (1997) (1997) (1	Form MD-3	Dfgdfg Hjkghjk (India) - 415451	In Process		

Figure 41 : Screen of after click on Submitted Application

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

Menu ≡				Wel	come Ms.KajalSharma 🖨 Home	🖸 Change I	Þassword 😃 Logout
	Central Dr	System for Medical Devices ugs Standard Control Organisation If Health & Family Welfare, Government of Inc					
-		Show 10 v entries			Search:		
		File No II	Form Name	Address	li Status li	Action	
		• IMP/MD/2017/906	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process		
		MFG/MD/2017/857	F Are	you sure?	In Process		
d		IMP/MD/2017/854	Fi You want to V	Vithdraw the application ?	In Process	# •	
4		IMP/MD/2017/850	F	Carlos I	In Process		
		IMP/MD/2017/819	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process	# •	
and the		• IMP/MD/2017/806	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process		
		MFG/MD/2017/804	Form MD-3	Dfgdfg Hjkghjk (India) - 415451	In Process		

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



lical Devices anisation e, Government of India								
			Search:					
11	Form Name	Addrese	li Status II					
	Form MD-14	You have successfully withdrawn the application	In Process					
C III	Form MD-3	ОК	In Process					
		Are you sure?						
	Form MD-14	You want to Withdraw the application 2 Digiting Hysgnik (India) - 415451 OK Canvel	In Process					
	Form MD-14	Dīgdīg Hjkghjk (India) - 415451	In Process					
	Form MD-14	Dfgdfg Hjkghjk (India) - 415451	In Process					

Figure 43 : Popup Message- Successfully Withdraw the application