# **Applicant User Manual**

For

# Form MD-41

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### **1. Introduction**

Online system for Sell, stock, exhibit or offer for sale and distribution (Form MD41). The following sections details about the various steps

### **User Registration**

- ▶ How to Register a New user into the form MD-41?
- User can directly search <u>www.cdscomdonline.gov.in</u> and a Page should be visible same in *Figure 1.*
- This Registration is OTP based registration for fresh User, and Existing User no need to register for the Form MD-41.



Figure 1: Login Screen

## **Registration Page**

**Dash Board Screen**: After clicking on Login/Register a page is visible where User have to select **REGISTER HERE** shown in **Figure 2**.

Thu Nov 17 2022, 14:40		
Online System for Medical D	LOGIN	* About Us Contact Login/Begister
Directorate General Of Health Services Ministry of Health & Family Welfare, Government	USER NAME	
Note : For Medical devices which are under voluntary registratio	Vser Name PASSWORD	ber of firm.
	Password	
	59 <b>386</b>	nline System
	Enter Captcha 🗘	for
	FORGOT PASSWORD?	n of Medical Devices
	REGISTER HERE	ication Submission
	Register Here	cense/NOC
Core to the second		
	L	

After clicking a new window will open where you can select the purpose of Registration, as shown in Figure 3.

	<b>Online System for</b> I	Medical Devices	*
Но	me / Registration Purpos	se	
	Registration Purpose		
	Registration Purpose:*	For Registration of whole sale licenses for medical device	
		🖺 Submit 🛛 🛪 Cancel	
		Submit	
			_

After clicking on submit Button A registration Page will be opened where User have to fill a Valid email Id and document that is required on specific field and document should be in PDF format, and User can create there on password. After compliance the process a OTP will be sent on email id and after entering the OTP registration will be successful. Then User may proceed through login while filling user id and password. Then a user Dashboard will be visible which shown in Figure 4.



#### > Dashboard

## **Adding Competent Person details**

➤ After successful login, the system will be re-directed to the user dashboard where user can click the "Menu-→Add Competent Person details →Add person details as shown in Figure 5.



> After clicking the Add Person Details User have to add person name qualification experience and valid Aadhar no.

## Add Address

➢ For new user applicant can add their address by clicking on Menu→Add Address→Add Indian Addresses the added address is will be we used further while filling the application as shown Figure 6.



## Filling form of MD41

After adding the competent person details and address now user have to start the filling form of MD41 while clicking on submit Application tile shown on **figure 7**.

Menu =	Welcome Mr.AkashSingh(Wholesale Lincense Registration) 🗰 Home 🤁 Change Password 😃 Logout
Online System for Medical Devices	
🖵 Dashboard	¢ 🍰
Submit Application Saved(Draft) Applications	<b>(3)</b>
Submit Application	
Submitted Application Approved Ap	plications
Query Raised/ Responded	

After clicking on submit user will be directed to next page where user have to select select License Type (Sell, stock, exhibit or offer for sale and distribution) and Form MD-41 as shown in Figure 8.

Menu =	Welcome Mr.AkashSingh(Wholesale Lincense Registration)	🖀 Home 🤁 Change Password 🖒 Logo	ut
Online System for Medical Devices			
Home / Submit Application / Online Forms Submit	ssion		
Select License Type:	Sell, Stock, Exhibit or Offer For Sale or Distri	~	
Select Form:	Form MD-41	~	
I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.			
	😫 Submit		

- After clicking on submit user have to Redirect to next page Where he have to select the type of Application (Fresh) and firm address details shown in **figure 9**.
- > Here firm details you have to select in figure 6.

	Sell, Stock, Exhibit or Offer For Sale or Distribute	e
* All fields are mandatory		
1. Applic	ant Detail 2. Competent Person Detail	
Type of Application		
Type of Application: *	Fresh 🖌	
Applicant details(These Details Are	Fetched From The User Profile)	
<ol> <li>Name of Applicant/Firm: Sfslskljs</li> <li>Nature and constituton of Authorise</li> </ol>	d agent: Government	
Corporate/ registered office address	÷	
Cdsco, East Delhi, , Delhi-566363, India <u>P</u> : 9668443353 <u>F</u> : 8953635874 <u>Email</u> : sdfsdjsdfhj@gmail.com		
Address of Premises to be Registere	d	
Select Applicant/Firm Details:	Medical Devices ,Room NO 1, 6th Floor,Hamilton Building, B-wing Address in this section are fetched from sites added under menu	
		Activate Windows

## **Adding competition Person Details**

- In Next user to select the Competition person details which he have filled the previously shown in **figure 5**.
- ➢ Figure 10.

Menu ≡ Online System for Medical	Welcome Mr.AkashSingh(Wholesale Lincense Registration) <b>#</b> Home <b>2</b> Change Pas Devices	ssword 🖒 Logout
Home / Dashboard / Online Forms Sub	mission / MD Form 41	
	Competent Person Detail Importer site(s)	
Competent Person Details		
Select Competent Person Detail(s):	XYZ - Graduation - 2 years         Kindly add competent person details in User Menu >> Add Person Details(MD-41)	
← Previous	🖺 Save	

After clicking on save User will redirect to next page where User have to option to edit Form and proceed to checklist as show in Figure 11.

MD-41			
APPLICATION F	OR GRANT OF REGISTRATION CER INCL	Form MD-41 [See sub-rule (2) of rule 87A] TIFICATE TO SELL, STOCK, EXHIBIT OR OFFER F UDING IN VITRO DIAGNOSTIC MEDICAL DEVICE	OR SALE OR DISTRIBUTE A MEDICAL DEVICE
1.Name of Applica	ant: Medical Devices		
2.Address of the p	premises to be registered: Room NO 1, 6th	Floor,Hamilton Building, B-wing, ,Mumbai City Maharasl	ntra ,400607, India
3.Contact details	of applicant : 02261322601		
4.Nature and cons	4.Nature and constitution of applicant: Government		
5.Name, qualificat	tion and experience of competent person	appointed:	
Person Name	e	Qualification	Experience
XYZ		Graduation	2 years
XYZ Showing 1 to 1 of 1	1 entries	Graduation	2 years
XYZ Showing 1 to 1 of 1 6.Fee paid on rece	l entries eipt/challan/transaction id .	Graduation	2 years
XYZ Showing 1 to 1 of 1 6.Fee paid on rece 7.I have enclosed	l entries eipt/challan/transaction id . the documents as specified in the sub-ru	Graduation ule (3) of rule 87A of the Medical Devices Rules, 2017.	2 years
XYZ Showing I to 1 of 1 6.Fee paid on rece 7.I have enclosed <b>Place</b> :	l entries eipt/challan/transaction id . the documents as specified in the sub-ru	Graduation ale (3) of rule 87A of the Medical Devices Rules, 2017.	2 years
XYZ Showing 1 to 1 of 1 6.Fee paid on reco 7.I have enclosed Place: Date:	l entries eipt/challan/transaction id . the documents as specified in the sub-ru 	Graduation ale (3) of rule 87A of the Medical Devices Rules, 2017.	2 years

## Checklist

After proceeding to the checklist User we will be directed to checklist page where he have fill the checklist all the checklist should be mandatory as shown in **figure 12**.

Menu ≡	Welcome Mr.AkashSingh(Wholesale Lincense Registration) 🏾 Home 🤤 Chang	ge Password 😃 Logout			
Home / 1	Home / Dashboard / Online Forms Submission / Applicant Checklist				
Show 25 v entries Search:					
S.No 🏨	CheckList Item 4	Document Upload Status			
1	* Details of the applicant or firm including its constitution, along with identification proof, such as, Aadhar card or PAN card	×			
2	* Documentary evidence in respect of ownership or occupancy on rental of the premises *				
3	* Educational Qualification Details of competent technical staff				
4	* Experience Details of competent technical staff X				
5	* Brief description on other activities carried out by applicant, namely, storage of drugs, medical items, food products, stationeries, etc., or any other activities carried out by the applicant in the said premises	×			
6	* Self-certificate of compliance with respect to Good Distribution Compliance				
7	* An undertaking to the effect that the storage requirements to sell, stock, exhibit or offer for sale or distribute a medical device will be complied with	×			
1 to 7		Previous 1 Next			
	▲ Submit				

#### Payment

- After submitting the checklist challan Page should be reflected to Payment page .Where you have to enter your challan details and PDF of your challan which you have to submitted Your Concern state FDA, shown on Figure 13.
- $\triangleright$
- Payment should be done in state FDA and User have to submit challan details in the portal shown in figure 13.

	Payment Details	
Click here to view Fees Details(Fees as per seco	nd schedule of MDR 2017)	
Mode of Payment * Challan	✓ Purpose *	Registered for sale of Medical Devices
Challan Details		
Challan No. *	Challan Date *	Currency* Amount*
563324	✓ 11/07/2022	■ INR → 3000 →
Bank Name *	Branch Code *	Upload Challan *
ICICI BANK	✔ 0075	✓ Choose file Form.pdf
Total Amount of Uploaded Challans 3	000	

# **Final Print of form MD41**

After clicking on submit button Form MD41 Page should be reflected where you have to download your legal form and signed the legal form manually at your End shown in Figure 14.

orm MD-41			
APPLICATION FO.	Form MD-41 [See sub-rule (2) of rule 87A] APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE		
1.Name of Applican	nt: Medical Devices		
2.Address of the pr	emises to be registered: Room NO 1, 6th	Floor,Hamilton Building, B-wing, ,Mumbai City Maharas	htra ,400607, India
3.Contact details of	f applicant : 02261322601		
4.Nature and const	itution of applicant: Government		
5.Name, qualificatio	on and experience of competent persor	appointed:	
Person Name		Qualification	Experience
XYZ		Graduation	2 years
Showing 1 to 1 of 1 e	entries		
6.Fee paid on <b>07/N</b>	ov/2022 INR 3000 receipt/challan/trans	action id 563324.	
7.I have enclosed th	7.1 have enclosed the documents as specified in the sub-rule (3) of rule 87A of the Medical Devices Rules, 2017.		
Place:			
Date:	11-Nov-2022	1	Name, designation & signature of Director/Proprietor/Partner
	[	▲ Download PDF	-

## Uploading of signed legal form MD-41.

After clicking on next you have to upload your signed legal form which you have downloaded and signed in previous step shown in Figure 14 and uploading of form in figure 15.

Online System for Medical Devices		
Home / Dashboard / Online Forms Submission ,	/ Upload Final Form	
Legal Form	Choose file Form_MD_76.pdf ✓	
	C Submit	

- After clicking on submit Button your Application will be submitted and file no will be generated shown in **figure 15**.
- > After the generation of file no then application is successful done and submitted.
- > The submitted application will be shown in submitted application tab.

🏽 🛞 MD-Medical Devices 🛛 🗙 🎯 Email: Search results 🛛 🗙 🛛 🚼 Medical device - Google Sh. 🗙 🛛 M Fwd: FW: MEDICAL DEVICE: 🗙 🛛 🏵 MD - Medical Devices	× +	~ - 0	×
← → C ▲ Not secure   https://220.156.188.151/NewMedDev/FinalSubmission	i€ ☆	* 🗆 🎨	
Menu ≡ Welcome Mr.AkashSingh(Wholesale Lincense Registration) ♣ Home 🏾	Change Passwor	d 😃 Logout	
Online System for Medical Devices			
Your Application has been submitted successfully. Kindly note your file no. <i>MH/MUM/MD41/2022/76</i> for future correspondence.			
Activ ৰগিউক Designed, Developed and Maintained by CDAC	vate Windows PC settings to activa	te Windows.	l
	- <b>···</b>	1:13 1	PM 2022