

Ministry of Health

Registration of Medical Device Manufacturer User Manual

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1. Registration

You can create or a register a new account to use in the system using two different types: Individual and Company. You start from the Login page as shown below:

	R	
	Login with Mobile PKI	
To use this k	ogin method, you need a PKI enable	ed SIM car
	Learn More	
	Enter Mobile Number	
6	Login	

Click your mobile number and click **Login**, when the system recognizes that it is not registered in the system, it will navigate you to the following page:

	Select Account Type	
	Individual The user should have a valid civil ID, email and phone number	>
(a)	Company The company must have a valid CR registered in MOCI system and the user must be registered as a signatory/authorized for the selected CR	>

You can select an account type by simply clicking on any of them.



1.1 Register an Individual Account

To register an individual account, follow the steps below:

1. Click on	Individual The user sl phone nur	nould have a valid civil ID, email and nber	, and follow	ing page appears	:
Individual Regis	stration				
ID Card Number	89177579	ID Expiry Date *	dd-mm-yyyy	m	
					Verify Q

- 2. Enter your resident card number and expiry date.
- 3. Click verify Q, and the system will retrieve your information automatically as shown below:

D Card Number		ID Expiry Date *		en l	
	, <mark>Anne S</mark> é	ib capity butc	55		Verify O
					Verity Q
Personal Inform	ation				
full Name (En)		Date of Birth	03-01-1986	Ê	
Full Name (Ar)		Gender	Male	~	
Nationality	JORDANIAN	Age	37		
Governorate	Muscat 🗸	Willayat	Select Willayat	~	
/illage	Select Village 🗸 🗸				
Nobile *	Send OTP Mobile Number		OTP *		
Communication	Preferences]		
anguage *	h Oc				
vietriod	SMS Email				
			1		

- 4. Enter the location which consists of Governorate, Wilaya, and village.
- 5. Enter email address and mobile number, then click send orp for both platforms, and then enter the OTP which you have received on both platforms.



- 6. Select the communication language if it's in Arabic or English.
- 7. Select the communication method if it's by SMS or Email or both.
- 8. Click save , and a message appears indicating that the account has been successfully registered.

1.2 Register a Company Account

To register a company account, follow the steps below:

. Click or	P	Company The company must have a valid CR registered in MOCI system and the user must be registered as a signatory/authorized for the selected CR	, and the following page appears:	
Compan Corp CR NU	y Registr	ation ercial Register		Verify Q

2. Enter the CR number and then click the verify d button, and the system will retrieve your company's information as shown below:

Corporate Commerc	ial Register				
CR Number *	119				Verify Q
Corporate Information	on				
Company Name (En)			Company Name (Ar)		
CR Status	Valid		CR Expiry Date	04/23/2024	m
Person Identity					
ID Card Number		ID Expiry Date *	06-03-2027	**	
					Verify Q

3. Then you need to enter the person's information by entering the resident card number and expiry date, then click verify q and the system will retrieve the person's information automatically as shown below:



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		ID Expiry Date *		A4	
D Card Number	_	ID EXPISY Date			Verify
Personal Informa	ation				
Full Name (En)		Date of Birth	03-01-1986		
Full Name (Ar)		Gender	Male	~	
Nationality	JORDANIAN V	Age	37		
Governorate	Muscat 🗸	Willayat	Select Willayat	~	
Village	Select Village 🗸 🗸				
Mobile *	Send OTP		OTP *		
Mobile *	Mobile Number		OTP *		
	Send off				
Communication	Preferences				
Communication	Preferences Englis Arabi O h C				
Communication Language * Method	Preferences Englis Arabi h C Sws				
Communication Language * Method	Preferences Preferences C Englis Arabl C SMS Email				

- 4. Enter the location which consists of Governorate, Wilaya, and village.
- 5. Enter email address and mobile number, then click Send OTP for both platforms, and then enter the OTP which you have received on both platforms.
- 6. Select the communication language if it's in Arabic or English.
- 7. Select the communication method if it's by SMS or Email or both.
- 8. Click save , and a message appears indicating that the account has been successfully registered.



2. Login

You can login to the system with your account using two different methods: Mobile PKI and Card PKI. The **Login** page appears as shown below:

Card PKI
To use this login method, you need a PKI enabled national ID and card reader.
Learn More
Login

- For Mobile PKI, you enter your mobile number then you click common on the left side, and it you enter your password on your phone.
- For Card PKI, you click Login on the right side, then you use the ID card reader to read your card, and then you enter your password on the computer screen.

3. Registration of Medical Device Manufacturer Service

Through this page you register a new medical device manufacturer. The process is as follows:



The **Registration of Medical Device Manufacturer Service** page appears as shown below:

Registration Of	Medical Device M	lanufacturer			
		Fill e-Form		Receive Confirmation	n
Establishment Info	Establishment I	nformation			
Manufacturer	- Applicant Detail	s			
Info Info	Name (En)	Establishment Owner	Name (Ar)	Name	
Attachments	Civil ID	EstablishmentOwner	Mobile Number	Mobile Number	
Preview	Role	Owner			
	- Select Establish	nent			
	Establishment	Select Establishment	~		
					Verify Q
	- Establishment D	etails			
	CR Number	CR Number	CR Status	CR Status	
	Phone Number	Phone Number	Email	Email	
	P.O Box	P.O Box	Activities	Activities	
			Next >		

To apply for the service, follow the steps below:

- 1. Select the establishment from the dropdown list, and the details appear automatically.
- 2. Click verify e button, and you get a notification in green on top of the page if the establishment is valid and you can continue with the process. The notification appears as shown below:



3. Click and the following page appears:



Manufacturer Reg	stration				
Is Manufacturer Registe SFDA?	red in * Yes 🗿 No				
Manufacturer Deta	əil				
Manufacturer Legal Name	* Select Manufacturer	~	QMS Certificate Name *	QMS Certificate Name	
QMS Certificate ExpiryDate	* dd-mm-yyyy	**	Is Manufacturer SubSite/SubContractor Available	* Yes 🗿 No	
City * Postal Code * P.O.Box * Street *			Select Country City * Postal Code * P.O.Box *	Select	
Tel No. *	•		Street *		
Fax Nu.	•		Tel No. *	+	
Email *			Fax No. *	+	
			Email *		
		1			

4. Select whether the manufacturer is registered in SFDA. If yes, the following field appears:

MADMA No *	
	Verify Q

Enter MADMA number and click verify Q button.

- 5. Enter manufacturer details which consist of legal name, QMS certificate name, QMS certificate Expiry Date.
- 6. Select whether the manufacturer subsite/subcontractor is available or not. If yes, the following fields appear:



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ubcontractor/Subsite 🗼 Iame	Select Manufacturer	~			
Nanufacturer Type	Manufacturer Type	~		ManufacturerDetails	
			Manufacturer Details *		

- 7. Select subsite/subcontractor name from the dropdown list, if you select "other", enter the name manually.
- 8. Select manufacturer type and enter the details.
- 9. Enter postal address details which consist of country, city, postal code, PO Box, street, phone number, fax number, and email.
- 10. Enter physical address details, if it's the same as postal address details, click the checkbox and the fields are automatically filled.

Establishment Info	Attachments			
Manufacturer Info	Legal Manufacturer Details			
Attachments	Requried Attachment	Description	File Name	Action
Preview	Commerce Agency Certificate *	Allowed FileTypes (jpg,pdf,png) & size must not • exceed 2 MB		🔔 Upload file
	Manufacturer Layout *	Allowed FileTypes (jpg,pdf,png) & size must not • exceed 2 MB		🔔 Upload file
	Manufacturing/ Production * Process	Allowed FileTypes (jpg,pdf,png) & size must not • exceed 2 MB		🔔 Upload file
	QMS Certificate Evidence *	Allowed FileTypes (jpg,pdf,png) & size must not • exceed 2 MB		1 Upload file
	Recent Audit Report *	Allowed FileTypes (jpg,pdf,png) & size must not • exceed 2 MB		🔔 Upload file

- 12. Upload the required attachment using the button. Once done, it will activate the button.
- 13. Click and the following page appears:



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Manufacturer					
Info	Name (En)	Establishment Owner	Name (Ar)	Name	
Attachments	Civil ID	EstablishmentOwner	Mobile Number	Mobile Number	
Prevlew	Role	Owner			
	Establishment Det	ails			Ø
	Establishment Name	Al Madina Development and Supply	CR Number	1197509	
	CR Status	Active	Phone Number	94898410	
	Email	Email	P.O Box	P.O Box	
	Activities	WHOLESALE			
Postal Address	8		- Physical Address		
Select Country	Oman	~	Select Country	Oman	~
City	Muscat		City	Muscat	
Postal Code	11212		Postal Code	11212	
P.O.Box	63625		P.O.Box	63625	
Street	street		Street street	street	
Tel No.	+ 0 970	02288	Tel No.	+ 0 97002288	
Fax No.	+ 0 970	02287	Fax No.	+ 0 97002287	
Email	thamer@almadin	agroup.net	Email	thamer@almadinagroup.net	
tachments					C
claration					
I hereby declar incorrect infor	re that all the informatio mation that may lead to	n provided in the application form is the rejection of the application and	true and correct. I also the Directorate of Priva	o understand that if I provided any r ate Health Establishments will take I	nisleading on the necessa

14. Review all the details. Once done, add a tick to the checkbox to declare that the entered information is true and correct.

15. click submit >, and the following message appears:



Confirmation	×
Are you sure you want to proceed?	
Confirm Cancel	

1

16. Click **Confirm** button, and the following page appears:

m		Receive Confirmation
Application Information	1	
Application Number: Application Submitted At:	RMDM0308272496217C 17-03-2024 09:13:56	
~	B My Applications	

Your request is sent to DGPA for approval.

You can view your applications using the My Applications button.