

Ministry of Health

Medical Device Variation Request User Manual

16/05/2024



Table of Contents

1.	Reg	zistration	2
	-	Register an Individual Account	
		Register a Company Account	
2.	Log	;in	6
3.	Me	dical Device Variation Request	7



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:

	E8	
	Login with Mobile PKI	
To use this k	ogin method, you need a PKI enable	d SIM card
	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 shi phone num	ould have a valid civil ID, email and ber	, and follow	ing page appears:	:
Individual Regi					
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 *		#	
					Verify Q
Personal Informa	ation				
Full Name (En)		Date of Birth	03-01-1986	m	
Full Name (Ar)		Gender	Male	~	
Nationality	JORDANIAN	✓ Age	37		
Governorate	Muscat	V Willayat	Select Willayat	~	
Village	Select VIIIage	~			
Nobile *	Send OTP Mobile Number		OTP *		
Communication Language * Method	Preferences Englis Arabi h C SMS				
	Email				

- 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:

1.	Click on	Ð	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:	
	CR Numb	ate Commer ber *	rcial 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 Commer	cial Register				
CR Number *	119				Verify Q
Corporate Informat	ion				
Company Name (En)			Company Name (Ar)		
CR Status	Valid		CR Expiry Date	04/23/2024	m
ID Card Number	9	ID Expiry Date *	06-03-2027	<u> </u>	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:



ID Card Number ID Expiry Date * Personal Information Full Name (En) Full Name (A) ID Expiry Date of Birth Odder of Birth ID Expiry Date of Birth </th <th></th> <th></th> <th></th> <th></th> <th>Person Identity</th>					Person Identity
Full Name (En) Date of Birth 03-01-1986 Full Name (Ar) Gender Male Nationality JORDANIAN Age 37 Governorate Muscat Willayat Select Willayat Village Select Village Village Contact Details E-mail address E-mail address E-mail address E-mail address E-mail address OTP Mobile Number Send OTP Mobile Number Send OTP Communication Preferences Language * Communication Preferences Communication Preferences Communication Preferences Communication Preferences Communication Preferences Communication PreferenceS Communication PreferenceS Communication PreferenceS Communication PreferenceS Communication PreferenceS Communication PreferenceS Communication PreferenceS Communication Prefer	ID Expiry Date *	ID E		_	ID Card Number
Full Name (Ar) Gender: Male Nationality JORDANIAN Age Governorate Muscat Willayat Select Village Willayat Contact Details E-mail address E-mail addres E				nation	Personal Inform
Nationality JORDANIAN Age 37 Governorate Muscat Willayat Select Willayat Village Select Village Vi	Date of Birth 03-01-19	Date			Full Name (En)
Governorate Muscat Willayat Select Village Contact Details E-mail address E-mail address OTP Send OTP Mobile Number OTP * Send OTP Mobile Number Send OTP Communication Preferences Language * Englis Arabi Communication 	Gender Male	Gen			Full Name (Ar)
Village Select VIllage Contact Details E-mail address OTP Send OTP Mobile Number OTP * Communication Preferences Language * Englis Arabi Communication Send OTP Communication Preferences Language * Communication Send OTP Send OTP Send OTP Communication Send OTP Sen	✓ Age 37	∨ Age	I.	JORDANIAN	Nationality
Contact Details E-mail address OTP ■ Send OTP Mobile * Mobile Number OTP *	✓ Willayat Select W	 ✓ Willa 		Muscat	Governorate
E-mail address OTP Send OTP Mobile * Mobile Number OTP * Send OTP Communication Preferences Language * O Englis Arabi O Method S SMS	~	~	ge	Select Village	Village
Communication Preferences anguage * O h Arabi Atthod V sws			end OTP pile Number	Send Mobile	
L Email			glis O Arab c s	 Englis h SMS 	Language *
			nail	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:

(R)	
Login with Mobile PKI	Card PKI
To use this login method, you need a PKI enabled SIM card	To use this login method, you need a PKI enabled national ID and card reader.
Learn More Enter Mobile Number	Learn More
Login	Login
	Login

- For Mobile PKI, you enter your mobile number then you click 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. Medical Device Variation Request

Through this page you request for medical device variation. The process is as follows:



The Medical Device Variation Request page appears as shown below:

Medical Device Va	riation Request			(v)	
		Fill e-Form		Receive Confirmation	
Establishment Info	Establishment Info	rmation			
Device Info	- Applicant Details -				
-	Name (En)	Establishment Owner User	Name (Ar)	gov	
Attachments	Civil ID	test_EstablishmentOwner	Mobile Number	Mobile Number	
Preview	Role	Owner			
	- Select Establishmen Establishment *	Select Establishment	<u>~</u>]		Verify Q
	- Establishment Detai	lls			
	CR Number	CR Number	CR Status	CR Status	
	Phone Number	Phone Number	Email	Email	
	P.O Box	P.O Box			
	·		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:



Establishment Info						
Device Info	Registration No. With MOH	Registration Number				
Attachments						Verify
Preview	Registration Status	Registration Status		Medical Device Name	Device Name	
	DeviceType	Device Type		Risk Classification	Risk Classification	
	Device Grouping	Device Grouping		Device Category	Device Category	
	Regulatory Jurisdiction	Regulatory Jurisdiction				
	Variation Details					
	Variation Type	select Variation Section	×			
	ID Field I	Name	Cuurent Value	New	Values	Action
	-					

- 4. Enter Registration number with MOH.
- 5. Click verify Q button, and the device details appear automatically as shown below:

Registration No. With MOH					Verify
Registration Status	Registered		Medical Device Name	14	verny
DeviceType	MD		Risk Classification	Class C	
	System		Device Category	In Vitro Diagnostics	
Device Grouping	and the second				
Device Grouping Regulatory Jurisdiction riation Details	Japan				
Regulatory Jurisdiction	Japan				
Regulatory Jurisdiction		M			

- 6. Select variation type from the dropdown list.
- 7. Click and the following page appears:



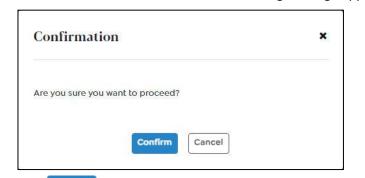
Establishment Info	Attachments 🛈				
Device Info	Attachments				
Attachments	Section 7: Product verification	⊊ validation			
Preview	Requried Attachment	Description	File Name	Action	
	Evidence Of Confirmity	Allowed FileTypes (pdf,jpg,png) & size must not exceed 2 MB		🔔 Upload file	
	\				
		Sack Next >			

- 8. Upload the required attachment using the upload file button.
- 9. Click and the following page appears:

Establishment Info	Applicant Details				
Device Info	Name (En)	Establishment Owner User	Name (Ar)	gov	
Attachments	Civil ID	test_EstablishmentOwner	Mobile Number	Mobile Number	
Preview	Role	Owner			
	Establishment Details				I
	Establishment Name	auto by variation	CR Number	1196822	
	CR Status	Active	Phone Number	54554545	
	Email	tesst@gmail.com	P.O Box	P.O Box	
	Device Info				ľ
	Medical Device Detai	ls			
	Registration No. With MC	H MD248179			
	Registration Status	Registered	Medical Device Name	14	
	DeviceType	MD	Risk Classification	Class C	
	Device Grouping	System	Device Category	In Vitro Diagnostics	
	Regulatory Jurisdiction	Japan			
Declaration					^
The second		on provided in the application form o the rejection of the application an			000-0500-0400
		K Back Contin	ue to Payment 义		

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

11. click **Continue to Payment >**, and the following message appears:



12. Click confirm button, and the following page appears:

e-Form		Receive Confirmation	
	Payment Summary		
	Applicant Name	Establishment Owner User	
	Application Reference Number	VRMD0508332432016M	
	Payment Reference Number	POVRMD60001281616052401	
	Application Fees	10.000 OMR	
	Total Fees :	10.000 OMR	
	< Back	Pay Now 🔰	

13. Click Pay Now >, you will be transferred to the payment page.

Once done, you will receive QR code as shown below:

xc100923001024 -10-2023	Pay Online	
	1	
10-2023		
10-2023		
er Reference Number	Transaction Date Time	2'4(*)
NRC0000309910092301	10-09-2023 09:42 AM	
ment Status Description	Transaction Amount	
cess - CAPTURED	30 OMR	
ck ID		
2		Show this QR at a Private Medical Center
		📥 Download QR as an Image
My Appli	cations / Nearest Medical Center	
(
6		
	ment Status Description cess - CAPTURED :k ID 2	IRC0000309910092301 10-09-2023 09:42 AM ment Status Description cress - CAPTURED 30 OMR ck ID 2 My Applications 7 Nearest Medical Center

