



# Registration of a Medical Device

User Manual



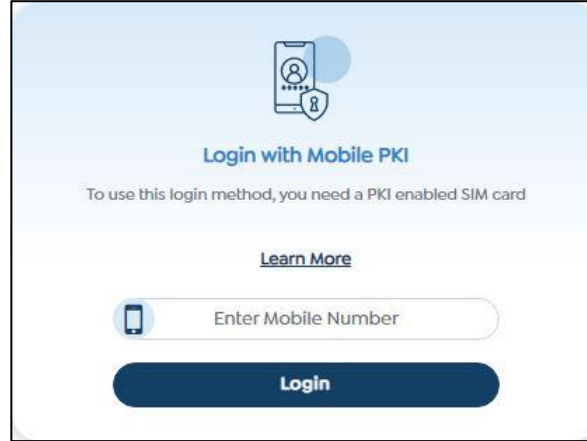
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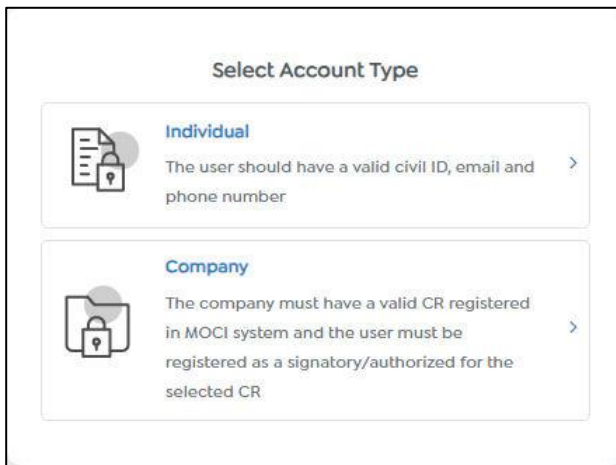


## 1. Registration

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:



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:




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 , and following page appears:

### Individual Registration

**Person Identity**

ID Card Number  ID Expiry Date \*

[Verify](#)

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

**Person Identity**

ID Card Number  ID Expiry Date \*

[Verify](#)

**Personal Information**

Full Name (En)  Date of Birth

Full Name (Ar)  Gender

Nationality  Age

Governorate  Willayat

Village

**Contact Details**

E-mail address   Send OTP

Mobile \*   Send OTP

**Communication Preferences**

Language \*  English  Arabic

Method  SMS  Email

[Save](#)

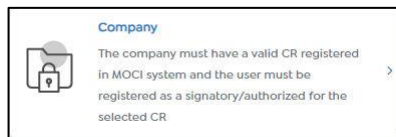
4. Enter the location which consists of Governorate, Wilaya, and village.
5. Enter email address and mobile number, then click  Send OTP for both platforms, and then enter the OTP which you have received on both platforms.




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.

## 1.2 Register a Company Account

To register a company account, follow the steps below:



1. Click on , and the following page appears:

**Company Registration**

**Corporate Commercial Register**

CR Number \*

**Verify Q**

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


**Company Registration**

**Corporate Commercial Register**

CR Number \*


**Verify Q**

**Corporate Information**

Company Name (En)	<input type="text" value=""/>	Company Name (Ar)	<input type="text" value=""/>
CR Status	Valid	CR Expiry Date	04/23/2024 

**Person Identity**

ID Card Number

ID Expiry Date \*  

**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:



**Person Identity**

ID Card Number  ID Expiry Date \*

Verify

**Personal Information**

Full Name (En)  Date of Birth

Full Name (Ar)  Gender

Nationality  Age

Governorate  Willayat

Village

**Contact Details**

E-mail address  OTP

Send OTP

Mobile \*  OTP \*

Send OTP

**Communication Preferences**

Language \*  English  Arabic

Method  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  , 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:

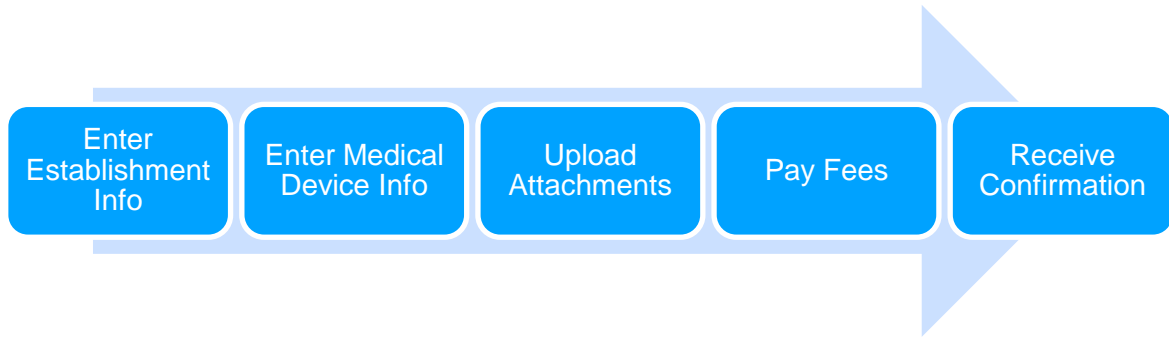
The screenshot shows two login options side-by-side. The left option is 'Login with Mobile PKI', which includes a mobile phone icon, a text box for 'Enter Mobile Number', and a 'Login' button. The right option is 'Card PKI', which includes a card reader icon and a 'Login' button. Both options have a 'Learn More' link above their respective 'Login' buttons.

- For **Mobile PKI**, you enter your mobile number then you click **Login** button on the left side, and if 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 Service

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



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

Registration of a Medical Device

Fill e-Form      Pay Online      Receive Confirmation

**Establishment Info**

Medical Device Info

Attachments

Fees

Preview

**Establishment Information**

**Applicant Details**

Name (En)	Establishment Owner User	Civil ID	test_EstablishmentOwner
Mobile Number	Mobile Number	Role	Owner
Email	rabnawaz@almadinagroup.net		

**Select Establishment**

Establishment \*

**Establishment Details**

CR Number	CR Number	CR Status	CR Status
Phone Number	Phone Number	Email	Email
P.O Box	P.O Box		

To apply for the service, follow the steps below:

1. Select the establishment from the dropdown list, and the details appear automatically.
2. Click  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
- Medical Device Info
- Attachments
- Fees
- Preview

### Medical Device Information

*This section defines the IVD device and accessories information, IVD device grouping/bundling, and regulatory jurisdiction.*

#### Section 1 : Application Type

**Search Application Type**

Is Medical Device Registered in SFDA?  Yes  No

**Application Type Details**

Medical Device Name *	<input type="text" value="Device Name"/>	Device Type *	<input type="text" value="Select"/>
Risk Classification *	<input type="text" value="Select"/>	Device Grouping	<input type="text" value="Select"/>
Device Category	<input type="text" value="Select"/>	Regulatory Jurisdiction	<input type="text" value="Select"/>

#### Section 2 : Manufacturer Information

**Search Manufacturer**

Select Manufacturer

**Manufacturer Details**

Registration Status	<input type="text" value="Name"/>	Country	<input type="text" value="Country"/>
Tel No.	<input type="text" value="Tel No."/>	Fax No.	<input type="text" value="Fax No."/>
Email	<input type="text" value="Email"/>	QMS Certificate Name	<input type="text" value="Certificate Name"/>
QMS Certificate Expiry Date	<input type="text" value="yyyy-mm-dd"/>		

4. Select whether the medical device is registered in SFDA or not by clicking “Yes” or “No”.
5. Enter application type details which consists of medical device name, device type, risk classification, device grouping, device category, and regulatory jurisdiction.
6. Select manufacturer from the dropdown list.
7. Click  and you get a notification in green on top of the page if the manufacturer is valid and you can continue with the process. The notification appears as shown below:



Then you move to section 3 as shown below:



**Section 3 : Medical Device Information**

**Medical Device Information**

Principle of Operation / Mode of Action \*

Method Of Traceability \*

Nomenclature GMDN/UMDNS/JMDN Select

Batch/Lot Reference No. Select

First year Sold Year

Manufacturer Device ID Device ID

Single Use Select

Shelf Life In Months \* Months

Model Number \* Model Number

Serial number \* Serial Number

HS Code HS Code

Intended Use \* Select

Countries Where the Device Used Select...

Storage Conditions \*

**Including Products**

**Accessories**

[Back](#) [Next](#)

- Enter medical device information which consists of principle of operation, method of tracibility, model number, serial number, etc.
- Click on “Including Products” tab to view the section as shown below:

**Including Products**

[Refer to bundling and grouping guidance for more information \(Click Here\)](#)

**Grouping and Bundling**

Select Manufacturer \* Select

Medical Device Name \* Select

Risk Classification \* Select

Device Category \* Select

Model Number \* Model Number

Device Description \*

[+ Add Including Products](#)

Manufacturer	Device Name	Risk Classification	Device Category	Model No.	Device Description	Action
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- Enter product details which consist of manufacturer, medical device name, risk classification, device category, model number, and device description.
- Click [+ Add Including Products](#) and the details are added.
- Click on “Accessories” tab to view the section as shown below:



**Accessories**

**Accessories Details**

Select Accessory \*  Risk Classification \*

Model No. \*  Serial Number

GMDN  Batch/Lot Reference No.

Description \*

[+ Add Accessory](#)

Accessories	Risk Classification	Serial Number	Description	GMDN	Model No.	Batch/Lot ReferenceNo	Action
-------------	---------------------	---------------	-------------	------	-----------	-----------------------	--------

- Enter accessory details which consist of type, risk classification, model number, serial number, GMDN, Batch/Lot Reference No., and description.
- Click [+ Add Accessory](#) and the details are added.
- Click [Next >](#) and the following page appears:

**Attachments**

Establishment Info

Medical Device Info

**Attachments**

Fees

Preview

**Section 4 : Labelling**

Requried Attachment	Description	File Name	Action
Instruction for Use	• Both side • Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
Products Label and packing	• Both side • Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>

**Section 7: Product verification & validation**

Requried Attachment	Description	File Name	Action
EC Verification	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
full Quality Assurance	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
Others	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
Product Design Examination	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
Product Quality Assurance	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>
Type Examination	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>

**Section 11: DOC**

Requried Attachment	Description	File Name	Action
Declaration Of Conformity	• Allowed FileTypes (pdf,bmp,jpg,gif,png,xls,xlsx,zip,doc,docx,dcm) & size must not exceed 2 MB		<a href="#">Upload file</a>

[Back](#) [Next >](#)

- Upload the required attachment using the [Upload file](#) button.



17. Click **Next >** and the following page appears:

Fee Details	
Fee Details	
Validity Period	60 Months
Fees to be paid	100 OMR
<a href="#">Back</a> <a href="#">Next &gt;</a>	

18. View the fee that needs to be paid, then click **Next >** and the following page appears:

Applicant Details			
Name (En)	Establishment Owner User	Name (Ar)	gov
Civil ID	test_EstablishmentOwner	Mobile Number	Mobile Number
Role	Owner	Email	rabnawaz@almadinagroup.net
Establishment Details			
Establishment Name	auto by variation	Message	Eliligable
CR Number	1196822	CR Status	1196822
Phone Number	54554545	Email	tesst@gmail.com
P.O Box	asas		
Section 1 : Application Type			
Is Medical Device Registered in SFDA ?	<input checked="" type="radio"/> Yes <input type="radio"/> No	Device Id With SFDA	0
Medical Device Name	Device 232	Device Type	IVD
Risk Classification	Class B	Device Grouping	Single
Device Category	Active implantable device	Regulatory Jurisdiction	EU

Fees	
Validity	60 Months
Service Fees	100 RO
Declaration	
<input type="checkbox"/> I hereby certify that all the information filled in this form, all submitted documents are true and accurate and changes will not be made until they are approved by MOH, Oman.	
<a href="#">Back</a> <a href="#">ContinueToPayment &gt;</a>	

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

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



### Confirmation

Are you sure you want to Confirm and Proceed for Payment?

[Confirm](#) [Cancel](#)

21. Click [Confirm](#) button, and the following page appears:

Fill e-Form Pay Online Receive Confirmation

#### Payment Summary

Applicant Name	Establishment Owner User
Application Reference Number	RMDE0507122475715K
Payment Reference Number	PORMDE60001276915052401
Application Fees	100.000 OMR
<b>Total Fees :</b>	<b>100.000 OMR</b>

[Back](#) [Pay Now](#)


22. Click [Pay Now](#) , you will be transferred to the payment page.

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

Fill e-Form Pay Online Receive Confirmation

#### Payment Transaction Info

Application Number:	NRC100923001024	
Application Expiry Date:	10-10-2023	
Payment Id	Order Reference Number	Transaction Date Time
600202325312161403	PONRC0000309910092301	10-09-2023 09:42 AM
Transaction Ref	Payment Status Description	Transaction Amount
325305024684	Success - CAPTURED	30 OMR
Card Number	Track ID	
411111*****1111	3802	



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