



Import of a Non-Registered 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](#)

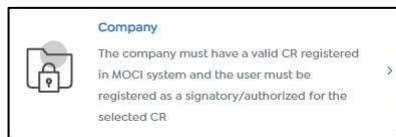
4. Enter the location which consists of Governorate, Wilaya, and village.
5. Enter email address and mobile number, then click [Send OTP](#) for both platforms, and then enter the OTP which you have received on both platforms.




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 <input type="text" value="Valid"/>	CR Expiry Date <input type="text" value="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:

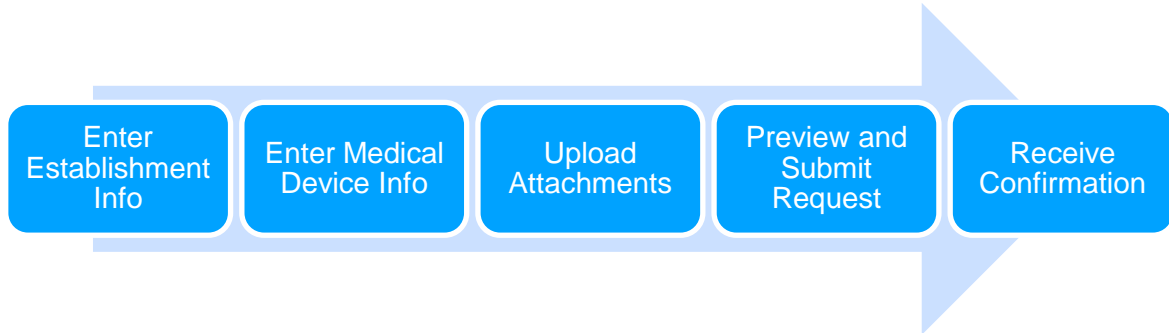
The screenshot shows two login options side-by-side. The left option is 'Login with Mobile PKI', which includes a mobile phone icon, a text box for 'Enter Mobile Number', and a 'Login' button. The right option is 'Card PKI', which includes a card reader icon and a 'Login' button. Both options have a '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. Import of a Non-Registered Medical Device Service

Through this page you apply for importing a Non-Registered Medical Device. The process is as follows:




The Import of a Non-Registered Medical Device page appears as shown below:

To apply for the service, follow the steps below:

1. Select the establishment from the dropdown list.
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. Add a tick to the checkbox if you are the local agent of the medical device.
4. Click  and the following page appears:



Establishment Info

Medical Device Info

Attachment

Preview

Manufacturer and Medical Device Information

Manufacture Details

Manufacturer Name *

Manufacturer Country *

Manufacturer Contact Number

Manufacturer Email

Manufacturer Address

Manufacturer QMS Number

LPO Details

Shipment To

Institution Name

Institution Address

LPO Number

LPO Date

Medical Device Details

Medical Device Name *

Medical Device Model *

Medical Device Category *

Medical Device Classification

Reason to Import Non Registered Medical Device

Medical Device Description

Intended Use

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5. Enter manufacturer details which consist of name, country, contact number, email, address, and QMS number.
6. Enter LPO details which consist of place of shipment, institution name, institution address, LPO number , and LPO date.
7. Enter medical device details which consist of name, mode, category, classification, reason of import, description, and intended use.
8. Click [Next](#) and the following page appears:



Establishment Info

Medical Device Info

Attachment

Preview

Attachments

Local Agent

Required Attachment	Description	File Name	Action
Local Agency Proof	<ul style="list-style-type: none"> Confirmation letter from MOCI that proves the establishment is the local agent of the device Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>

LPO

Required Attachment	Description	File Name	Action
LPO	<ul style="list-style-type: none"> Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>

QMS

Required Attachment	Description	File Name	Action
QMS Document	<ul style="list-style-type: none"> Copy of a valid QMS Certificate Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
QMS Document	<ul style="list-style-type: none"> Copy of a valid QMS Certificate Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>

Medical Device Documents

Required Attachment	Description	File Name	Action
Country of Origin Regulatory Approval	<ul style="list-style-type: none"> Country of Origin regulatory approval Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
Declaration of Conformity	<ul style="list-style-type: none"> Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
Device Labeling	<ul style="list-style-type: none"> Package Insert and label Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
Free Sale Certificate from origin country	<ul style="list-style-type: none"> Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
Picture of the Device	<ul style="list-style-type: none"> Clear picture of the device for all sides Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>
Reference Country Approval	<ul style="list-style-type: none"> Country of Origin regulatory approval Allowed FileTypes (jpg,pdf,png) & size must not exceed 5 MB 		<input type="button" value="Upload file"/>

9. Upload the required attachments using the button.

10. Click and the following page appears:

Establishment Info

Medical Device Info

Attachment

Preview

Applicant Details

Name (En)	Establishment Owner	Name (Ar)	Name
Civil ID	EstablishmentOwner	Mobile Number	Mobile Number
Role	Owner		

Establishment Details

Establishment Name	[Redacted]	CR Number	[Redacted]
CR Status	Active	Phone Number	[Redacted]
P.O. Box	+1234	Email Address	[Redacted]

Is Local Agent of the Medical Device

Manufacturer Details

Manufacturer Name	manufactur	Manufacturer Country	BANGLADESH
Manufacturer Contact Number	324242354	Manufacturer Email	e@gmail.com
Manufacturer Address	w	Manufacturer QMS Number	w



Declaration

I confirm that I will submit all the requirements from Medical Control Department within 6 months.

[← Back](#) [Submit →](#)

11. Review all the details. Once done, add a tick to the checkbox to declare that you will submit all the requirements from Medical Control Department within 6 months.
12. Click [Submit →](#) and the following message appears:

Confirmation ✕

Are you sure you want to proceed?

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

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

[Fill e-Form](#) [Receive Confirmation](#)

Application Information

Application Number:	NRMD1100902437406X
Application Issue Date:	06-11-2024 14:45:12

[My Applications](#)

You can view your applications using the [My Applications](#) button.



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