

nhra
MEDICAL DEVICES
APPLICATION



أجهزة
AJHEZA
www.ajheza.nhra.bh

Online Submission of Documents for Authorized Representative Registration

Prepared by:

Adliya Business Center staff

Step 1

Firstly, book an appointment in order to submit your application.

APPS & PAGES

- Dashboard
- Registration
- Ar Applications
- Mdr Applications
- Appointments**

Appointments

Show 10 entries

Search:

SL NO	COMPANY NAME	DATE	TIME	APPOINTMENT TO	STATUS	SERVICES	ACTION
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Step 2

You can simply book an appointment by clicking the highlighted dates and filling in the required details. Once done, click on **BOOK**.

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- Appointments

Book Appointment

Service *
Select Service

Service Type *
Select Service Type

November 2022

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	1	2	3
4	5	6	7	8	9	10

Select Date To View Available Slots

Your Details

Name
User

Email
user@adliya-bh.com

Company *
Company Name

Book ←

Step 3

After booking an appointment, go back to the dashboard and select **Authorize Representative Registration** under **NHRA**.

APPS & PAGES

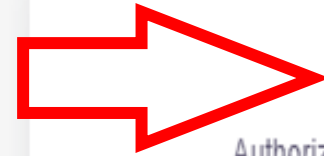
Dashboard

Registration

AR Applications

MDR Applications

Appointments



Authorized Representative Registration

(NHRA)



Authorized Representative Registration

(FAST TRACK)



Medical Device Registration

(NHRA)



Medical Device Registration

(FAST TRACK)

Step 4

Then select the type of registration you require and press **NEXT**.

APPS & PAGES

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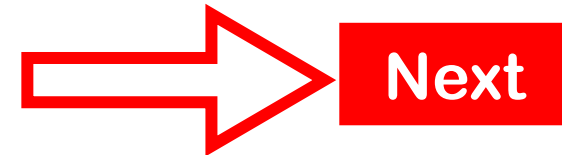
Select Type of Registration

For New Authorized Representative

Authorized Representative Registration **New**

For Existing Authorized Representative

Authorized Representative Registration **Variation / Renewal**



Step 5

After going through the AR checklist, click **NEXT**.

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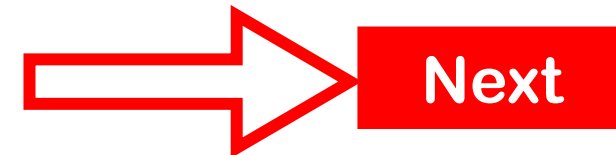
AR Application | NEW

- Check List
- AR details
- Description
- Staff requirements
- Storage
- QMS
- Scope
- Policies
- Maintenance
- Complaint

Initial Approval Requirement Medical Devices Authorized Representative Registration Check List

1. Medical Device Company Registration form. (All sections should be filled).
2. Valid Commercial Registration (CR). (For new companies, you can write the CR application number on 8(1)(1)(1)).
3. List of company's staff and:
 - A) CVs
 - B) Offer letter signed and stamped by the employee.
 - C) Qualifications, training courses certificates if any .
 - D) CPR / Passport.
4. Storage if external (CR, contact agreement, inventory record capture) , if any.
5. Quality management system (QMS) , if any.
6. List of products if the table is not enough.
7. Authorization Letters or Agreements and should be valid, signed and stamped by the manufacturers.
8. Copy of Company Policies (should be signed and stamped) including full details about:
 - A) Distribution.
 - B) Importation.
 - C) Recalls.
 - D) Services Maintenance.
 - E) Field safety notice.
 - F) Alerts & modifications.
 - G) Complaint handling.
 - H) Adverse events.
9. Copy of company forms including full details about:
 - A) Distribution.
 - B) Importation.
 - C) Recalls.
 - D) Services Maintenance.
 - E) Field safety notice.
 - F) Alerts & modifications.
 - G) Complaint handling.
 - H) Adverse events.
10. Capture of company system (Software) to monitor and trace:
 - A) Distribution.
 - B) Importation.
 - C) Recalls.
 - D) Services Maintenance.
 - E) Field safety notice.
 - F) Alerts & modifications.
 - G) Complaint handling.
 - H) Adverse events.
11. Copy of company records if any including full details about:
 - A) Distribution.
 - B) Importation.
 - C) Recalls.
 - D) Services Maintenance.
 - E) Field safety notice.
 - F) Alerts & modifications.
 - G) Complaint handling.
 - H) Adverse events.
12. Service contract, if any.

For more information about the requirements of New Companies, please refer to Section 8 In Authorized Representative Registration Guideline.



Step 6

Please fill in all the mandatory columns in the AR details and press **SAVE & CONTINUE.**

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Mdr Applications

Check List AR details Manufacturer details Medical Device Details Medical Device Supportive Docs Medical Device documents Terms & Regulations

Please note that all sections must be clearly filled along with checklist documents in order to consider reviewing your application

Details of the Authorized Representative(AR)

Company Name *

Please fill this field

AR Reference Number *

MDR Reference Number *

Authorized Representative Name *

Email *

Mobile *

AR License Number *

AR License Attachment *

 Browse

AR License Expiry *

CR Number *

CR Attachment *

 Browse

CR Expiry *

Address

Office/Flat/Shop No *

Building No *

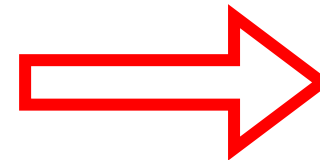
Road Address *

Block No *

Area *

Google Location

← Prev



SAVE & CONTINUE

Step 7

Please fill in a brief description about your company and click on **SAVE & CONTINUE.**

APPS & PAGES

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AR Application | NEW

Check List

AR details

Description

Staff requirements

Storage

QMS

Scope

Policies

Maintenance

Complaint

Brief Description of the Authorized Representative

Brief Description *

Example (it was Established in the Year of... Vision and Mission,Started with a Small Team... etc.)

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SAVE & CONTINUE

Step 8

Fill in all the staff details in the blanks provided and click on **SAVE & CONTINUE.**

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AR Application | NEW

Check List AR details Description Staff requirements Storage QMS Scope Policies Maintenance Complaint

Staff Requirements(CV , Qualifications/Training Certificates,Offer Letter)

CPR / Passport *

CPR / Passport

Person Name *

Person Name

Qualifications *

Qualifications

Position *

Position

CV *

Choose file (pdf/jpg)

Browse

Qualifications/Training Certificates *

Choose file (pdf/jpg)

Browse

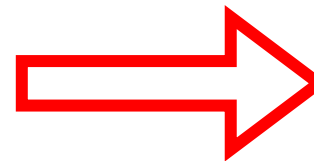
Offer Letter *

Choose file (pdf/jpg)

Browse

+

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SAVE & CONTINUE

Step 9

Please choose an option applicable on your behalf and fill in with the required details. Then click on **SAVE & CONTINUE**.

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AR Application | NEW

Check List AR details Description Staff requirements Storage QMS Scope Policies Maintenance Complaint

Storage

Select Storage Type *

Main Office

If storage is Inside the main Office.

Outside Main Office

If storage is Inside the Outside the main Office.

Out Source

If storage is Out Sourced.

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SAVE & CONTINUE

Step 10

Please QMS if available. If not continue to **SAVE & CONTINUE**.

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AR Application | NEW

Check List AR details Description Staff requirements Storage **QMS** Scope Policies Maintenance Complaint

Quality management system (QMS) **"If any"** Please mention below the type of the QMS granted to your Authorized Representative, state the certification body and its validity:

Attach Certificates

Choose file (pdf/jpg)

Browse

Certification Body

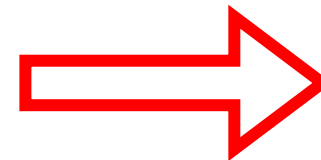
Certification Body

Valid Till

dd----yyyy



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SAVE & CONTINUE

Step 11

Please select the required scope and fill in with the scope details.
Then click on **SAVE & CONTINUE**.

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Check List AR details Description Staff requirements Storage QMS **Scope** Policies Maintenance Complaint

Scope of Service

(A) (List of products aimed to cover/List of Agencies (if more, please **attach** a list structured as below) **Not mandatory of new companies.**)

Manufacturer Name:

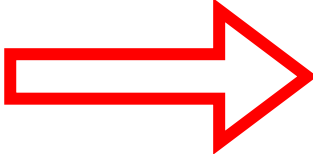
COO (Country of Origin):

Authorization letter:

Medical Device Type:

(B) List of Scopes (please select scope of service) *

<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Surgical	<input type="checkbox"/> Electro Mechanical Devices
<input type="checkbox"/> Respiratory	<input type="checkbox"/> CSSD	<input type="checkbox"/> Lab/In Vitro Diagnostic
<input type="checkbox"/> Endoscopy	<input type="checkbox"/> Ophthalmology	<input type="checkbox"/> Radio Active Material
<input type="checkbox"/> Dental	<input type="checkbox"/> Dermatology/Cosmetic	<input type="checkbox"/> General Hospital
<input type="checkbox"/> Dialysis	<input type="checkbox"/> Plastic Surgery	<input type="checkbox"/> Pediatric
<input type="checkbox"/> Urology	<input type="checkbox"/> Neurology	<input type="checkbox"/> Psychiatric
<input type="checkbox"/> Cardiovascular	<input type="checkbox"/> Orthopedic	<input type="checkbox"/> Home Use Medical Devices
<input type="checkbox"/> Andrology	<input type="checkbox"/> Obstetrics & Gynecology	<input type="checkbox"/> Other
<input type="checkbox"/> WoundTherapy	<input type="checkbox"/> Physical Medicine	
<input type="checkbox"/> ENT	<input type="checkbox"/> Radiology	



Step 12

Fill in the policies of **DISTRIBUTION**, **IMPORTATION** and **RECALL** and then click on **SAVE & CONTINUE**.

1-Attached Polloiy must be in clear, organized, readily searchable and unambiguousmanner and with company name and logo.

2-Polloiy can be in English or Arabio language.

3-For more information, please refer to "Polloies and Proeedures of Medical Devices Authorized Representative guideline" on NHRA website.

Recalls

Brief Description *

Write a Brief Description

Capture of system *

Choose file (pdf/jpg)

Browse

Form (if not on system) *

Choose file (pdf/jpg)

Browse

Policy *

Choose file (pdf/jpg)

Browse

Record of Last Month, if any

Choose file (pdf/jpg)

Browse

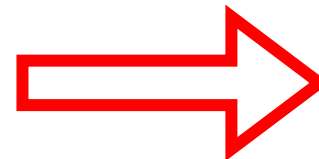
Note:

1-Attached Polloiy must be in clear, organized, readily searchable and unambiguousmanner and with company name and logo.

2-Polloiy can be in English or Arabio language.

3-For more information, please refer to "Polloies and Proeedures of Medical Devices Authorized Representative guideline" on NHRA website.

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SAVE & CONTINUE



Step 13

Fill in the policies of **SERVICE & MAINTENANCE** , **FSN** and **ALERT & MODIFICATION** and then click on **SAVE & CONTINUE**.

2-Polloy can be in English or Arabic language.

3-For more information, please refer to "Policies and Procedures of Medical Devices Authorized Representative guideline" on NHRA website.

Alert & Modifications

Brief Description *

Write a Brief Description

Capture of system *

Choose file (pdf/jpg)

Form (if not on system) *

Choose file (pdf/jpg)

Policy *

Choose file (pdf/jpg)

Record of Last Month, if any

Choose file (pdf/jpg)

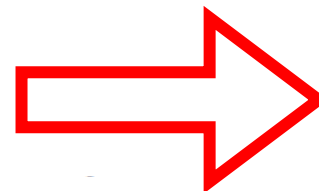
Note:

1-Attached Polloy must be in clear, organized, readily searchable and unambiguous manner and with company name and logo.

2-Polloy can be in English or Arabic language.

3-For more information, please refer to "Policies and Procedures of Medical Devices Authorized Representative guideline" on NHRA website.

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SAVE & CONTINUE

Step 14

Fill in the policies of **COMPLAINT HANDLING AND ADVERSE EVENTS**.
Once reading through the Terms & Conditions, please fill in all the mandatory fields and then click on **SAVE & CONTINUE**.

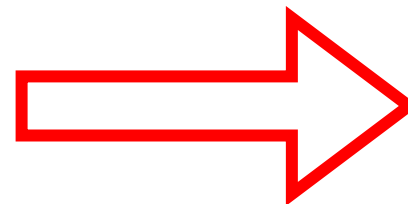
Document Type

Supportive Attachment

Description



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SAVE & CONTINUE

Please Fix Appointment Before Submission



Step 15

Once the data is saved, you can submit the application on the assigned date.

Other Additional Supportive Documents (If any)

Document Type
Other

Supportive Attachment
Choose file (pdf/jpg) Browse
32308125_24112022104927_mdr_additi...

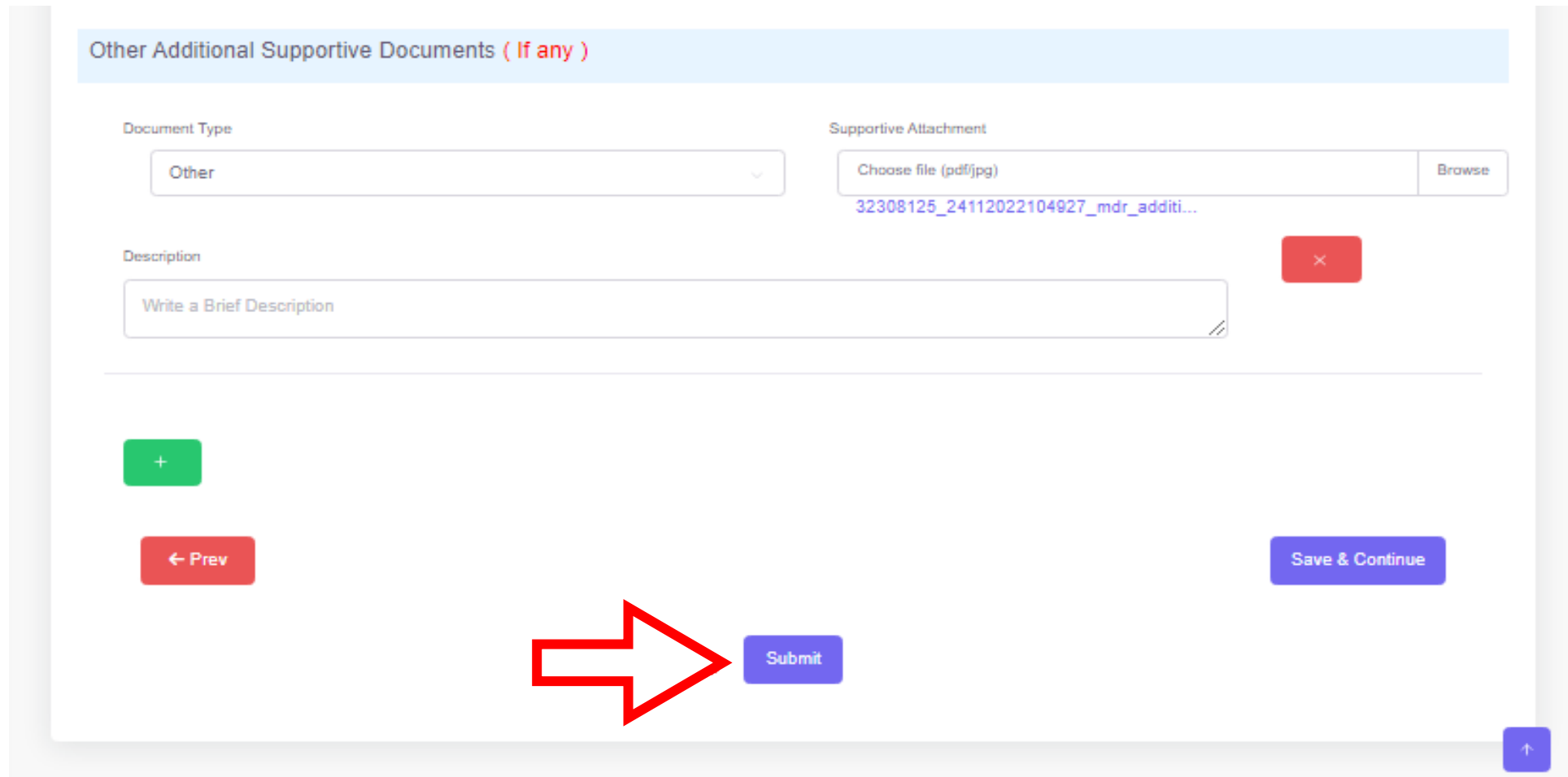
Description
Write a Brief Description

+
← Prev

Submit

Save & Continue

↑



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Thank
you!