



Online Submission of Documents for Medical Device Registration (MDR)

Prepared by:

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Step 1

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

APPS & PAGES

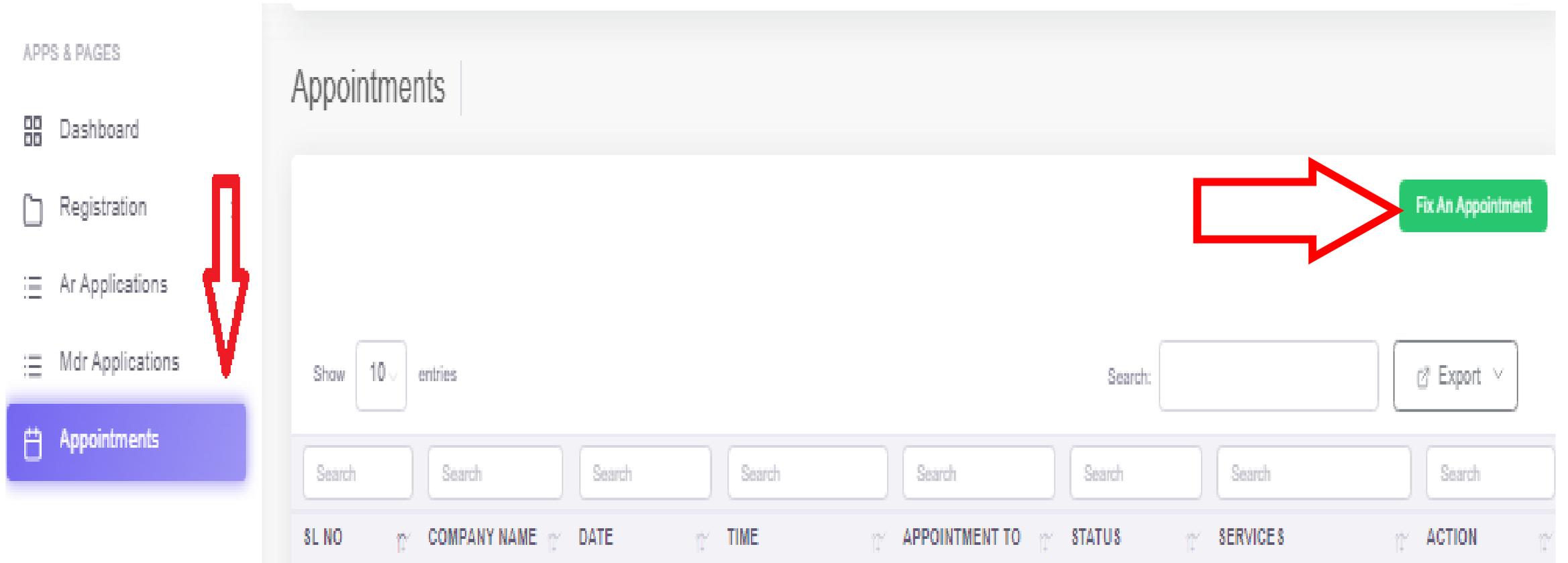
- Dashboard
- Registration
- Ar Applications
- Mdr Applications
- Appointments**

Appointments

Show 10 entries

Search:

SL NO	COMPANY NAME	DATE	TIME	APPOINTMENT TO	STATUS	SERVICE \$	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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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 **Medical Device Registration** under **NHRA**.

APPS & PAGES

Dashboard

Registration >

Ar Applications

Mdr Applications

Appointments

nhra
BAHRAIN

Authorized Representative Registration

(NHRA)

abc

Authorized Representative Registration

(FAST TRACK)

nhra
BAHRAIN

Medical Device Registration

(NHRA)

abc

Medical Device Registration

(FAST TRACK)

Step 4

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

APPS & PAGES

Dashboard

Registration

Ar Registration

Mdr Registration

Ar Applications

Mdr Applications

Appointments

Select Type of Registration

For New MDR Registration

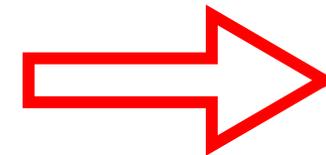
Medical Device Registration **New**

For Renewal MDR Registration

Medical Device Registration **Renewal**

For Variation MDR Registration

Medical Device Registration **Variation**



Next

Step 5

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

APPS & PAGES

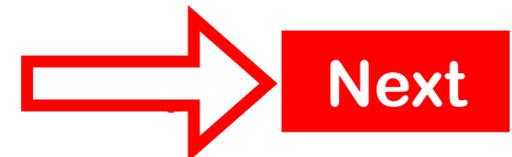
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Check List AR details Manufacturer details Medical Device Details Medical Device Supportive Docs Medical Device documents Terms & Regulations

Medical Devices Registration Check List

1. Medical Devices Registration Application Form. **(All sections should be filled)** .
2. Technical Details such as User manual, Catalogue, and Service Manual.
3. Art Work i.e. Label of the Medical Device. Should include the Name, UDI (**Unique Device Identification**) code, and legal manufacturer with address
4. Agreement or Authorization letter issued by the legal manufacturer to the Authorized Representative for the distribution of the applied Medical Device/s in the Kingdom of Bahrain
5. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors (**if applicable**) regarding the medical device(s). Full addresses must be stated.
6. Instruction for use (**IFU**) issued by the Legal Manufacturer with the address matching the artwork.
7. List of countries the medical device has been marketed in, issued by the Legal manufacturer.
8. If the device has been marketed in Bahrain for a minimum of 5 years, only Bahrain market field safety notice records for the past 5 years are required. If the device has not been marketed in Bahrain for a minimum of 5 years, worldwide and Bahrain market field safety notice records for the past 5 years are required.
9. Last Audit Report for recalled devices and adverse events (**Required only if there are recall or Adverse events record**) .
10. List of End-users in case the medical device exists in the Bahrain market.
11. Quality Management System Certificate (**QM8**) - ISO 13485 for the Physical manufacturer with the address matching requirement 5.
12. Quality Assurance Certificate (**QAC**) - CE directive 93/42/EEC or FDA Certificate to Foreign Government (**CFG**) for the Legal manufacturer with the address matching the artwork. For class 1 non-sterile or General/other IVD medical devices, a Declaration of Conformity (**DOC**) can be submitted instead.
13. For class III medical devices as well as class DIVD's, an EC Design examination certificate or an FDA Certificate to Foreign Government (**CFG**) for the legal manufacturer is required. This document needs to be submitted for class IIB medical devices if available
14. Verification evidence for required document 11,12, and 13.
15. Free Sale Certificate (**F3C**) or Certificate of foreign government issued by the regulatory authority of the country of origin or a reference country. *
16. Declaration letter or Declaration of Conformity (**DOC**) issued by the legal manufacturer including the risk classification and the GMDN code.
17. If the medical device contains animal tissues/derivatives, a letter issued by the legal manufacturer stating that the product is free from porcine derivatives is required (**Not applicable for In Vitro Diagnostic (IVD) Medical devices**).
18. In some cases, it might be requested to fulfill the classification criteria where NHRA classification letter issued from MDR department should be provided.
19. Provide a screen capture of the medical devices registration listing email sent to NHRA.

For more information about the requirements, Please refer to official website of NHRA [MDR Guidelines](#) for further clarification.



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 *	AR Reference Number *	MDR Reference Number *
<input type="text" value="Company Name"/> <small>Please fill this field</small>	<input type="text" value="AR Reference Number"/>	<input type="text" value="MD Reg Q4 2022 00203"/>
Authorized Representative Name *	Email *	Mobile *
<input type="text" value="Authorized Representative Name"/>	<input type="text" value="Authorized Representative Email"/>	<input type="text" value="Authorized Representative Mobile"/>
AR License Number *	AR License Attachment *	AR License Expiry *
<input type="text" value="AR License Number"/>	<input type="text" value="Choose file (pdf/jpg)"/> <input type="button" value="Browse"/>	<input type="text" value="dd----yyyy"/>
CR Number *	CR Attachment *	CR Expiry *
<input type="text" value="CR Number"/>	<input type="text" value="Choose file (pdf/jpg)"/> <input type="button" value="Browse"/>	<input type="text" value="dd----yyyy"/>

Address

Office/Flat/Shop No *	Building No *	Road Address *
<input type="text" value="Authorized Representative Office/Flat/Shop No"/>	<input type="text" value="Authorized Representative Building Number"/>	<input type="text" value="Authorized Representative Road Address"/>
Block No *	Area *	Google Location
<input type="text" value="Authorized Representative Block No"/>	<input type="text" value="Authorized Representative Area"/>	<input type="text" value="Address Google Location"/>

Step 7

Under manufacturer details, please fill in all the mandatory columns and then click on **SAVE & CONTINUE**.

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Mdr Applications

Check List | Alt 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

Manufacturer Details

Legal Manufacturer Name *	Legal Manufacturer Address *
<input type="text" value="Legal Manufacturer Name"/>	<input type="text" value="Legal Manufacturer Address"/>

Physical Manufacturer Name *	Physical Manufacturer Address *	<input type="button" value="+"/>
<input type="text" value="Physical Manufacturer Name"/>	<input type="text" value="Physical Manufacturer Address"/>	

Relationship Letter * ⓘ	Relationship License Expiry	<input type="button" value="+"/>
<input type="text" value="Choose file (pdf/jpg)"/> <input type="button" value="Browse"/>	<input type="text" value="dd----yyyy"/>	

Invoice issuer Name *	Invoice issuer Address *
<input type="text" value="Invoice issuer Name"/>	<input type="text" value="Invoice issuer Address"/>

Authorization Letter Issuer

Issuer *

Legal Manufacturer Other

Step 8

For Medical Device Details select the appropriate option and then fill in the product details. After filling click on **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

Details of the Medical Device

Single (Only One Device)
 Bundle

Devices

Show entries Search:

SR. NUM	DEVICE NAME	DEVICE MODEL	DEVICE TYPE	HS CODE	GMDN CODE	USE TYPE	RISK CLASSIFICATION	SHELF LIFE	MARKET ENTRY DATE
No data available in table									

Showing 0 to 0 of 0 entries < Previous Next >

← Prev

SAVE & CONTINUE

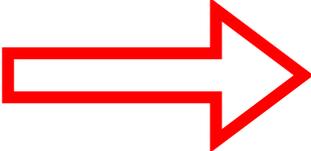
Step 9

Once product details are filled, provide in all the mandatory documents associated with the same and then **SAVE & CONTINUE**.

APPS & PAGES

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List of End-Users ⓘ	Select Related Medical Device
<input type="button" value="Choose File"/> No file chosen	<input type="text" value="Select Related Medical Devices"/> <input data-bbox="2028 412 2109 458" type="button" value="+"/>
<hr/>	
Porcine Derivates Letter ⓘ	Select Related Medical Device
<input type="button" value="Choose File"/> No file chosen	<input type="text" value="Select Related Medical Devices"/> <input data-bbox="2028 612 2109 658" type="button" value="+"/>
<hr/>	
NHRA Classification Letter ⓘ	Select Related Medical Device
<input type="button" value="Choose File"/> No file chosen	<input type="text" value="Select Related Medical Devices"/> <input data-bbox="2028 812 2109 858" type="button" value="+"/>
<hr/>	
List Of Countries Device Has Been Marketed ⓘ	Select Related Medical Device
<input type="button" value="Choose File"/> No file chosen	<input type="text" value="Select Related Medical Devices"/> <input data-bbox="2028 1041 2109 1086" type="button" value="+"/>



Step 10

Fill in all the mandatory columns and click on **SAVE & CONTINUE**.

Dashboard

Registration >

Ar Applications

Mdr Applications

Appointments

Quality Assurance Certificate (QAC)

QAC Certificate Number

QAC Certificate Number

Notified Body

Notified Body

QAC Certificate ⓘ

Choose file (pdf/jpg) Browse

Expiry Date ⓘ

dd----yyyy

Verification Evidence QAC ⓘ

Choose file (pdf/jpg/html) Browse

Confirmation

The Legal manufacturer is the holder (or one of the sub-facilities) of the quality assurance certificate (Same name and address)



EC Design Examination (For Class III and High Risk Medical Devices)

EC Design Certificate Number

EC Design Certificate Number

Notified Body

Notified Body

EC Design Examination Certificate ⓘ

Choose file (pdf/jpg) Browse

Expiry Date ⓘ

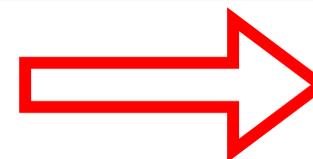
dd yyyy

Verification Evidence EC Design ⓘ

Choose file (pdf/jpg/html) Browse



← Prev



SAVE & CONTINUE

Step 11

Once reading through the Terms & Conditions, please fill in all the mandatory fields and then click on **SAVE & CONTINUE**.

APPS & PAGES

Dashboard

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Appointments

Authorized Person Name *

Please fill this field

Authorized Person Email *

Authorized Person Mobile *

Position *

Date *

Signature *

Company Stamp *

Other Additional Supportive Documents (If any)

Document Type

Supportive Attachment

Description

Please Fill Application

Step 12

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

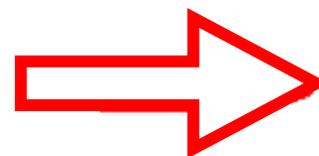
Other Additional Supportive Documents (If any)

Document Type

Supportive Attachment

32308125_24112022104927_mdr_additi...

Description



nhra



أجهزة
AJHEZA

www.nhra.gov.ae



Thank
you!