استمارة تقديم طلب تسجيل ممثل معتمد للأجهزة والمستلزمات الطبية

Medical Devices Authorized Representative Registration Form

nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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) details

Name: **Ref No :** AR-Q-

Application Type :

○ **Adding new branch** ○ New Authorized Representative ● **Existing** Authorized Representative

- **Contact Email**
- **CEO Email**
- **CEO Name**
- **Mobile No**
- **CR Copy/ Sijilat application No.** **(Attach)**
- **Address** **Flat/shop No** **building** **road** **block**

  Area

  Location on google map

Brief description of the Authorized Representative

Example (it was established in the year of…, vision and mission, started with a small team…. etc.):

- ……
- ……
- ……
- ……

*For new Authorized representative only

E-mail: medical_devices@nhra.bh Website: www.nhra.bh Tel: 17113337 /P.O.Box: 11464

Staff requirements

- CV (not less than 3 employees) **Attach**
- Qualifications/ Training Certificates, if any. **Attach**
- Offer letter. **Attach**

Storage

- **Storage type:** ☐ In the main office ☐ Outside the main office ☐ Outsource

- **In case of outside the main office / outsourced:**
  1. **CR copy** **Attach**
  2. **Contract agreement** **Attach for outsourced only**
  3. **Storage record capture** **Attach**

Quality management system (QMS)

- **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 #

Section (2) 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 Authorized Representatives.

Manufacturer Name	COO	Authorization letter (Attach if any)	Medical device Type
XY	USA	Attached	x-ray machine, ECG, Patient Monitor .....

Note: 1st Row is an example.

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

○ Anesthesia	○ Surgical	○ Electro-Mechanical devices
○ Respiratory	○ CSSD	○ Lab / In Vitro Diagnostic
○ Endoscopy	○ Ophthalmology	○ Radio Active Material
○ Dental	○ Dermatology/Cosmetic	○ General hospital
○ Dialysis	○ Plastic surgery	○ Pediatric
○ Urology	○ Neurology	○ Psychiatric
○ Cardiovascular	○ Orthopedic	○ Home use medical devices
○ Andrology	○ Obstetrics & Gynecology	Other, please specify:
○ Wound Therapy	○ Physical Medicine	_____
○ ENT	○ Radiology	_____
		_____

Section (3) Policies and Procedures

Distribution			
Process in Brief	.....		
Capture of system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**
Importation			
Process in Brief	.....		
Capture of system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**

*For new Authorized representative only

Services maintenance			
Process of Brief	…… …… …… …… …… ……		
Capture of system	**Attach**		
Form, if not on system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**
Field Safety Notice			
Process of Brief	…… …… …… …… …… ……		
Capture of system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**
Alert & modifications			
Process of Brief	…… …… …… …… …… ……		
Capture of system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**

Complaint handling			
Process of Brief	…… …… …… …… …… ……		
Capture of system	**Attach**		
Form, if not on system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**
Adverse Events Reporting			
Process of Brief	…… …… …… …… …… ……		
Capture of system	**Attach**		
Form, if not on system	**Attach**		
Policy	**Attach**	Record of last month, if any	**Attach**

Notes:

- ***Attached Policy must be in clear, organized, readily searchable and unambiguous manner and with Authorized Representative name and logo.***
- ***Policy can be in English or Arabic language.***
- ***For more information, please refer to "Policies and Procedures of Medical Devices Authorized Representative guideline" on NHRA website.***

Section (4) Terms & Conditions

1. To use license issued for Medical devices that comply with **NHRA regulations.**
2. Ensuring that all supplied Medical devices to Healthcare Facilities are **licensed by NHRA.**
3. Ensuring that the medical devices will only be supplied to an **NHRA Licensed Health Care Facility.**
4. Ensuring to comply with NHRA timeframe of completing the registration requirements **within 3 months.**
5. Ensuring all Medical devices are Registered **within 2 years**, from the Authorized Representative registration date.
6. Ensuring all Medical devices are properly shipped, stored, installed and monitored as per manufacturer standards.
7. Active medical devices that require major physical installation (Ex. MRI or CT) should be reported to NHRA to insure compliance with **NHRA regulations.**
8. Combined medical devices with pharmaceutical ingredient will be sold with prescription only.
9. Termination of license will be done once the agent has performed any action against the regulation of NHRA or it was found that the documents provided at the time of approval are incorrect.
10. Termination of agency: incase agency is canceled or amended, **NHRA should be reported for further action.**
11. Ensuring all Registered Medical devices, **Recalls** and **alerts** are reported **immediately to NHRA**.
12. Ensuring all Medical devices imported are New and not refurbished.
13. To maintain a list of imported Medical devices when needed.

Section (5)
I hereby declare that all the information I have provided is correct and all the attached documents are genuine; I will inform NHRA about any changes to this information.

Name of Authorized Person

Position

Date

Signature

Authorized Representative **Stamp**

In case of the electronic stamp and signature are not available, Please provide a declaration letter stating that all the provided information in the above or attached form are correct and authentic.

*For new Authorized representative only

Initial Approval Requirement
Medical Devices Authorized Representative
Registration Check Lists

Documents required

1. Medical Device Authorized Representative Registration form. (All sections should be filled).

2. Valid Commercial Registration (CR).
(For new Authorized Representative, you can write the CR application number on Sijillat.)

3. List of Authorized Representative's staff and:
A) CVs **B)** Offer letter signed by the employee. **C)** Qualifications, training courses certificates **if any**.

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 Authorized Representative Policies including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.
E) Distribution. **F)** Importation.

9. Copy of Authorized Representative forms including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.

10. Capture of Authorized Representative system (Software) to monitor and trace:
A) Distribution. **B)** Services Maintenance. **C)** Recalls. **D)** Adverse events. **E)** Complains.
F) Alerts & modifications. **G)** Field safety notice. **H)** Importation.

11. Copy of Authorized Representative records **if any** including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.
E) Distribution. **F)** Importation.

12. Service contract, **if any.**

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

*For new Authorized representative only