nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Medical Devices Authorized Representative Registration Form

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

Section (1) Details of the Authorized Representative						
Ref No: AR Q						
Application Type	**Adding new branch New Company**			**☐ Existing Company**		
Authorized Representative name:						
Contact Email:						
CEO Email:				**CEO name:**		
CR Copy/ Sijilat application no.*:	**(Attach)**			**Mobile no:**		
Address	**Flat/Shop No**		**Building**		**Road**	
Area			**Block**			
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.): • …… • …… • …… • …… • ……						
Staff Requirements						
CV (not less than 3 employees)	**Attach**					
Offer Letter	**Attach**	**Qualifications/ Training Certificates, if any.**		**Attach**		
Storage						
Storage type	**☐ In the main office ☐ Outside the main office ☐ Outsource**					
In case of Outside the main office / Outsourced						
CR copy	**Attach**					
Contract agreement	**Attach for outsourced only**					
Storage record capture	**Attach**					

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 #

*For new Authorized representative only

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 for new companies.***

Manufacturer Name	CoO	Authorization letter (Attach if any)	Medical Device Type
XY	USA	attached	X-ray machine, ECG, patient monitor, laser machine…

Note: 1st Row is an example.

(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/Cosmetics**	☐ **General Hospital**
☐ **Dialysis**	☐ **Plastic Surgery**	☐ **Pediatric**
☐ **Urology**	☐ **Neurology**	☐ **Psychiatric**
☐ **Cardiovascular**	☐ **Orthopedic**	☐ **Home use medical devices**
☐ **Andrology**	☐ **Obstetrics & Gynecology**	**Others, 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**

Services maintenance			
Process in Brief	----------		
Capture of system	**Attach**		
Form, if not on system	**Attach**		
Policy	**Attach**	**Record of last month, if any**	**Attach**

*For new Authorized representative only

Field Safety Notice			
Process in Brief	----------		
Capture of system	**Attach**		
Policy	**Attach**	**Record of last month, if any**	**Attach**

Alert & Modifications			
Process in Brief	----------		
Capture of system	**Attach**		
Policy	**Attach**	**Record of last month, if any**	**Attach**

Complaint Handling			
Process in Brief	----------		
Capture of system	**Attach**		
Form, if not on system	**Attach**		
Policy	**Attach**	**Record of last month, if any**	**Attach**

Adverse Events Reporting			
Process in 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 company 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 (5) 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 company 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 (6)

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		**Company Stamp**

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Initial Approval Requirement
Medical Devices Authorized Representative Registration Check List

➢ **Documents Required**
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 Sijillat.)
3. Copy of Company Policies including full details about: **a)** Services maintenance **b)** Complaint handling **c)** Adverse events **d)** Recalls **e)** Distribution **f)** Importation
4. Authorization Letters or Agreements and should be valid, signed and stamped by the manufacturers.
5. Capture of company system (Software) to monitor and trace the distribution of medical devices, maintenance, recall and adverse events.
6. List of company's staff and: **a)** CVs **b)** Offer letter signed by the employee. **c)** Qualifications, training courses certificates if any.
7. Service contract (In case of outsource storage).
8. List of clear scope of service (ex: dental, ortho, surgical, lab, ENT…).

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