Authorized Representative Registration Variation / Renewal Form

Please note that all sections must be clearly filled to consider reviewing your application

Details of the Authorized Representative (AR) details

Authorized Representative name:	
Registration certificate No.	
Contact email:	
Mobile No:	

(1) Renewal of Registration Certificate

Any changes to the previously submitted details? ☐ **Yes**, if so please fill in the variation form. ☐ **No**

Please provide updates or updated version (with a minimum validity of one year) of the following document:

- List of employees for medical devices and their qualification.
- List of manufacturers distribution authorization letter or contracts.
- Quality management system **(QMS)** for the Authorized representative, **if any**.
- Commercial Registration CR.
- List of service contracts being provided to local Healthcare Facilities licensed by NHRA with the validity period.
- updated Policies
- List of recalls and adverse events from the previous license date of issuance including each case final report.
- List of locally discarded items including all the following information - Product name, manufacturer name, Country of origin, batch number, serial number, quantity, reason, discarding evidence.
- List of returned items to the manufacturer including all the following information - Product name, manufacturer name, Country of origin, batch number, serial number, quantity, reason, return evidence.
- List of supplied medical devices to Health Care Facilities as per the Permit to Use guideline.

*For new Authorized representative only

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

VARIATION

(2) Adding New 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	Authorization letter (Attach if any)	Medical device Type
XY	USA	Attached	x-ray machine, ECG, Patient Monitor .....

Note: 1st Row is an example.

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

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

Other, please specify:

_____
_____
_____
_____

*For new Authorized representative only

(3) Storage

- **Storage type:** ☐ Same Existing Store ☐ New Store
- **If New:** ☐ Outside Main Office. ☐ Outsourced

1. **CR copy** — Attach
2. **Contract agreement** — Attach for outsourced only
3. **Storage record capture** — Attach
4. **Inspection request form** — Attach
5. **Engineering Drawing (Receiving area, Dispatch area, quarantine area ….)** — Attach

(4) Removing Scope of Service

- **Scope:**
- **Medical Devices Name:**
- **Manufacturer Name:**
- **New Supplier Name:**
- **Termination Letter:** Attach
- **List of previously supplied medical devices (end users):** Attach
- **Authorization Latter:** Attach

*For new Authorized representative only

(5) changing Address

Old Address: Area Flat No. Building Road No. Block No.

New Address: Area Flat No. Building Road No. Block No.

Old CR Copy: Attach

capture of application on Sijilat: Attach

☐ **Same storage area conditions as old site** Declaration letter

☐ **If Not** Attach Amended policies and clarification

Inspection Request Form Attach

*For new Authorized representative only

NHRA Comments for Registration Certificate Renewal

For NHRA Use Only

Violations

☐ Violations Records ☐ N/A

	Type	No.	N/A
Violation	Importation		
	Registration		
	Marketing		
	Post Market Surveillance		
	Storage		
	Transportation		

Renewal Request Status

☐ Approved ☐ Rejected

- NHRA Comments:

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_____

_____

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Medical Devices Registration

No. of submitted Applications Last Year

*For new Authorized representative only