الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Device Authorized Representative Registration Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

With reference to **Decision (48) 2020, Article (6)** "Importers, distributors, manufacturers and authorized representatives of manufacturers engaged in the supply or distribution of medical devices and products must obtain a license from the Authority."

NHRA issued this guideline to all Medical Devices Importers and suppliers in Kingdom of Bahrain to clarify the requirements and procedures of **"Registration"** Which will bring many benefits to the registered authorized representative including:

- Facilitate the importation process by reducing the time frame and requirements of obtaining the pre-approval.
- Registered Authorized representatives will be listed on NHRA website as qualified, well-known reputable authorized representative for importing and handling medical devices for marketing purposes.
- Participation in national tenders.
- Registered Authorized representatives will be able to register their medical devices to ensure the safety and quality of the imported and marketed medical devices in Kingdom of Bahrain as per international standards, and thus maintaining patient's life and public health.

2. General Rules

1. In order to apply for registration, Authorized Representative should have valid commercial record (CR) allow for medical devices importation.

2. Authorized Representative should have an **Integrated System** for monitoring, importation, marketing, transportation, storage and recalls, complaints, adverse events and alerts and modifications and tracing the distributed medical devices and link them with the end-users.

3. Authorized Representative should have a qualified staff specialized in the field of marketing and maintenance of medical devices, where the number of staff must be

adequate to run the business without affecting the safety and quality of the devices and the qualifications must be related to the scope of the imported/marketed medical devices.

4. Authorized Representative should have an adequate and proper store for the medical devices based on the needs of the stored medical devices and in case of storage is not needed, this should be stated in the policy provided at the time of submission, on the other hand in case of outsourced storage, it should fulfill medical devices regulation.

5. The Authorized Representative Registration Certificate will be valid for minimum **1 years** and must be renewed, 6 months before its expiry date.

6. The scope of the imported medical devices will be mentioned in the Authorized Representative license (ex: Dental, Ortho, ENT…), scopes can be selected from scope list in **(Annex 6)** where each scope have different requirements and this will be evaluated by NHRA team.

7. In case of adding the activity of importing medical devices into an **existing firm (same address)**, they should have an isolated area for the medical devices activity including but not limited to: distribution, storage, service, sales… etc.

8. After approving the Authorized Representative, in case of violation letter submitted, on the fourth written notice, or in case a major violation was found in the practice of the AR affecting the safety or the quality of the users this violation will be immediately added to Sijilat to be reflected on CR activity, he violation will not be removed for three months until the AR shows the CAPA, and do not violate NHRA regulation in this period. In case violation was done during this period the CR will be suspended for one year.

3. Submission of Registration

In order to apply for Authorized Representative registration, applicant should first fix an appointment through **Microsoft Booking System** for submitting the required documents.

Then applicant should pay the fees for the application, then a Notice to Pay will be issued and valid for one month, within this one-month applicant can re-submit up to 3 times to complete the required documents for the registration before it is being rejected.

If the applicant submits in-complete registration request at the first attempt and then re-submit the missing requirements after one month of issuing the NTP, then it will be considered a new request and applicant must pay the fees for new application.

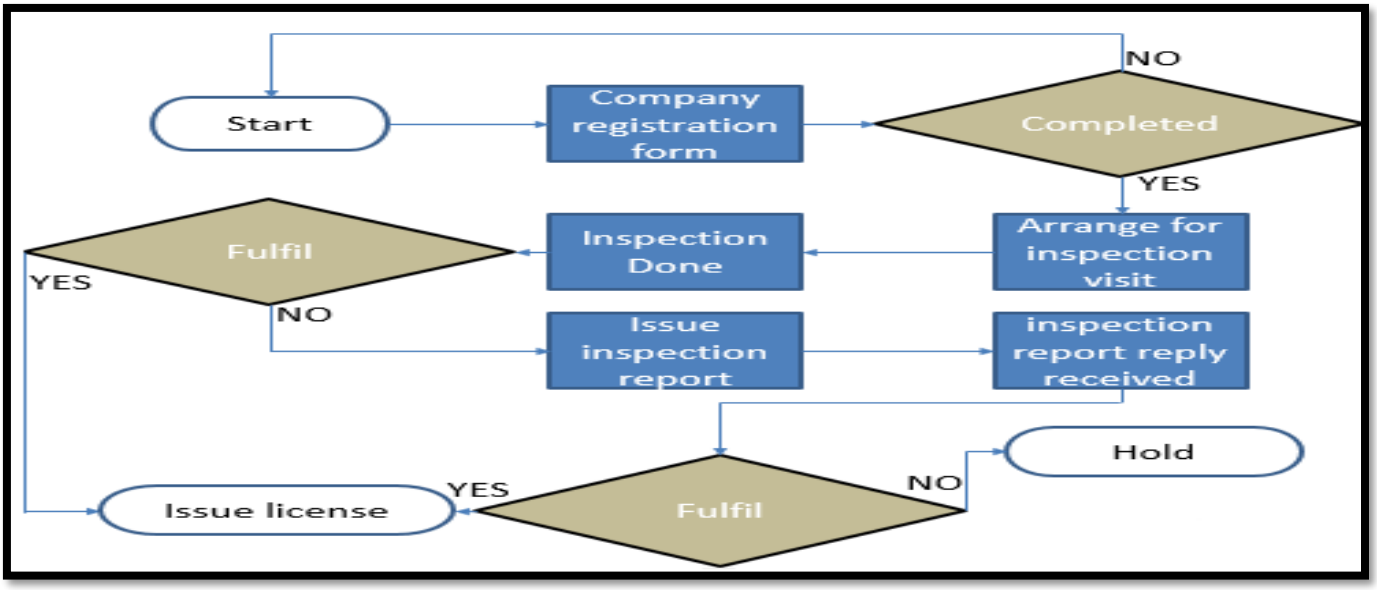
After application fees is paid, the documents will be reviewed and assessed at the same time.

In case the request documents and requirements did not fulfill NHRA regulation at the time of submission it will be rejected then a new application must be submitted by booking a new appointment.

If the requirements are full filed, then an` inspection visit will take place as explained below in **section 5.**

If the inspection was successful, the Authorized Representative license will be issued with a validity of **1 years.**

The following flowchart can simplify the process of Authorized Representative registration:



4. Requirements

The required documents are:

1. **Registration Form**. **(Annex 1)**.

2. **Valid Commercial Registration** (CR) for existing authorized representative **OR application number from Sijilat for new authorized representative.**

3. List of Manufacturers and **Authorization Letters OR Agreements** (valid, signed and stamped) ...if any.

4. **Policy of the Authorized Representative** including: importation, Distribution record, Maintenance, complain handling, Recall and Adverse event procedures and it should be mentioned that it is being reported to NHRA.

   For more information about how to write policy, please refer to the guideline "Policies and Procedures for medical devices Authorized Representatives Guideline" (Annex 5)

5. List of Authorized Representative staff with the **CVs / offer letter signed by the employee**, and **qualifications and medical training certificates if any**, staff should not be less than 3 employees, at least one of them an engineer (depending on the scope of the service), for example: engineer for handling medical devices (installation and maintenance), finance and admin.

6. **List of scope of service. (Annex 6)** to be selected where the registration certificate will include these scopes. Each scope has certain requirements NHRA will be evaluating authorized representative of the authorized representative to it. Please select only those that are not in the management plan.

7. In case of outsource storage, **service contract** should be provided.

8. **Capture of the system** should be provided. **(Excel sheet is not accepted).**

9. **List of service contracts** being provided to local Healthcare Facilities licensed by NHRA with the validity period

5. Inspection process and Elements

If the documents are fulfilled then an inspection form **(Annex 3)** will be given to the Authorized Representative to ensure that NHRA requirements are fulfilled, this form should be submitted back to NHRA signed and stamped by the AR to schedule an inspection visit by NHRA medical devices team and **all authorized representative staff should attend the inspection** to ensure that all employees are aware of NHRA medical devices rules and regulations and in case of certain recommendations or modifications to be done by the Authorized Representative (ex: storage condition, safety, system…) an inspection report will be sent to the Authorized Representative stating the recommended requirements.

A letter from the Authorized Representative should be provided to NHRA to confirm the implementation of the required modifications with an evidence (ex: pictures) and according to this, another inspection visit will be scheduled (if required) or the Authorized Representative license will be issued directly.

- **Inspection Elements:**

- authorized representative Sign on the building.
- Tracing system **(Software).** including LOT no, Batch no, Serial no , End user, recalls, complaints and adverse events.
- Recalls, complaints and adverse event Forms.
- Access Control for store
- Register with FDA+MHRA+ SFDA, for FSN.
- Labeling for (Damage area-expired Items)
- Staff should be fully aware of submitted polices
- Labeling for products.
- Destruction records in software and hardware.
- Temperature log (excel sheet registered the date, time temperature log).
- Fire extinguisher available and maintained.

- **Storage Conditions:**

- Storage space or Store location.
- Cold room if needed. (with temperature log).
- UBS / generator in cases of power failure.

- Receiving and delivering area.

6. Registration Certificate Renewal / Variation

Applicant should submit **Authorized Representative Renewal / Variation form (Annex 4).** and select the type of variation and provide the required documents as clarified below.

- **Registration Certificate Renewal**

Applicant should submit for registration certificate renewal 6 months before expiry date where the required documents are:

1) **List of employees** for medical devices and their qualification.
2) List of manufacturers distribution **authorization letter or contracts.**
3) **Quality management system** (QMS), if any.
4) **Commercial Registration CR**.
5) **List of service contracts** being provided to local Healthcare Facilities licensed by NHRA with the validity period
6) **Policies.**
7) **List of recalls and adverse events** from the previous license date of issuance including each case final report.
8) **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.
9) **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.
10) **List of supplied medical devices to Health Care Facilities** as per the Permit to Use guideline

- **Adding new scope**

During the validity of the registration certificate, AR should submit a **letter of the new scope** to NHRA to be evaluated and set the needed requirements for the new scope to be implemented and after ensuring the implementation, the new scope can be added to the registration certificate.

- **Changing the address of the authorized representative**,

Applicant should submit **copy of the CR** with the new address and **inspection request from** to schedule an inspection visit to the new address and ensure the compatibility with NHRA regulations and requirements. Then the registration certificate will be updated accordingly.

- **Adding new branch**

In case of adding a new branch of the same AR, applicant should submit a **new registration request** for the new branch and the same registration process will take place.

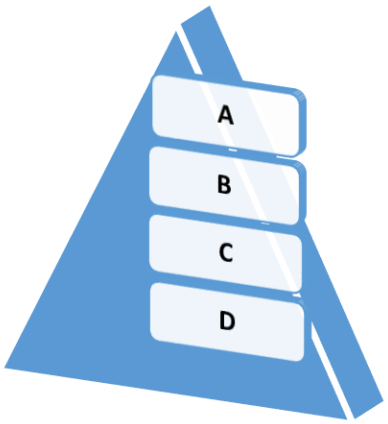
- **New Storage**

In case AR planning to have outside / outsourced storage, an **inspection request form** must be submitted to NHRA and an inspection visit will be scheduled to ensure that the new store is in compliance with NHRA regulations.

7. Registered Authorized Representative Classification

Registered authorized representative are classified as follows based on a scoring criteria extracted from the AR registration essential principles:

- **Class A**: Authorized representative scoring from **12 to 20**
- **Class B**: Authorized representative scoring from **9 to 11**
- **Class C**: Authorized representative scoring from **5 to 8**
- **Class D:** Authorized representative scoring **(≤ 5)**



Where the above score based on AR Registration essential parameters:

Weight	Parameters
3	• Service Team
3	• Integrated System
3	• Medical Devices Class III
2	• Storage
2	• Qualifications
1	• Medical Devices Class II
1	• Medical Devices Class Is
1	• Medical Devices Class I
1	• Medical Devices IVD
2	• ≤ 10 years' experience

8. Commercial Registration Certificate

In order to insure patient safety and public health and to ensure that the medical devices are being imported to Bahrain market by highly qualified and trusted personal, new importers who are planning to open new authorized representative should obtain **NHRA approval** to have a commercial registration (CR) with an activity **"Sale/Trade in other machinery and equipment and parts-Medical Devices supplies and Related Parts"** that allow them to practice the above stated activity in the kingdom of Bahrain. This activity includes **importation, exportation and sale in Bahrain market.**

Applicant should apply for new CR on **Sijilat** https://intranet.sijilat.bh/ which is an advanced electronic system that was established for the registration and licensing of commercial establishments in the Kingdom of Bahrain, The code for **medical devices importation activity is 4659**, the process is similar to the submission of Authorized Representative registration request:

No.	Requirements
1	Registration Form.
2	Policy of the Authorized Representative clarifying the procedures that should be implemented in medical devices importation including the distribution process, complaint handling, recall and adverse events.
3	System (software) for tracing and monitoring the imported and marketed medical devices including device name, model, lot number, serial number, manufacturer name and end-user details.
4	Letter of Initial approval issued by NHRA.

At the time of the final approval NHRA Authorized Representative registration certificate must be attached to Sijilat to obtain the CR.

9. Annex

Please refer to NHRA Website for more information about:

1. **Authorized Representative Registration Form.**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/MD%20Authorized%20Representative%20Registration%20Form%20(2).pdf

2. **Checklist**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Company%20Registration%20Check%20List1%20(1).docx

3. **Inspection form**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Inspection%20Request%20Form%20(1).pdf .

4. **Authorized Representative Registration Renewal / Variation Form.**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Authorized%20Representative%20Registratn%20Variation-Renewal%20form.pdf

5. **Policies and Procedures for medical devices Authorized Representatives Guideline.**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/Policies%20and%20Procedures%20Guideline%20for%20Medical%20Devices%20Authorized%20Representatives-%20Ver%202.0.pdf

6. List of Scopes.

1	Anesthesia	11	Surgical	21	Electro-Mechanical devices
2	Respiratory	12	CSSD	22	Lab / In Vitro Diagnostic
3	Endoscopy	13	Ophthalmology	23	Radio Active Material
4	Dental	14	Dermatology/Cosmetics	24	General Hospital
5	Dialysis	15	Plastic Surgery	25	Pediatric
6	Urology	16	Neurology	26	Psychiatric
				27	Home use device
7	Cardiovascular	17	Orthopedic		
8	Andrology	18	Obstetrics & Gynecology		
9	Wound Therapy	19	Physical Medicine		
10	ENT	20	Radiology		