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Authorized Representative Registration

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Presentation outline:

Process of application submission

Initial approval requirements

Inspection requirements

Companies classification

Variation & renewal procedure

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AR Registration Enforcement

As per Circular No. 39 for the year 2020 which state that all companies with medical devices activity (ISIC4 :4659) "Sale/Trade in other machinery and equipment and parts - Medical Devices, Supplies and Related Spare Parts" should be registered as an authorized representative for medical devices within a period not more than 31st of December 2022.

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HOW TO REGISTER

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There are two routs to submit an application to register the establishment as an authorized representative for medical devices:

1- Direct application

The applicant is requested to submit the registration application during a booked appointment by email

2- Through fast track conformity assessment body (ABC)

The applicant is directly submit the registration application on ABC system where the application will be received to NHRA for the approval after ABC team review the application and recommend the necessary corrections if needed

1- Direct application

To sumit a direct authorized representative registration application, the following steps should be followed:

Fill out the application form

Prepare all the required documents then book an appointment on MS Bookings

Submit the application through email

A NTP will be sent after submitting the application

Summit through SIJILAT

If final approval requirements are met, NTP will be issued based on AR classification parameters

Prepare the facility for the inspection visit then submit the inspection form

Initial approval will be issued if the application fulfil the requirements

Summit through SIJILAT

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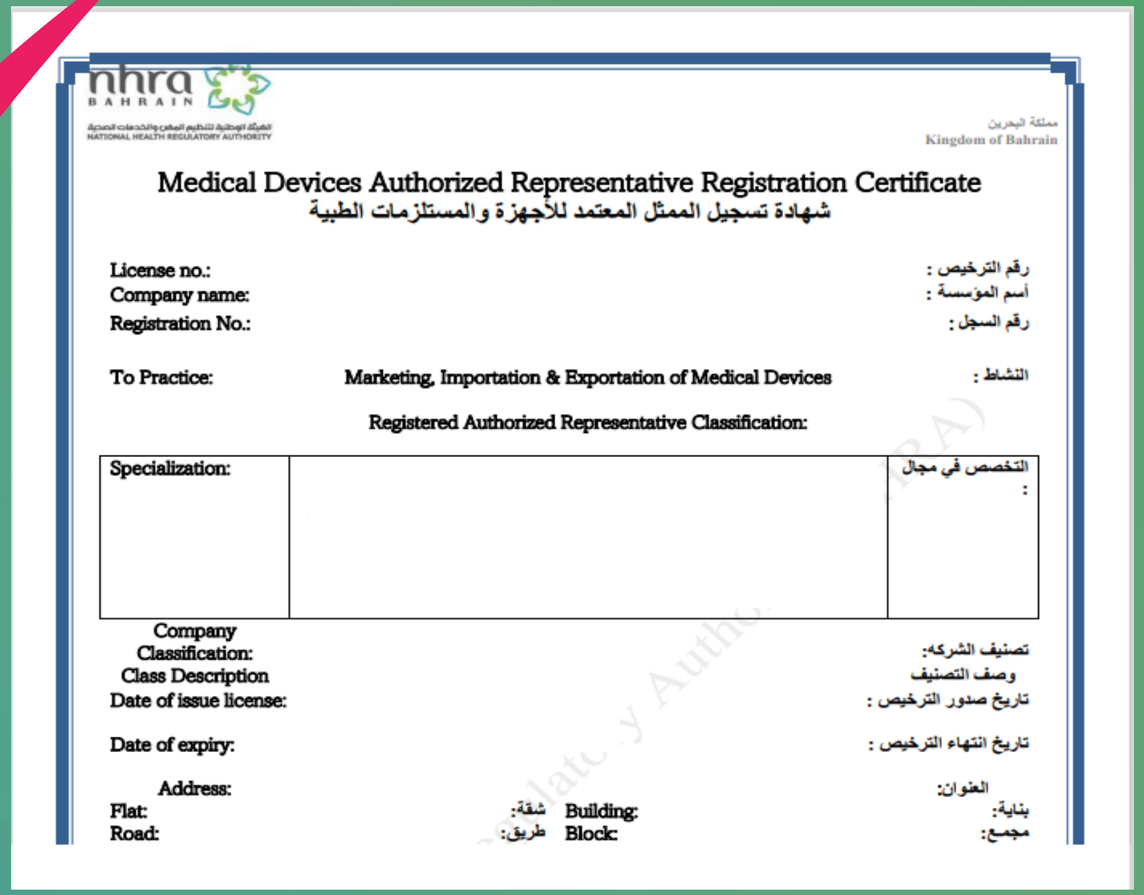
AR registration process is completed



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الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Devices Authorized Representative Registration Certificate
شهادة تسجيل الممثل المعتمد للأجهزة والمستلزمات الطبية

License no.: رقم الترخيص :
Company name: أسم المؤسسة :
Registration No.: رقم السجل :

To Practice: Marketing, Importation & Exportation of Medical Devices النشاط :

Registered Authorized Representative Classification:

Specialization:		التخصص في مجال :

Company Classification: تصنيف الشركه:
Class Description وصف التصنيف
Date of issue license: تاريخ صدور الترخيص :

Date of expiry: تاريخ انتهاء الترخيص :

Address: العنوان:
Flat: شقة: Building: بناية:
Road: طريق: Block: مجمع:

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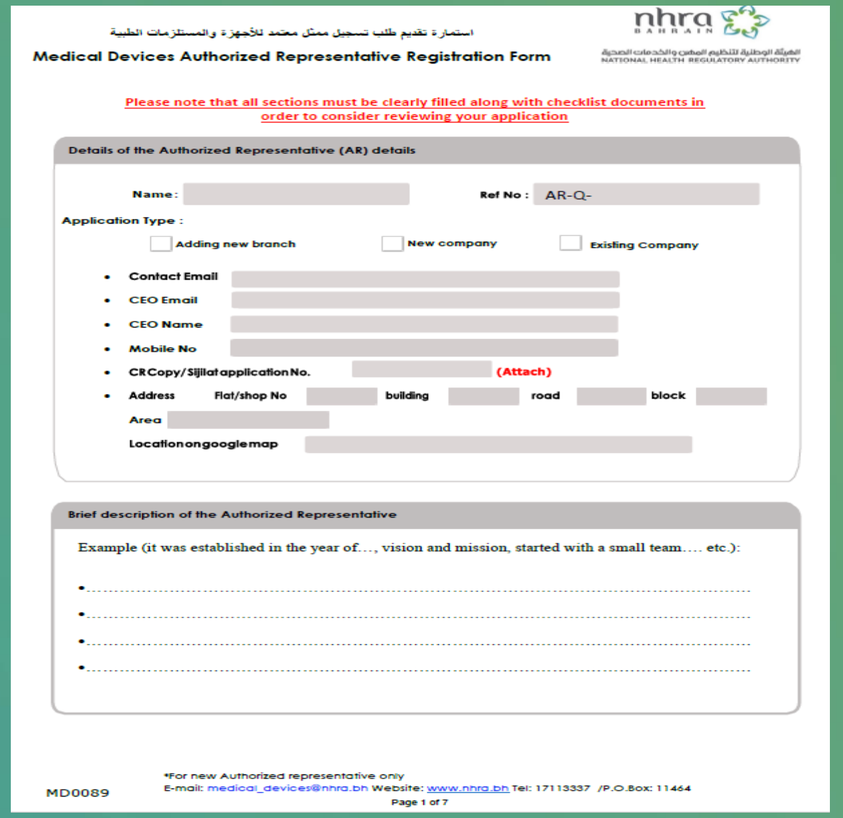
Registration Requirments (inital approval)

In order to obtain the authorized representative license, the following points should be met in the submitted application:

- The completed authorized representative Application Form.
- At least three employees to handle the AR processes.
- The establishment has to have a valid commercial registration (CR).
- A contract agreement with the outsource storing facility along with the associated CR ,for outsource storing facilities only.
- Authorization Letters or Agreements with medical devices manufacturers ,not mandatory for new companies.
- AR policies as per NHRA guidelines.
- Forms to be used for AR processes.
- An active tracing system (software) to monitor and track AR processes.

1-Application form

Full company's details should be included in the form and Brief description about the company in addition to brief summary of each AR policies.



استمارة تقديم طلب تسجيل ممثل معتمد للأجهزة والمستلزمات الطبية

Medical Devices Authorized Representative Registration Form

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الهيئة الوطنية لتنظيم المنتجات 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 company ☐ Existing Company

- Contact Email
- CEO Email
- CEO Name
- Mobile No
- CR Copy/ Sijil at 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.):

- ……
- ……
- ……
- ……

MD0089

*For new Authorized representative only
E-mail: medical_devices@nhra.bh Website: www.nhra.bh Tel: 17113337 /P.O.Box: 11464
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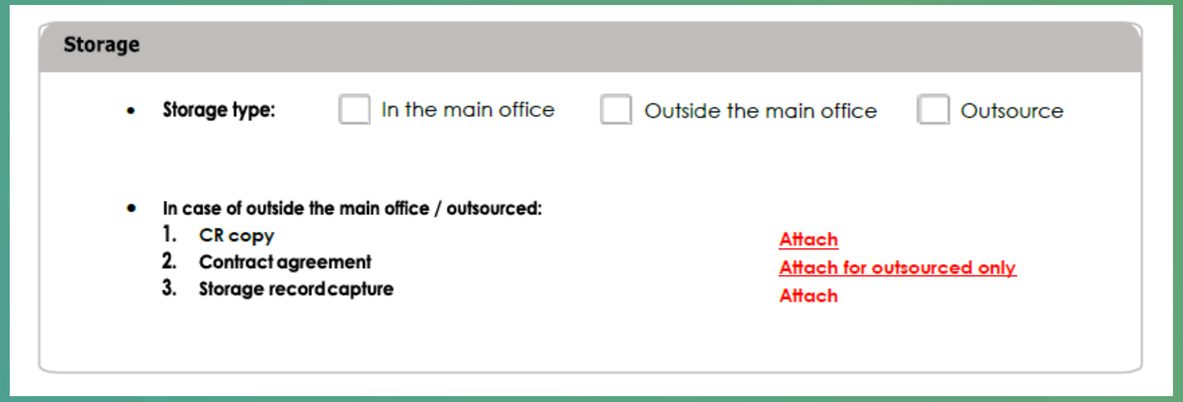
1-Application form

Storing facility type (in the main office, outside or outsource)



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

1-Application form

List of manufacturers of MDs along with country of origin and medical device type.

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.

1-Application form

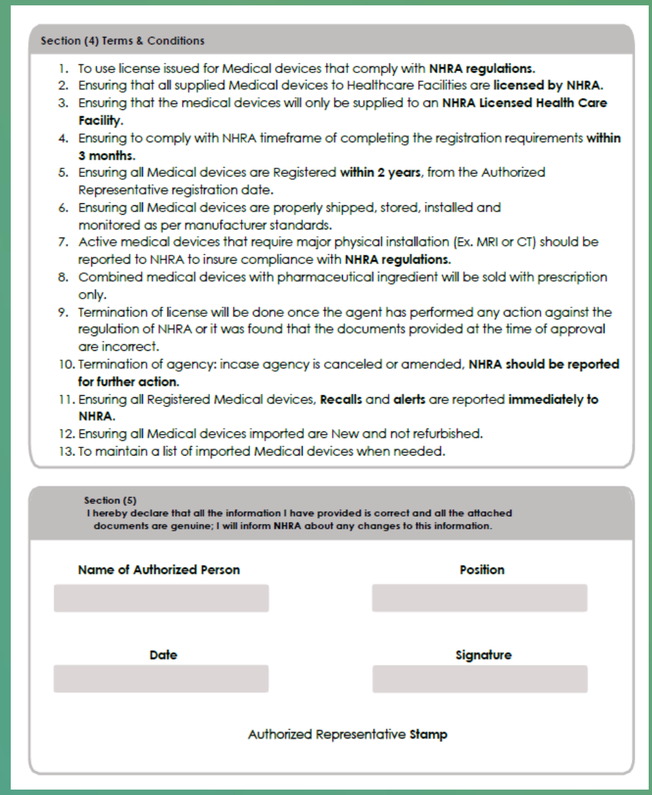
List of medical devices scopes to be registered

(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	
○ Wound Therapy	○ Physical Medicine	Other, please specify:
○ ENT	○ Radiology	_____
		_____
		_____

1-Application form

Sign and stamp terms & conditions section



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.

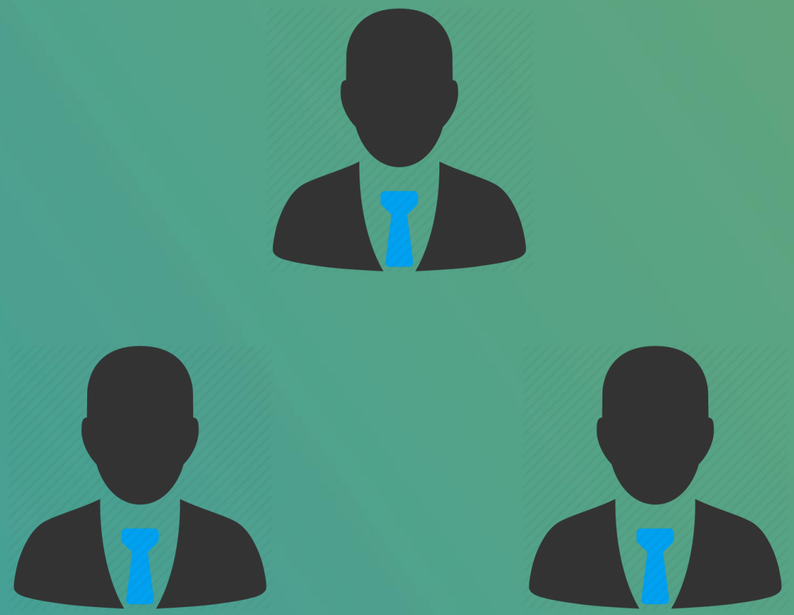
Name of Authorized Person | **Position**

Date | **Signature**

Authorized Representative **Stamp**

2- Staff

At least three CVs along with three offer letter is required



2- Staff

- ✓ Qualified
- ✓ & with medical devices background

Remark: Service team with medical devices qualifications should be available if MDs to be distributed require service maintenance.

3- The commercial registration

✓ Valid

✓ Match with the detail is the application form

Due Date		تاريخ الاستحقاق	Registration Date		تاريخ القيد	Registration No.		رقم القيد
Group Name								اسم المجموعة
Commercial Name								الاسم التجاري
Registration Type	With Limited Liability Company							نوع القيد
CR Status	ACTIVE				نشطة			حالة القيد
Commercial Address	P.O.BOX ص.ب	Area المنطقة	Block مجمع	Road طريق	Building مبنى	Flat/Shop No. شقة/محل		العنوان التجاري

Activities	الأنشطة
Sale/Trade in other machinery and equipment and parts - Medical Devices, Supplies and Related Spare Parts	تجارة/بيع الآلات والمعدات الاخرى - الأجهزة والمعدات والمستلزمات الطبية

4- Storing facility

In the main office

- Fulfil inspection chicklist as in the inspection form

Outside the main office

- Copy from the previous records in any
- Copy from the CR
- Copy from NHRA license for the warehouse as per circular number 1 for the year 2022

Outsource

- Copy from the previous records in any
- Copy from the outsource storing facility CR
- The contract agreement for the outsource storing facility

5- Authorization letters from MDs manufacturers

- Valid
- Signed & stamped

6- The tracing system (software)

Importation

Complaint handeling

Distrubution

Adverse event

Field safety notice

Alerts & modification

Service maintenance

Recall

Example of required details

Remark: tracing system is not limited to the following points and more details can be included if necessary

- **Importation**: purchase date, OFOQ ref No, device serial and batch/Lot No.
- **Distribution**: end-user details, device serial and batch/Lot No.
- **Services Maintenance**: date of maintenance, reason for maintenance (e.g. PPM, complaint, etc), next PPM date, device serial and batch/Lot No.

Example of required details

Remark: tracing system is not limited to the following points and more details can be included if necessary

- **Recall**: date of recall, recall description , device serial and batch/Lot No.
- **Adverse events**: date of the adverse event, adverse event description,customer details, patient details (if effected),device serial and batch/Lot No.
- **Complains**: date of complaint, complaint description ,complaint issuer ,device serial and batch/Lot No.

Example of required details

Remark: tracing system is not limited to the following points and more details can be included if necessary

- **Alerts & modifications**: date of modification, description, alerts & modification issuer ,device serial and batch/Lot No.
- **Field safety notice**: FSN risk classification, FSN issuer, FSN description, FSN date, device serial and batch/Lot No.

7- AR forms

Complaint handeling

Adverse event

Field safety notice

Service maintenance

Used forms should include the full details of :

1. The medical device
2. The end-user
3. Process/ event

8- AR policies

Importation

Complaint handeling

Distrubution

Adverse event

Alerts & modification

Service maintenance

Recall

Importation

Documentation of the internal process implemented by the AR in importation phases starting from the order confirmation where the phase must highlight the responsible person designation and the roles. The policy must include the AR understanding of NHRA import permit in phases and how the documentation is managed internally to avoid rejection and/or violation.

Distrubution

Records of distribution including (invoices, LPO, service reports…etc), should be kept and maintained in a tracing system (software) including all details related to the imported and marketed medical devices in Bahrain market in addition to arrangements to insure proper delivery of the devices to the end-user.

Complaint handeling

A documented process describing the sequence followed for handling complaint starting from receiving the complaint via email, phone call or online contact form passing through investigation process and root cause analysis until the corrective action taken to solve and close the complaint to eliminate the risks associated with the concerned medical device.

Adverse events

A documented process describing the sequence followed to receive the adverse event related to the use of a medical device including investigating and defining the main causes of the adverse even at the corrective action taken by the authorized representative to prevent the recurrence of the adverse event.

Recalls

A documented process describing the sequence followed starting from receiving the field safety notice from the manufacturer, withdrawal of the defected medical device from Bahrain market until the destruction OR return back of the defected medical device to the manufacturer.

Alerts and modifications

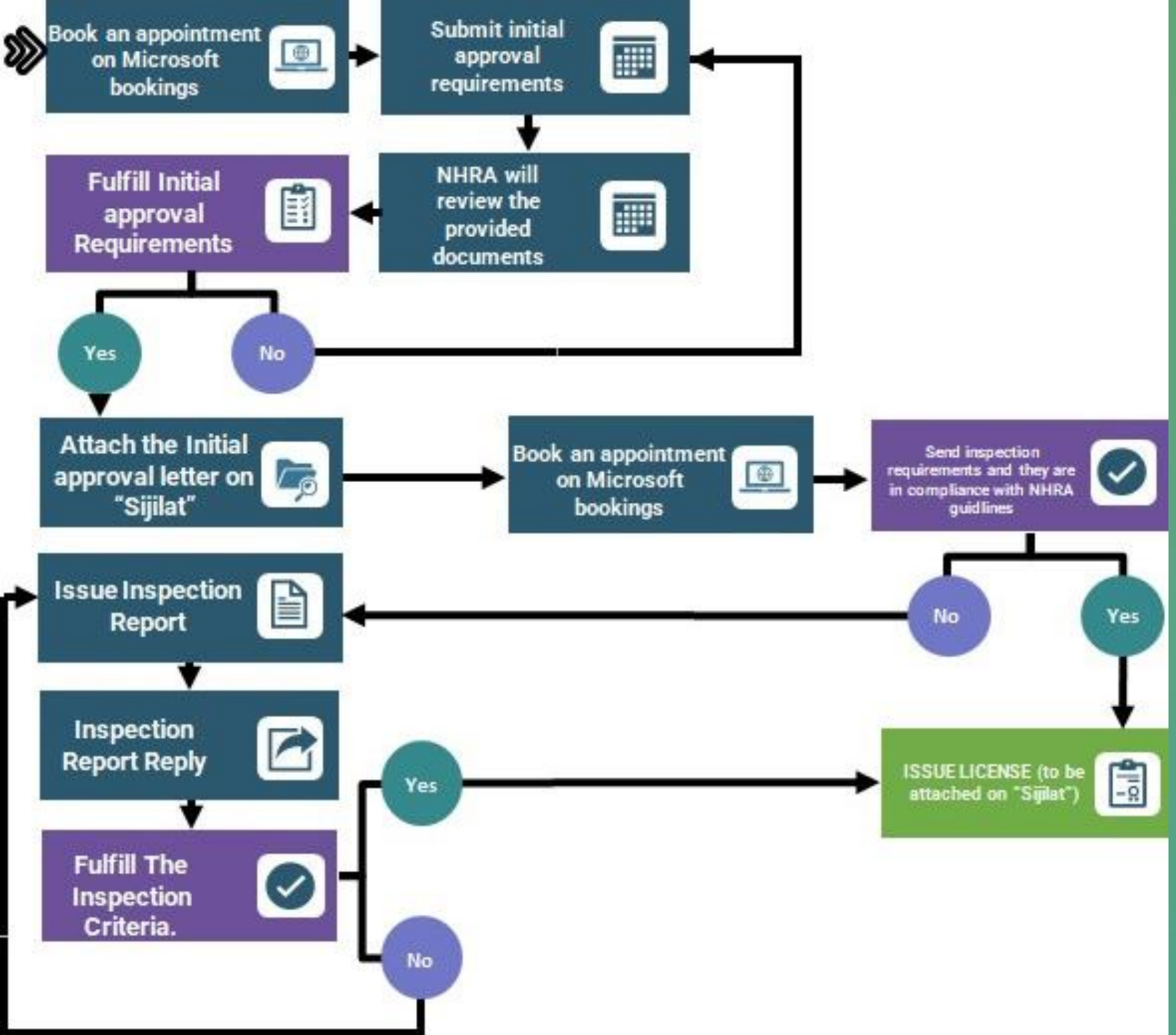
A documented process describing the sequence followed in case of modification of medical devices including (changes in manufacturing process of the medical device or the design, the materials, changes in sterilization that may unintentionally affect device performance, or software upgrading or releasing a new model or updated version of medical device).

Registration Requirments (Inspection -Final approval)

Before submitting the request for the inspection visit, please make sure that the following points are available:

1. Tracing system (Software). including LOT no., Batch no., Serial no., End user, recalls, complaints.
2. Recalls, complaints, and adverse event Forms.
3. Access Control for store.
4. Register with FDA+MHRA+ SFDA, for FSN
5. Labeling for (Damage area-expired Items).
6. Staff should be fully aware of submitted polices.

7. Labeling for products.
8. Destruction records in software and hardware.
9. Temperature log (excel sheet registered the date, time temperature log).
10. Fire extinguisher available and maintained.
11. working hours clearly represented at the main entrance in additional to QR code for reporting safety issues related to medical devices should be placed on visible area for customers.
12. for renewal application, NHRA license must be displayed for visitors.



Process recap

P.O. Box: 11464

AR classification

Weight	Parameters	Score
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 Class IVD	
2	< 10Years' experience	

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)**	

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General Remarks

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- ✓ By 2023 all medical devices importer companies should be registered as an authorized representative where the activity of trading medical devices (ISIC4: 4659: Sale/Trade in other machinery and equipment and parts - Medical Devices, Supplies and Related Spare Parts) will automatically deleted from the commercial registration of Not registered companies.
- ✓ The applicant can submit the missing points in the registration application up to three times before consider the rejection of the application where new appointment should be booked to submit new application.
- ✓ All responsible employees to manage AR processes should be available during the inspection visit stage, otherwise a proper justification should be submitted to NHRA.

General Remarks

- ✓ If inspection points are not met during the visit as per inspection form, a re-inspection visit will be scheduled where re-inspection 50 BD NTP will be generated.
- ✓ Both initial and final approvals should be attached on SIJILAT system to avoid pending applications.
- ✓ NHRA may request for an additional requirements is needed.

AR license renewal/variation

AR license has a validity of 1 year

- The applicant should submit the AR license renewal application before 6 months of the expiry date.
- Same process of application submission will be followed.

Remark: Plenty will be implemented for the delayed renewal applications starting from the year 2023.

AR license renewal

1. List of employees for medical devices and their qualifications.
2. List of manufacturers distribution authorization letter or contracts.
3. Quality management system (QMS) for the Authorized representative, if any.
4. Commercial Registration CR.
5. List of service contracts being provided to local Healthcare Facilities licensed by NHRA with the validity period, if any.
6. Updated 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.

AR license variation

Variation types:

- Commercial address
- Storing facility type
- License scopes

AR license variation

1. Commercial address

- Copy from both old and the new CR
- SIJILAT application number
- Declaration letter for using the same storing conditions as in previous site
- Inspection form

AR license variation

2. Storing facility type

- Copy from the commercial registration of the storing facility, if not in the main office
- The contract agreement for the outsource storing facility
- Inspection form

AR license variation

3. License scopes:

- List of employees to handle the new scopes
- Authorization letters for the new scopes
- Additional requirements if needed

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Thank you!

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