1 — Steps to Open Medical device (AR)

Step 1: Create an Account
- Register on "Ajheza" system.

Step 2: Collect Required Documents
- Ensure you have all the necessary documents for registration.

Refer to:
• AR Guideline
• How to Write Policies Guideline

Step 3: Apply for CR
- Apply for a Non-active Commercial Registration (CR) for the new Authorized Representative on sijilat.

Step 4: Submit Application for NHRA Review
- Book an appointment on "Ajheza" system.
- Pay NHRA fees to review the application.

Step 5: Receive Initial Approval
- After review, NHRA grants initial approval through the "Ajheza" system (if requirements are met).
- Submit the initial approval letter on Sijilat.

Step 6: Facility Preparation & Inspection
- Prepare the facility according to inspection requirements.
- Submit the inspection request form through "Ajheza" system.

Step 7: Final Approval & Registration Certificate
- After passing inspection, complete the payment process.
- Obtain the registration certificate (final approval).
- Submit the final approval on Sijilat.

2 — How to Register Medical Devices

Step 1: Authorized Representative Requirement
- Applicants must first be registered as Medical Device Authorized Representatives

Step 2: Submission
- Book an appointment through "Ajheza" System.
- Submit all required documents on the scheduled date.

Step 3: Payment
- Applicable fees will be assigned.
- A Notice to Pay will be issued through "Ajheza" System.

Step 4: Approval
- Once requirements are met, an Approval Notice and the License Fee Request will be issued through "Ajheza" System.

Step 5: License Issuance
- After payment, the Medical Device Registration License will be issued and uploaded to "Ajheza" System.

3 — Medical Device Classification

Step 1: Book an Appointment
- Book an appointment through Microsoft Booking.

Step 2: Submission
On the appointment date, submit Classification Form and required documents via Medical_devices@Nhra.bh.

Step 3: Payment
- Pay the required fees once you receive the Notice to Pay through Fawateer.

Step 4: Certificate Issuance
- Once requirements are met, a Classification Certificate will be issued and will be sent through Medical_devices@Nhra.bh.

Steps to Open Medical device Authorized Represintive (AR)

4 — How to Import Medical Device

Step 1: Submission
- Submit your application for the permit to import through OFOQ System.
- Provide the requirements as per your case, refer to:
- Importation Guideline
- Shipment for individual
- Non-medical shipment

Step 2: Payment
- Contact MDR.fees@nhra.bh and pay the required fees once you receive the Notice to Pay through Fawateer.

Step 3: Revision
- Once the payment is made, the reviewers will receive the application, the application will be reviewed and once the decision is made the applicant can check the status of the application on the OFOQ System.
- Accordingly, the applicant can clear the shipment once they receive the approval on the OFOQ System.

6 — Medical Devices Destruction

Step 1: Submission
- Submit the Medical Devices Destruction Supervision Form to Medical_devices@Nhra.bh.

Step 2: Payment
- Pay the required fees once you receive the Notice to Pay through Fawateer.

Step 3: Appointment
- Arrange an appointment with one of the authorized disposal entities:
• Bahrain Waste Treatment
• Crown Industries

Step 4: Supervision and certificate issuance
- NHRA will supervise the destruction process, once completed, a Destruction Certificate will be issued and sent via Medical_devices@Nhra.bh.

5 — Permit to use (PTU)

Step 1: Book an Appointment
- Book an appointment through "Ajheza" System.

Step 2: Submission
- On the appointment date, submit all required documents.
Refer to: Medical Device Permit to Use Guideline

Step 3: Payment
- Once requirements are met, pay the required fees once you receive the Notice to Pay through "Ajheza" System.

Step 4: Obtaining the PTU certificate and visiting the site
- After the payment, NHRA will visit the site and label the approved medical devices.

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