الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Initial Approval Requirement
Medical Devices Authorized Representative
Registration Check Lists

Documents required

1. Medical Device Authorized Representative Registration form. (All sections should be filled).

2. Valid Commercial Registration (CR).
(For new Authorized Representative, you can write the CR application number on Sijillat.)

3. List of Authorized Representative's staff and:
A) CVs **B)** Offer letter signed by the employee. **C)** Qualifications, training courses certificates **if any**.

4. Storage if external **(CR, contact agreement, inventory record capture)**, if any.

5. Quality management system **(QMS)**, if any.

6. List of products if the table is not enough.

7. Authorization Letters or Agreements and should be valid, **signed and stamped by the manufacturers.**

8. Copy of Authorized Representative Policies including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.
E) Distribution. **F)** Importation.

9. Copy of Authorized Representative forms including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.

10. Capture of Authorized Representative system (Software) to monitor and trace:
A) Distribution. **B)** Services Maintenance. **C)** Recalls. **D)** Adverse events. **E)** Complains.
F) Alerts & modifications. **G)** Field safety notice. **H)** Importation.

11. Copy of Authorized Representative records **if any** including full details about:
A) Services maintenance. **B)** Complaint handling. **C)** Adverse events. **D)** Recalls.
E) Distribution. **F)** Importation.

12. Service contract, **if any.**

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

*For new Authorized representative only

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