

أستمارة تسجيل مصنع محلي للأجهزة الطبية

Local Manufacturer Application Form

Application No:

(For NHRA Use)

Section 1: Facility Details			
Applicant Name:			
Email Address:		Tel. No:	
		Mobile No:	
CR No:			
CR Activity:			
Scope of Work:			
Are the products sterile or non-sterile:	☐ Sterile	☐ Non-Sterile	
Storing Facility:	☐ Inside the manufacture	☐ Outsource (separate)	
Brief description about the manufacture:			

Location Details:	Area:
	Address:
	• Read: • Block: • Building:
	Google map link:

Section 2: Proposed products						
No.	Device Name:	Device Model:	Device risk Class:	Device type:	Device intended Use:	Authorized Representative:
1.						
2.						
3.						
4.						
5.						

Remark: Please attach Art-work for your products if available

Section 3: 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 the Authorized person:	Position:
Date:	Signature:
Manufacture Stamp	

List of the required documents:

1. Site Engineering drawing showing the following areas: (receiving, storage, production, labelling and packaging, quality check, dispatch).
2. Captures from the tracing system used to monitor the following processes:
 - a) Distribution. b) Complains. c) FSN. d) Recalls. e) Adverse Events.
 - f) Distraction of Defected products.
3. Facility material used in the site (for example, ventilation, paint flooring, etc.).
4. Raw material MSDS (Material Safety Data Sheet).
5. Products Art work, **if any**.
6. Manufacture internal policies and procedure.
7. Staff qualifications (CV) and offer letters (**stamped & signed by them**).
8. Adherence to NHRA regulation obligation letter from the manufacturer manager.
9. Signed and stamped terms and conditions form.
10. Storing facility CR, **if external**.

For more information, please refer to Local Manufacturer Guideline