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Medical Devices Local Manufacturing Facility Registration Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Version 1.1



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1. Introduction

Medical devices industry is very important and in demand, it is responsible for the design and manufacturing of a wide range of products used to diagnose and treat illnesses and improve health in patients. Because medical devices are essential for health care, and because these devices have direct impacts on public health and quality of life, their safety is mandatory.

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.**” This guideline is intended for new local manufacturers to guide them through the regulations and requirements to grant NHRA approval to ensure that the manufacturing process of the medical devices is in compliance with the international standards to guarantee the quality and efficacy of the final product.

2. General Rules

1. The manufacturer should be responsible for its marketed medical device in Bahrain market.
2. Should be aware of medical devices regulations in Bahrain
3. Should be aware of manufacturing sites requirements and other governmental entities approval.
4. Should have good management system in place.
5. Should have Qualified team related to final product.
6. Feasibility study to guarantee sustainable manufacturing.

3. Requirements of New Manufacturers

In order to grant NHRA approval for new local manufacturers, the below requirements should be provided:

- Medical Device Local Manufacturer Application Form. ([Annex 1](#))

Site Requirements:

- Site Drawing/layout including surroundings and whether there are any flammables in the surroundings. The following needs to be included in the drawing/layout:
 - ❖ Flow of the process - Site needs to be structured in a way that is systematic where the stages in the whole process do not overlap and goes smoothly. Flow example:
 1. Raw materials
 2. Production
 3. Packaging and Labeling
 4. Quality Control
 5. Dispatch
 - ❖ Raw materials storage
 - ❖ Dispatch storage
 - ❖ Administrative offices
 - ❖ Staff break room
 - ❖ Security of the factory such as access-controlled entrances.
 - ❖ Location of sprinklers, Smoke detectors, Thermometers and any safety equipment.
- Ventilation and air curtain in order to prevent dust from entering. The Ventilation specification needs to be provided.
- Sprinklers and cameras for safety.
- Paint used should be anti-bacterial, anti-fungal, anti-flammable.
- Floor/Ground should be medical grade - anti-static, anti- flammable, anti-fungal and anti-bacterial.
- MSDS (Materials Safety Data Sheet) of Raw materials – Needed to know the safety equipment needed in the site as there might be a temperature that the machine needs to be at to avoid over heat or the type of Fire extinguisher needed in case of fire, etc.
- Backup generator is recommended but it is not a mandatory requirement.

Production machine requirements:

- Production Capacity per day.
- Pre installation requirements of the device. Needed to know for example the distance between the device and the wall or ceiling to decide whether the site size is suitable.

NHRA doesn't have certain requirements or restrictions for the machine.

Medical Device (Final Product) requirements:

- Overview or description of the final product.
- Process of manufacturing
- Design and Development.
- Specifications (Including storage specifications that the final product needs to be stored in).
- Artwork (Label) sample. Points to include but not limited to:
 - Manufacturer Name, full address, and contact details.
 - Name of Medical Device.
 - Type of Medical Device.
 - Description.
 - Lot/batch number.
 - Model/reference number.
 - Storage instructions such as single use, temp high and low, keep dry along with their symbols (Where applicable).
 - Certifying body symbol or standard or CE mark.
 - Quantity.
 - If sterile, need to add sterile symbol.
 - Instructions for use either on the artwork or on a separate leaflet.
 - Contents (If applicable)
 - Please refer to ISO 15223-1 standard and find the following templates to simplify the process and find the attached template to simplify the process.

Quality of the Medical Device:

- Raw materials should be medical grade.

The requirements of the quality assurance will be determined depending on the medical device. For example: The manufacturing of surgical masks should follow the EN 14683 Standard to ensure the product quality and safety and to be in compliance with international standards.



Preventive Maintenance:

The manufacturing facility needs to include a trained employee for periodic preventive maintenance available at the site.

Management System:

- List of staff and their role. Example of needed roles:
 - Projection Manager
 - Project Manager
 - Quality officer to check the final product.
 - All staff should be aware of the ISO 13485 requirement and make.
- Policy and procedure (should be written and prepared as per ISO 13485 standard) for all processes including but not limited to:
 - Raw materials management.
 - Production line.
 - Physical Quality Check.
 - Packaging and Labeling.
 - Storage management and dispatch management.
 - Lab quality check.
 - Post market surveillance.
- An IAF accredited notifying body should be contacted to obtain the Quality Management System certificate with the ISO 13485 standard which is to make sure that the quality of the manufacturing facility is being managed as per international standards. All staff needs to be fully aware of the requirements of documentation (policies, procedures and guidelines) and management for medical devices.

Medical Devices Storing Facility Requirements (Annex 3)

- Medical devices Storing Facility application form. (Annex 4)
- Site Engineering drawing showing the following (receiving area, storage area, delivery area, quarantine area).
- Tracing System.
- Equipment and vehicles to be used inside the storing facilities
- Equipment and vehicles to be used medical devices transportation
- procedure and policies.
- name & number of employees (for medical devices) at the company and designation including CV's.
- Approvals of other government sectors if available (Civil Defense, Municipalities).
- Signed and stamped terms and conditions form.

E-Mail: medical_devices@nhra.bh Website: www.nhra.bh Tel.: 17113299 /P.O. Box: 11464



4. Approval Process

Applicant should take an appointment through the below link:

[Microsoft Booking](#) to submit the form and the required documents.

- **Initial approval process**

Medical devices regulation team will review the documents within **4-8 weeks** and if the requirements are fulfilled, a letter of initial approval will be issued including the required documents for final approval.

Then applicant should apply on Sijilat and submit NHRA initial approval letter to obtain the initial approval on Sijilat using the activity of manufacturing medical devices “325”.

- **Final Approval process**

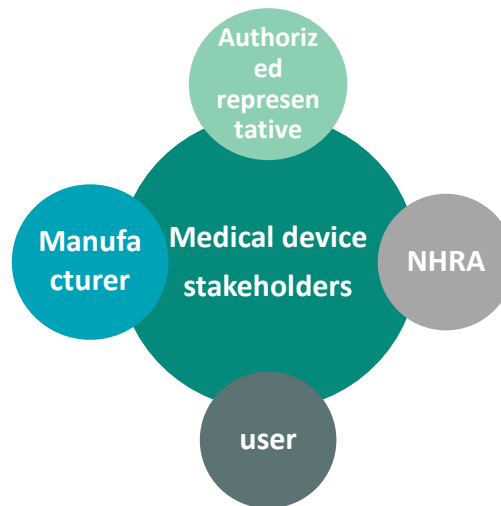
Once the manufacturing site final approval requirements are implemented, evidence should be submitted to NHRA stating that the applicant is ready for inspection visit.

Once inspection is done and all requirements are fulfilled, NHRA will issue the manufacturer license within **1-2 weeks**.

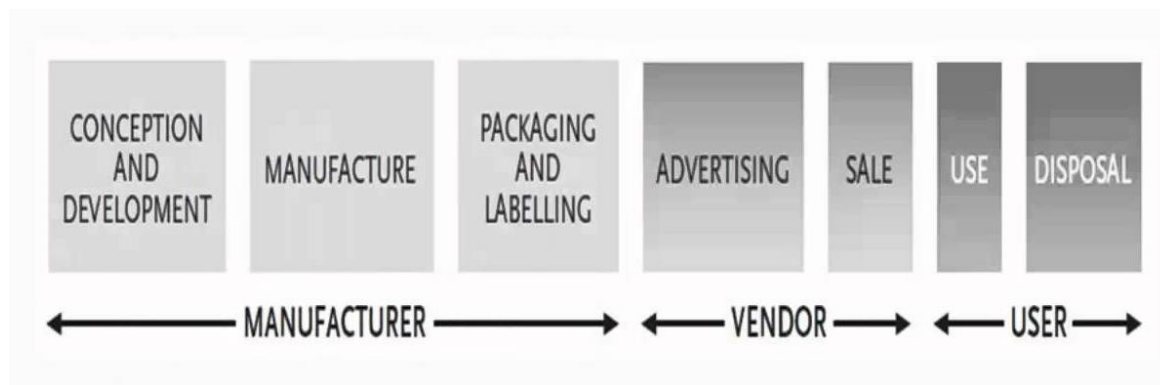
Then applicant should apply on Sijilat and submit NHRA final license to obtain the final approval of medical device manufacturing CR application.

5. Shared responsibility for medical device safety and performance

The ideal conditions that will ensure the safety and performance of medical devices require shared responsibility by all stakeholders. This need for cooperation is illustrated below. The circle formed by the stakeholders illustrates the shared responsibility.



➤ Roles and responsibilities of each stakeholder



Together, the Manufacturer, Supplier, User, and Government are the stakeholders. All play critical roles in ensuring the safety of medical devices. The most important factor that ensures the cooperation of all these stakeholders is an informed and common understanding of the issues. Shared understanding and responsibility are achieved through communication and mutual education, which can be effectively achieved by having all stakeholders participate in establishing the process that ensures safety and performance of medical devices.



Roles of Manufacturer:

- ❖ must ensure that it is manufactured to meet or exceed the required standards of safety and performance. This includes the three phases (design/development/testing, manufacturing, packaging and labeling) that lead to a product being ready for the market.
- ❖ Have a good communication system with suppliers, end-users and NHRA.
- ❖ Have a plan for handling complaint, adverse events and recalls.
- ❖ The manufacturer should ensure that it is manufactured to meet or exceed the required standards of safety and performance. This includes the three phases (design/development/ testing, manufacturing, packaging and labelling).
- ❖ Manufacturer should provide appropriate training to users / distributors.

Roles of Supplier / Vendor:

- ❖ should ensure that the products sold comply with regulatory requirements.
- ❖ vendors should be careful to avoid making misleading or fake claims about their medical devices.
- ❖ should provide after-sale service and proper training specially for home-use medical devices that might be used by a layperson.
- ❖ Participating in post-market surveillance (receiving and reporting customer complaints/ incidents) is important and required for ensuring medical device safety and performance.

Roles of Users:

- ❖ should make sure to have good qualifications and training in the proper use of the device, and is familiar with the instructions and operating procedures recommended by the manufacturer.
- ❖ Should have the responsibility to use the medical device only as per its intended purpose to not affect the safety and performance of the medical device.
- ❖ Should have the responsibility to ensure proper maintenance of medical devices during active use and safe disposal of obsolete medical devices.



6. Final Product Labeling

For more information about medical device labeling please refer to “**Medical Device Labeling guideline**” (**Annex 5**) on NHRA website.

7. Annex

1. Medical Device Local Manufacturer Application Form

<https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Checklists/Medical%20Device%20Factory%20Form1.pdf>

2. Medical Device Local Manufacturer Check list

<https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Checklists/Medical%20Devices%20factory%20requirements1.pdf>

3. Medical Devices Storing Facility Requirements Checklist

<https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Checklists/medical%20storage%20cheklist%201.pdf>

4. Medical Devices Storing Form

<https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Checklists/medical%20device%20storing%20facility%20form.pdf>

5. Medical Device Labeling guideline

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Devices%20Labeling.pdf