Ref. 2021-MDGUD-Q1-010

Medical Device Permit to Use Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

Jan 2021

Version 2.1

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1. Introduction

With reference to **Decision (48) 2020, Article (4) "**The Authority monitors the use of medical devices and products in the Kingdom and takes the necessary and appropriate measures to ensure the safety of their use and maintenance in order to ensure the safety of patients, the public and users of the medical device and product, and the authority shall notify patients or users once it is confirmed that the medical device or product is/are not complying with the of the provisions of this decision.**" And Article (8) "**All health facilities must take Authority permit to use medical devices and products before using them.**"**

This guideline is intended to guide all licensed Healthcare facilities on the process of obtaining the **Permit to Use** for their medical devices in the facility, where the medical devices should be in compliance with the specialization of the healthcare facility and international quality and safety standards.

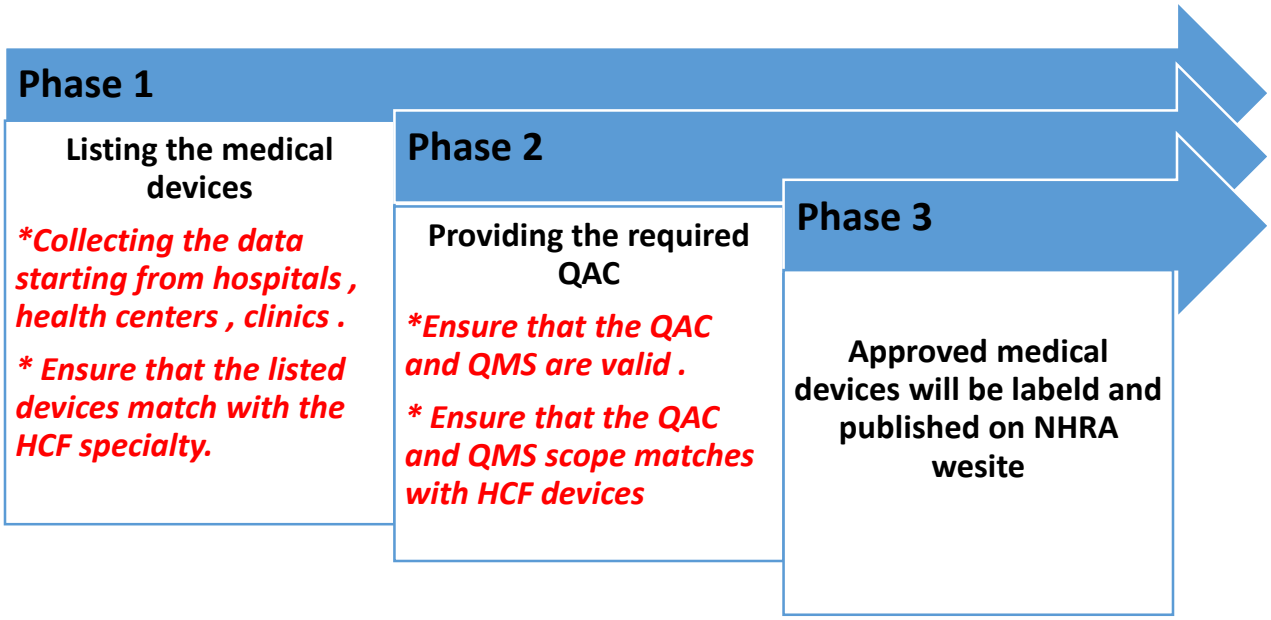
The main purpose of **PTU** process is to have a **National Medical Devices database** and to provide the **national insurance** with the available Medical Devices in Bahrain.

2. General Rules

1. HCF management should ensure that all medical devices existing in the facility is listed and approved for use by NHRA.
2. Permit to use is mandatory for all HCF before purchasing new devices
3. All Permitted to use medical devices will be labeled by NHRA label and listed on NHRA website as registered medical devices
4. All medical devices must be imported and cleared as per NHRA regulations.
5. Medical devices should match with healthcare facility specialization.
6. Healthcare facility must ensure that the medical device is already registered in NHRA by the supplier before purchasing.
7. "Permit to use" has no validity and is not renewable.

3. Method of Implementation

Permit to use process is done through 3 phases:



- **Phase 1: Listing the medical devices**

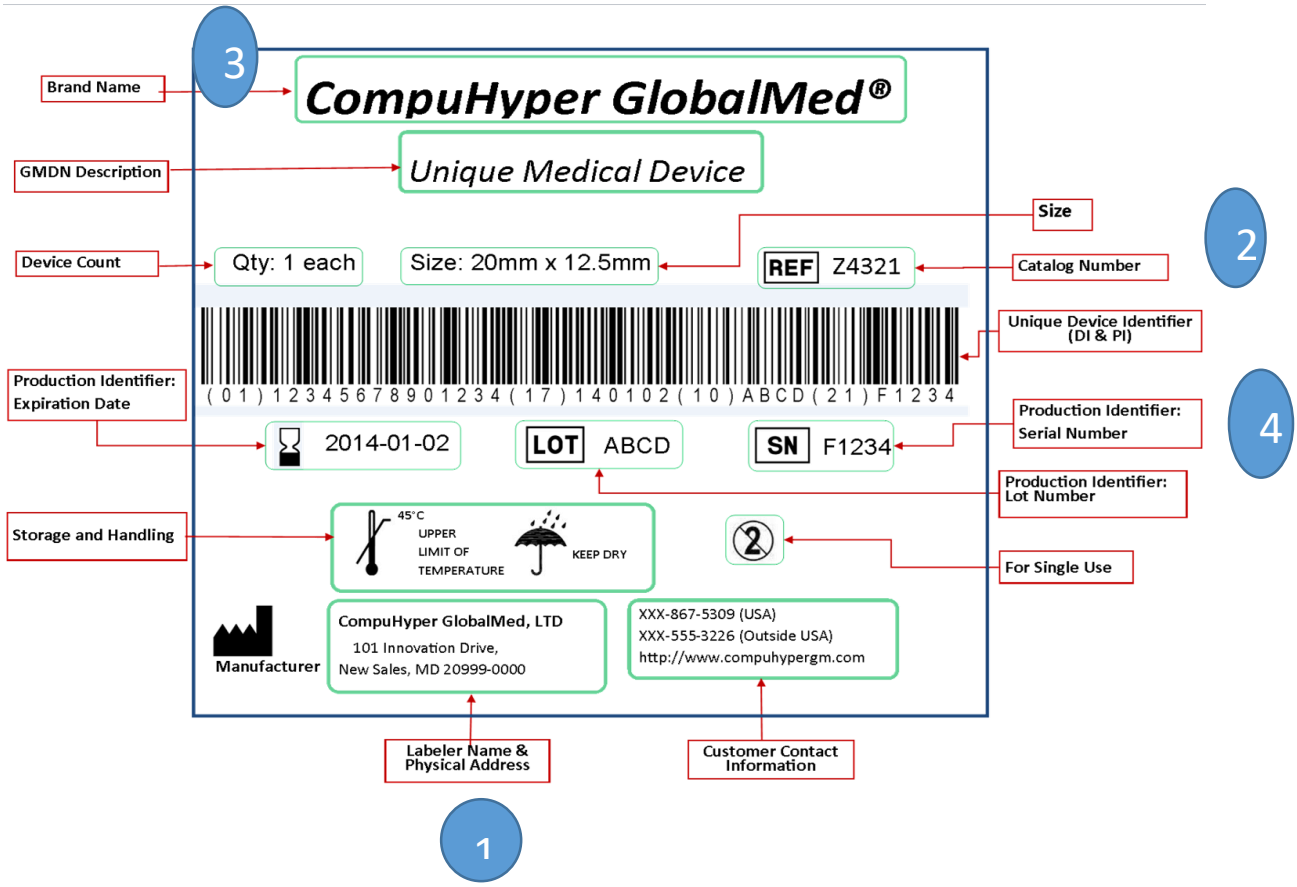
All HCF should provide **medical devices evaluation form** including full details about each **Active Medical device** (Any medical device that depends on a source of electrical energy or any source of power.) in the HCF as shown below:

Device Name	Model No.	Manufacturer	Installation Date	Country of Origin	Local Agent	Serial No.
3	2	1		1		4

In case of having more than one medical device of the same model, please provide the Serial Number of all the devices.

The medical devices evaluation form is available on NHRA website.

Where this information is already mentioned on the label of the medical device:



- **Phase 2 Providing the required QAC:**

1. Quality assurance Certificates (example: FDA, CE Mark, ISO 13485, SFDA), and the manufacturer name mentioned in the certificate should match with the name mentioned in the actual device.

2. Quality assurance Certificates should be verified by contacting the notifying body and attach verification.

- **Phase 3 Approved medical devices will be labeled and published on NHRA website:**

If all submitted documents are fullfield and verified as per NHRA Medical devices regulation. the healthcare facility will be inspected, and the approved medical devices will be registered, labeled and uploaded to NHRA website.

4. Requirements

1. A list of medical devices should be submitted by all healthcare facilities with clear description of medical device name, model, manufacturer name, serial number.
2. Valid NHRA Healthcare facility license.
3. Quality assurance certificate of the medical device. These certificates should be valid and with a scope matching with the function of the medical devices. (see verification guideline)
4. Invoice or OFOQ reference number should be provided for purchased medical devices since 2016.

5. Submission

Request of Permit to Use is done manually, applicant should send an email to "Medical_Devices@nhra.bh" to fix an appointment to submit the required documents.

Once the appointment is set the documents will be reviewed and assessed at the same time.

In case there are missing documents, the request will be given back to the applicant in order to fulfill the requirement.

If documents are fulfilled, request will be accepted and NHRA team will check:

- The validity of the submitted quality assurance certificates.
- The compatibility of the medical device with healthcare facility specialization.

If the above criteria match with the submitted list of medical devices, Permit to use will be granted to the healthcare facility and medical devices will be registered, labeled and listed on NHRA website.

If the medical devices not matching the facility specialization notification of rejection will be provided for the facility to take action accordingly either by adding the spatiality that matches with the device scope or device must be removed from the facility with immediate action.