الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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Medical Device Classification Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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1. Introduction

This guideline is intended to guide applicants through the medical device's classification criteria prior to importation or registration submission. Where classification rules and requirements are set to decide the risk level of a medical device in addition to whether the product is a medical device or not, these rules facilitate to the applicant the decision of submitting to comply with medical devices regulations, which may assist in creating a consistency in the classification method and decisions.

2. Important Rules

- Submission for classification of specific size doesn't mean that all other sizes have same classification.
- Classification Letter will be specifically related to the submitted product and it doesn't cover other similar sizes or lot numbers.
- Fees for Classification are applied, request review will be done after payment. ***(please refer to Medical Devices Fees Guideline).***
- It is not accepted to submit products with different intended use in one application, each request must contain products with same intended use and different packaging sizes or doses. (Maximum number of doses / sizes to be submitted in one application is **10**).
- Repeated submissions due to missing requirements is up to 3 times after that it will consider a new request with new fees payment.
- Timeline for reviewing the submitted documents after fees payment is 1 to 2 weeks.

2. Submission for Classification

In order to apply for classification, applicant should book an appointment using this link for submitting the required documents as per mentioned in classification form.

After completing fees payment, the documents will be reviewed by NHRA team, in case the product is classified as a medical device. applicant will receive a **classification letter** to be used for every importation request.

In case the product is not classified as a medical device, an email will be sent to the applicant clarifying the reasons of not classifying the product as a medical device.

3. Requirements of Classification.

1. **Free Sale Certificate OR Registration Certificate** issued from competent authority in country of origin classifies the product as a medical device.

2. **Free Sale Certificate OR Registration Certificate** issued from one of the following reference countries: (SFDA, USA, UK, Australia, Canada, Japan, Switzerland, Ireland, Denmark, Newzland, France, and Holland, Belgium.).

3. **Importer valid commercial record (CR).**

4. Attached the **relationship letter** between Legal Manufacturer & Physical Manufacturer.

5. **Quality Assurance Certificate** (ex: ISO 13485, CE Mark, FDA). It should be issued from a recognized certifying body, valid and verified. If product is class I and doesn't have CE a DOC from the manufacturer must be provided.

6. **Product intended use/ Artwork** issued from the manufacturer explaining the medical claim of the product.

7. **Product catalogue or leaflet** from the manufacturer explains the Mode of Action ***(how does the product act to perform the treatment).***

8. **Declaration from the manufacturer** shows the active ingredients percentage and it should not contradict with percentage for drug classification.

4. Classification based on level of risk

Medical devices are classified based on the level of risk inherent. Classification is determined based on a criteria applied to a vast range of different medical devices and technology at the time of manufacturing. These classifications are determined by the manufacturer to be considered by all healthcare regulations, organizations and users at all time.

Class	Meaning	Examples
I	Low Risk Medical Device	Electronic Thermometer, Surgical light, Surgical tube, etc…
IIa	Low to Medium risk device	Dental filling, ultrasound machine
IIb	Medium to High Risk Device	X-ray device, infusion pump
III	High Risk Device	Anesthesia, Ventilator, Heart lung machine, etc…

In-Vitro Diagnostic Medical Devices are classified based on the level of risk and clinical performance, as follows:

Class	Meaning	Examples
A	Low Individual Risk and Low Public Health Risk	Chemistry analyzer
B	Moderate Individual Risk and/or Low Public Health Risk	Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood Glucose self-testing
D	High Individual Risk and High Public Health Risk	HIV blood analyzer

In case of importing medical devices NOT manufactured in EU, please refer to below link for more information about classification rules of medical devices based on level of risk:

https://ec.europa.eu/health/system/files/2021-10/mdcg_2021-24_en_0.pdf

5. Classification rules based on product technical details

The following rules guides through the classification of medical device to decide whether the product is a medical device or not:

- **Primary Mode of Action**

  This is the Method by which the principal intended action is achieved. By other means, it is the therapeutic or diagnostic function which is considered to be the primary purpose of the product, which should be based on the mechanism of action.

- **Intended purpose of the product**

  Principal intended action of a product may be deduced from:

- The manufacturer's labelling and claims
- Scientific data regarding mechanism of action.

Note: (Although the manufacturer's claims are important, it is not possible to place the product in one or other category in contradiction with current scientific data.)

- **Method of product representation**

How the product is represented in the labeling, packaging, promotional materials and advertisements.

- Is the product represented in a manner suggesting it is used for treating, diagnosing, preventing, curing diseases, restoring, correcting or modifying organic functions in human beings
- how the product is likely to be understood by consumers
- A claim can be a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, pack insert, or through advertisements.

- **Mode of Action**

Typically the medical device function is fulfilled by physical means (including mechanical Action, physical barrier, replacement of or support to organs or body functions).

The Medical device does not achieve its action by pharmacological, immunological or metabolic means. (Refer to glossary).

A declaration from the manufacturer explaining how exactly the product acts on human body and achieve its intended use

- **The composition of the product**
  - Does the product's composition suggest it is an agent used for treating, diagnosing, preventing, curing diseases, restoring, correcting or modifying organic functions in human beings?
  - The presence of an ingredient at certain concentration may make the product pharmaceutical or a health product.

- **Other supporting details that can aid in the decision making process:**
  - Product must comply with international quality and safety standards represented in a quality assurance certificate issued by a recognized certifying body.
  - Product must be registered by the country of origin regulatory authority as a medical device.
  - Product details in an official document clarifying its technical details and image; ex: catalogue, leaflet or brochure.

6. Glossary

No.	Terminology	Definition
1.	**Medical device**	'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • Diagnosis, prevention, monitoring, treatment or alleviation of disease. • Diagnosis, monitoring, treatment, alleviation of or compensation for an injury. • Investigation, replacement, modification, or support of the anatomy or of a physiological process. • Supporting or sustaining life. • Control of conception. • Disinfection of medical devices. • Providing information by means of in vitro examination of specimens derived from the human body. And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
2.	**IVD (In-Vitro Diagnostic)**	• any Medical Device which is a reagent, reagent product, calibrator, control material, kit, instrument apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological state, or • concerning a congenital abnormality, or • to determine the safety and compatibility with potential recipients, or • To monitor therapeutic measures.

3.	**Pharmacological means**	In the context of the MDD and AIMD, is understood as an interaction between the Molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-Response correlation is indicative of a pharmacological effect.
4.	**Immunological means**	An action in or on the body by stimulation and/or mobilization of cells and/or products involved in a specific immune reaction.
5.	**Metabolic means**	An action which involves an Alteration, including stopping, starting or changing the speed of the normal chemical Processes participating in, and available for, normal body function. The fact that a product is itself metabolized does not imply that it achieves its principal intended action by metabolic means.

7. Annex

Please visit NHRA website www.nhra.bh for more information about the following forms and checklists

- **Product Classification Form**

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Classification%20Form%20april.pdf