nhra BAHRAIN

مملكة البحرين
Kingdom of Bahrain

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Medical -
Combined Medical Devices Registration

Guideline

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DEFINITIONS

Invasive Devices: a device in which, part of it or all of it, penetrates inside the body.

Active Implantable Medical Device (AIMD): a device intended to be totally introduced into the human body to be part of it as a whole.

Active Medical Device: any medical device that depends on a source of electrical energy or any source of power.

Adverse Event: any problem that can or caused an injury or death to the patient or the user.

FDA: Food and Drug Administration

WHO: World Health Organization

Importer: means any natural or legal person in the supply chain who is the first to make medical device, manufactured in another jurisdiction, available in Bahrain.

Manufacturer: means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.

OFOQ: an online system of shipment clearance managed by customs in Bahrain. It can be visit through the following website: http://www.ofoq.gov.bh/
Hs code: Harmonized system code used internationally for customs purposes

CE mark: Conformity European" which literately means "European Conformity". The term initially used was "EC Mark" and it was officially replaced by "CE Marking" in the Directive 93/68/EEC in 1993, declaring that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislations.

GHTF: a voluntary group of representatives from national medical device regulatory authorities (such as the U.S. Food and Drug Administration (FDA)) and the members of the medical device industry. The representatives from its five founding members (the European Union, the United States, Canada, Japan and Australia) actively regulate medical devices using their own unique regulatory framework.

GMP: Good manufacturing product certificate issued by the regulatory authority in the country of origin

1. INTRODUCTION

The NHRA works to protect the public and promote quality and patient safety setting appropriate guidelines and policies in line with international best practice. As medical devices represent a vast part of patient care, therefore it is vital to provide a harmonized regulatory system to ensure the quality and safety of all medical devices imported and prevents the entrance of ineffective or unsafe devices to Bahrain market.

This guideline was laid down to provide safeguard measures for Patients, appliers, users and third parties against possible hazards they may be exposed to while operating such devices. Medical device control and regulation in Bahrain is supervised by National Health regulation Authority (NHRA) which grants all imported medical devices a certificate of importing based on international standards and defined process covered in this document. Any medical device intended to be placed in the market, should be governed by this guideline. Accessories or spare parts associated with a medical device shall be assessed and authorized in accordance with this guideline.

2. MEDICAL-COMBINED MEDICAL- DEVICE DEFINITION:

Medical Device: means all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability that does not achieve its action by pharmacological, immunological or metabolic means.

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.

Combined medical device: is a medical device that is mixed with pharmaceutical or chemical or biological materials and its principle intended action is physical or mechanical.

3. PURPOSE OF THIS DOCUMENT

- Set a single guideline for all medical devices manufacturer, local agent, importers or distributors. Guiding through proper rules and regulations to consider before and after importing a medical device to the Kingdom of Bahrain market.
- Standardize the process and requirement of medical devices registration and importation.
- Control the quality of medical devices imported to Bahrain medical field, to ensure patient and users safety.
- To set the fine line between pharmaceuticals and medical devices, which clarifies the followings:
  - Combined medical devices with pharmaceutical ingredients.
  - Pharmaceutical products which is classified as medical devices in the Kingdom of Bahrain.
  - Non pharmaceutical nor medical devices but must be monitored by NHRA medical devices with medicinal ingredients; such as IVD medical devices.

4. MEDICAL COMBINED MEDICAL DEVICES RULES AND REGULATION

This Medical Devices Rules and Regulations have been referred to from various international guidelines including: FDA, WHO, SFDA, Australian department of health and the European regulation of medical devices Violation to one or the whole requirement published in this document will be considered as a non- compliance to the national regulation of medical devices importation. This shall constitute a legitimate factor to reject the importation of the medical device into Bahrain port.

4.1 Classification of medical devices

All medical devices are registered in a unique code in the Universal\Global Medical Device Nomenclature System (UMDNS\GMDNS) which is a standard international nomenclature and computer coding system for medical devices, it is utilized in NHRA for the same purpose.

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, for example; the intended use, the duration of contact with the body and the degree of invasiveness. These classifications are determined by the manufacturer to be considered by all healthcare regulatory, organizations and users at all time. Bahrain classification criteria have been adopted from internationally developed classification category as mention in Annex 1. NHRA regulates the importation of only Class II and III.

Classification of accessories or spare parts shall be done according to its main primary intended use thus the core medical device class type. When a medical device classification is applicable to several rules, the highest risk class applies. Classification is done based on the intended use not the accidental use. Classification does not change if the device was used in method not intended in few cases where certain medical devices are not classified.

Software interrelated to a medical device, falls under the same classification. However software that has no influence on a medical device intended use is classified individually. Similarly the multi-functional equipment, such as printers, are classified as medical device if the manufacturer identify them in the market with a medical device purpose, otherwise they are not considered as a medical device.

4.2 Classification of combined medical devices

1. All products with pharmaceuticals HS codes (see Annex. 4), must comply with classification criteria below first, except for those that are used for diagnostic and are not in a direct contact with the internal body organs.
2. The criteria of Medical devices classification are as below, where product must be in compliance with all criteria in order to classify the product as medical device:
    i) Product is classified in country of origin as medical devices and does not contain pharmaceutical ingredients.
    ii) GHTF two founding member jurisdictions or SFDA classifies the product as a medical device.
    iii) The product is FDA approved or CE marked.
    iv) Product principle intended action is physical or mechanical.
3. If the above criteria are not met, the item will then be sent to the classification team for assessment based on the recoginized standards.
4. The product classification result will be applied on all similar products from other companies containing similar ingredients concentration and dosage for same indication.
5. Product classified as medical device in the country of origin but has pharmaceutical ingredients will be assessed based on the pharmaceutical and health product list established on the NHRA web site regardless of the percentage, if there were no pharmaceutical ingredients, the product will then be classified as medical device, otherwise it will be directed to classification team for assessment.
6. Combined medical device requirement is mentioned in 4.3.
7. All Combined Medical devices registered before April 2016 will be reviewed once are tended to be renewed to match with the new classification requirement stated above.
8. All registered combined medical devices that were classified by the product classification team members, can be renewed without reclassification.

4.3 Medical combined medical device registration

Any medical device placed in Bahrain Market should be first registered by submitting the application and required documents (Annex 2 Medical device registration requirement)(Annex 3 medical device registration form) once all prescribed data are submitted , it will be evaluated and listed in the registered medical devices list along with its respective local agent. Manufacturers with no local agent in Bahrain must appoint a registered Authorized Representative with a valid Medical Device Distribution certification. All local agents Should be registered in NHRA as a Medical Device Distributor initially to be added in the supplier list in order to request for a medical device registration, registration forms is available on NHRA website, no healthcare organization i.e. Hospitals, Health centers or Clinics are authorized to import medical devices for marketing purpose. Once a supplier is listed, a company registration file will be created to be linked whenever a new medical device is to be registered. A single type of a medical device need to be registered with a validity of 5 years or based on the date of expiration of the quality assurance certificate, whichever precede, to validate the continuity of the medical device, application for renewal of registration should be done at least 90 days before its expiry date.

Acceptance of the medical device registration will be based on the availability of documents required (Annex 2 Medical device registration requirement). All documents provided should be in Arabic or English only. Once application has been done it will be evaluated then either accepted and registered in Bahrain medical devices list or further data/ samples will be requested; a period of Six months will be given from the time a written query notification has been raised, if no response has been done then the application could be subject to cancellation or rejection For the time being there are no fees for registration, please make sureyou visit our website for further updates.

The registration maybe suspended or revoked by NHRA based on the followings:

- Medical devices with pharmaceutical HS code will be registered manually; since OFOQ method selected for Medical Devices is not monitoring each shipment as decided for pharmaceuticals OFOQ monitoring process.
- All Medical devices registered before April 2016 will be reviewed once are tended to be renewed to match with the new requirement.
- All registered medical devices that were classified by the product classification team members, can be renewed without reclassification.
- Upon Supplier request.
- The requirements previously agreed have not been met after registering the device.

- At the time of assessment and monitoring the device given data are not similar to the actual device.
- The medical device was found harmful and\ or unsafe.

The registrant will receive a notification period of 30 days in written. Objection can be formally submitted in written and will be overlooked by the management. Modification to the registration details should be reported within 15 working days of the time it occur along with documents pertaining to the change reported.

4.4 Medical device importation

All medical devices must be first approved prior to importation. The following requirements should be full filled in order to grant the approval of importation:

1. Cover letter from the importer; should be stamped signed, dated, includes the GMDNS /UMDNS, stating the information of therequest and to whom it will be supplied..
2. Commercial invoice; including the HS code, manufacturer name, clear description of the item and its origin.
3. Country of origin certificate or SFDA (Saudi Food and Drug Administration) or a competent authority registration or free sale cetificate (FAC).
4. Quality managements system certificates (ISO 9001, FSC)
5. Quality Assurance Certificates (FDA, CE Mark, ISO 13485.)
6. GMP or ISO 13485 for combined medical devices.
7. Product label and artwork; stating the intended used and as per the international standards recognized.
8. Classification based on the level of risk; Class (I, II, II, A, B, C, D).
9. Authorization letter for combined medical onlydevices only; signed and stamped by the manufacturer.
10. Commercial record (CR) for medical device import/ export granted from the Ministry of industry and commerce (MOIC).
11. Product technical specification; for certain devices a further details might be requested.

All imported medical devices should be labeled by the manufacturer clearly; no used- refurbished devices are allowed to be imported into Bahrain.Medical devices that are exported from Bahrain for a donation purpose should comply with documents requirement mentioned in Annex 5.

Medical devices that are exported from Bahrain to be imported again for maintenance purpose should go proper channel of documentation and must have a pre importation permit sing and stamped by NHRA, see Annex 6.

4.5 Medical Device Local Agent

All medical devices manufacturers should authorize a local agent of a product type, the local agent will be representing the manufacturer in Bahrain and should be legally appointed in a written contract signed and stamp by the manufacturer. Safety and quality of service provided by the medical device will be under the responsibility of the local agent from the time of importatio. All local agent must register with NHRA first using the form in the website.

Once the manufacturer products are registered, through the right process, along with its respective local agent, the authorized representative is responsible to:

- Register any new product from the same manufacturer before importation.
- Providing a general company profile with all the details of the manufacturer (name, address, and number of employee, contact details, type and class of medical devices distributed in Bahrain, any specific manufacturer process and risks).
- Update any changes related to the product or the manufacturer.
- Ensure medical device is stored properly in certified medical store.
- Ensure medical devices are installed in a register healthcare facility by NHRA
- Ensure user awareness of safety precautions before utilizing the device.
- Provide any documents or information further requested by NHRA.
- Provide the status of device distribution.
- Maintain a post marketing surveillance general plan (i.e. maintain compliant handling procedures and records, risk assessment, alerts, recalls, manuals, precautions and training).
- Providing pre-installation requirements of active medical devices installation, in order to issue operating permit.

ANNEX 1: MEDICAL DEVICE CLASSIFICATION

Medical devices are classified based on the level of risk .The kingdom of Bahrain medical devices classification categories are as shown in the table below:

Class	Meaning	Examples
I	Low Risk Medical Device	Electronic Thermometer, Surgical light, Surgical tube, etc…
II	Medium Risk Device	EEG, ECG, Endoscopes, etc….
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

ANNEX 2: MEDICAL DEVICE REGISTRATION REQUIREMENT

The following list of documents and data are required at the time of medical device initial registration. The registration form in NHRA website should be filled along with the supporting documents.

Required Document	Device class applied	Remarks
Application form	All	Signed and stamped, latest form from the website
Commercial registration (CR) granted by Bahrain Ministry of industry and Commerce	All	Should be eligible for importing medical devices
Quality managements system certificates and declaration of conformity	All	(GMP, ISO, FSC, Full quality assurance, FDA, CE Marked, etc.)
Manufacturer authorization letter or contract of being the local distributor	All	Specifying the exact medical device category or model
Device distribution records	All except Class I\ Im\ Is and Class A	List of countries, it is marketed with their regulatory approval
Device user manual	All	Not the device Catalogue
Labeling	All	Must include: device Name, manufacturer details, expiry date and type of use (only in single use device) should be (EN,AR)
Safety and risk assessment data	Class III/ AIMD/C and D	Proof of device effectiveness and assuring its safety I.e. recalls or adverse event, year it was launched into the market, etc…
Special requirement based on the devices imported could be further requested	All	Can be subject to containing radioactive or biological materials.

ANNEX 3: MEDICAL DEVICE REGISTRATION FORM

PLEASE VISIT THE WEBSITE TO VIEW THE UPDATED FORM

ANNEX 4: HS CODE LIST OF COMBINED MEDICAL DEVICE (MANUAL APPROVAL)

قائمة البنود الجمركية الخاصة بالهيئة للمستلزمات الطبية المدمجة بالمواد الصيدلانية أو الكميائية (للموافقة اليدوية)

29362100	29372300	30021000	29372900
29362200	29362600	29371100	29375000
29362300	29362700	29371200	29379000
29362400	29362800	29371900	30012000
33049990	29362900	29372100	30031000
29369000	29372200	30019000	30044000
30022000	30032000	30041000	30045000
30029010	30033100	30042000	30049010
30029020	30033900	30043100	30049090
30029090	30034000	30043200	30063000
30039000	30043900	30066000	

MEDICAL DEVICES HS CODE (ONLINE APPROVAL - OFOQ)

قائمة البنود الجمركية الخاصة بالهيئة للمستلزمات الطبية (للموافقة على برنامج افق)

HS code	HS code	HS code	HS code
40 17 00 20	90 18 13 00	94 02 10 10	90 21 50 00
87 05 90 80	90 18 12 00	90 18 90 90	90 21 40 00
84 19 20 00	90 18 11 00	90 18 90 60	90 21 39 10
90 06 30 00	90 21 10 20	90 18 90 50	90 21 39 20
90 18 39 90	90 21 39 90	90 18 90 40	90 25 80 20
90 18 39 30	90 21 31 00	90 18 90 30	90 22 90 00
90 18 39 20	90 21 29 00	90 18 90 20	90 01 30 00
90 18 39 10	90 21 21 00	90 18 90 10	90 21 90 90
90 18 32 00	90 21 10 90	90 18 50 90	90 26 10 00
90 18 31 90	90 21 10 40	90 18 50 20	28 44 30 10
90 18 31 40	90 22 30 00	90 18 50 10	28 44 30 90
90 18 31 30	90 22 29 00	90 18 49 90	28 44 40 10
90 18 31 20	90 22 21 00	90 18 49 20	28 44 40 90
90 18 20 00	90 22 19 90	90 18 41 00	28 44 50 00
90 18 19 90	90 22 14 00	90 19 20 00	28 45 10 00
90 18 19 20	90 22 13 00	90 19 10 00	28 44 20 10
90 18 19 10	90 22 12 00	90 21 90 90	84 01 10 00
90 18 14 00	90 27 80 10	90 21 90 10	84 01 40 00
28 44 10 10	84 01 20 00	90 30 10 00	

ANNEX 5 :MEDICAL DEVICE DONATION/EXPORTATION REQUIRED DOCUMENTS:

Required Document	Remarks
Letter from the donor or exporter	Stating the initial source of this device, donated or exported to which country
Quality managements system certificates and declaration of conformity	(GMP, ISO, FSC, Full quality assurance, FDA, CE Marked, etc.)
Maintenance and quality check records	For donated and\or used medical device
Device user manual	Not device Catalogue
Labeling	Must include: device Name, manufacturer details, expiry date and type of use (only in single use device)
Safety and risk assessment data	Proof of device effectiveness and assuring its safety
Special requirement based on the devices imported could be further requested	Can be subject to containing radioactive or biological materials or based on the device status.

ANNEX 6: MEDICAL DEVICE EXPORTED FOR MAINTENANCE (AND WILL BE IMPORTED AGAIN)
REQUIRED DOCUMENTS:

- Letter from the local agent including the following:
- Device Name, Description, manufacturer, model and Serial Number
- Device registration reference number
- Breakdown report at the time of exportation; stating the fault
- Repairing and quality check letter from the manufacturer

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