مملكة البحرين
Kingdom of Bahrain

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

# Medical Devices Regulation Guidelines

## Ver 2.0

# Contents

## INTRODUCTION

The **National Health regulation Authority (NHRA)** works to protect the public and promote quality and patient safety by setting appropriate guidelines and policies in line with international guidelines and best practice. As medical devices represent a vast part of patient care, it is vital to provide a harmonized regulatory system to ensure the quality and safety of all medical devices imported and prevent 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 regulations in Bahrain are supervised by **NHRA** which grants all medical devices suppliers the permission of importation 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.

***This document is subject to frequent updates, therefore please use it to get general overview of Bahrain medical device regulations, however for requirements and details provided kindly make sure to visit the website to be updated with the latest information.***

## PURPOSE OF THIS GUIDELINE

- Set a single guideline for all medical devices manufacturer, local agent, importers, users and 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.

- Regulates Medical Devices **Pre - On -Post** marketing practices.

# MEDICAL DEVICES RULES AND REGULATIONS

This Guideline have been adapted from various international Regulations including:

1. **WHO** World Healthcare Organization
2. **FDA** Food and Drug Association
3. **The European Commission**
4. **SFDA** Saudi Food and Drug Administration
5. **TGA** Australian Government
6. **MHRA** Medicines and Healthcare Products Regulating Agency
7. **ISO** International Standards Organization
8. **AHWP** Asian Harmonized Working Party
9. **PMDA** Pharmaceuticals and Medical Device Agency

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, or any legal actions stated in the Kingdom of Bahrain Rules and Regulations.

**For more information about NHRA regulations and guidelines explained in this guidelines please visit**: https://www.nhra.bh/Departments/MDR/

## GENERAL RULES

1- NHRA regulates the importation of medical devices Class II and III only; which is mapped to the HS codes and listed on NHRA website to facilitate the importation approval for importers.

2- Health care facilities, Importer, clearance agents, regulatory affairs can apply on OFOQ.

3- Request submission on "OFOQ" must be before shipping the item in order to grant pre-approval before shipment arrives at Bahrain port.

4- All imported medical device should be installed or marketed to a licensed healthcare facility.

5- Importation of **used/refurbished medical device** is **prohibited**.

6- Maximum number of samples or for personal use allowed for importation without QAC is 3 only, the term of "sample" should be stated in the invoice.

7- Importation of Combined medical devices must be done through authorized representative from the legal manufacturer

8- If the product in the submitted request is registered as a medical device in Saudi food and drug and has a **valid SFDA** (Medical Device Marketing authorization) then it can be replaced for QAC & QMC and the request will be approved directly.

9- One of the following **15 reference countries** should classify the product as a medical device **(Saudi Arabia, America, Australia, Canada, Japan, New Zealand, Switzerland, United Kingdom, France, Ireland, Netherlands, Denmark, and Belgium).see Annex 1**

10- If the product classification is **class I, Non sterile** and made in one of the European Countries then a **Declaration of conformity** document from the manufacturer should be submitted with the request and can be replaced for QAC & QMC.

11- In case of importing **Cold chain products**, i.e. (2-8 ℃), the temperature data logger must be provided to NHRA to ensure good storage conditions; from the port of shipping "the manufacturer", to Bahrain ports. Conditional Preapproval will be granted before the shipment arrives, given that the importer does not distribute the devices until NHRA approves the data logger after the shipment arrives.

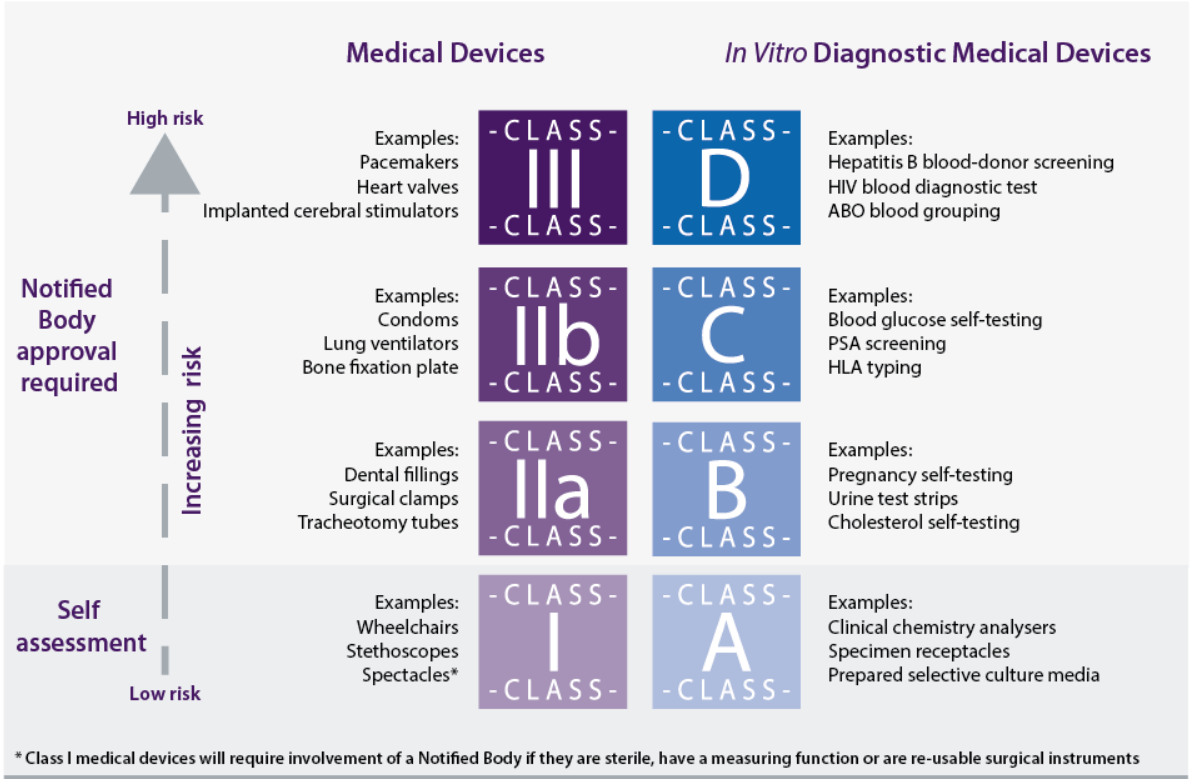
12- **Registration** is not linked to importation process whether HS code is regulated by NHRA or not.
13- Registration of medical devices is done after the registration of the authorized representative in NHRA.
14- All medical devices must be registered class I, II and III.
15- Only authorized representative can apply for medical device register.
16- In some shipments sample will be requested for evaluation, where approval cannot be granted until the shipment arrives, in these case the sample should be provided **sealed by customs** and should match with document provided in order to clear the shipment.

# CLASSIFICATION OF MEDICAL DEVICES 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, for example; the intended use, the duration of contact with the body and the degree of invasiveness.

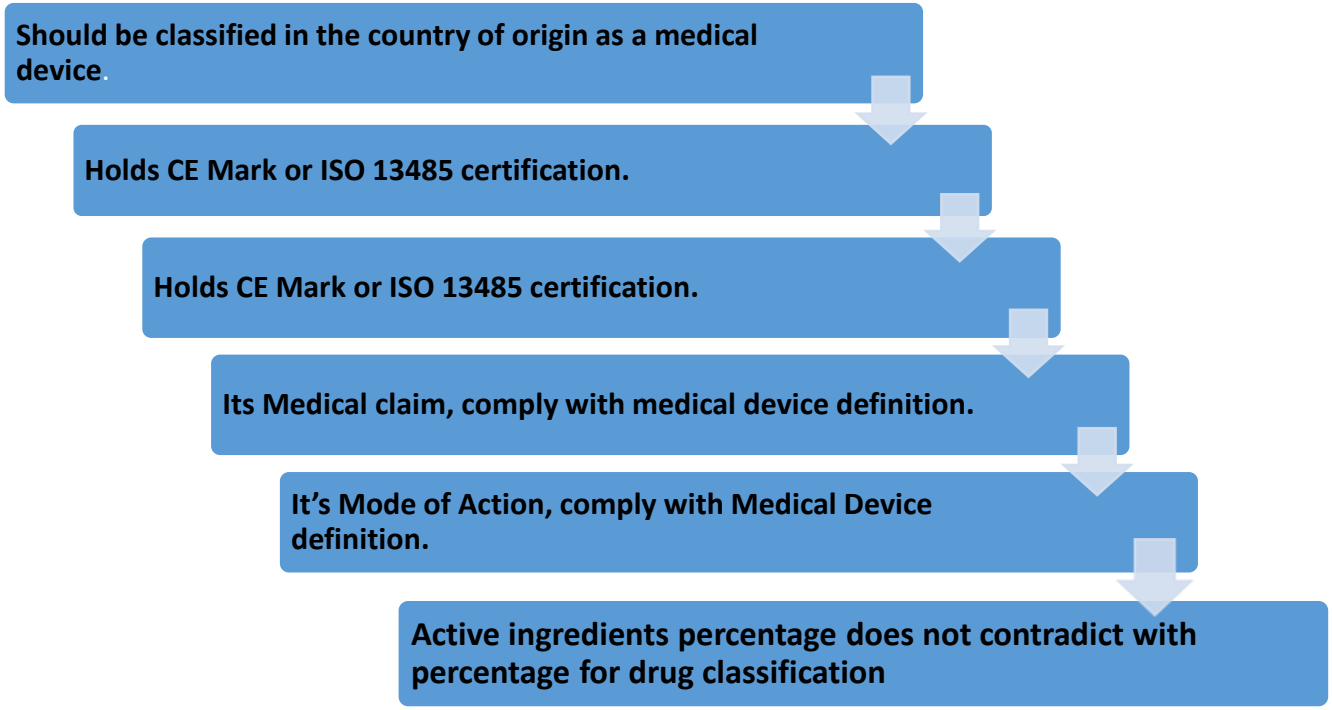
These classifications are determined by the manufacturer to be considered by all healthcare regulators, organizations and users at all time.

The Kingdom of Bahrain medical devices classification categories are as shown in the table below:



## CLASSIFICATION OF MEDICAL DEVICES BASED ON ITS MODE OF ACTION:

1. If the product was not classified as a medical device in one of the regulatory authorities of **reference countries**, the following criteria must be full filled:




2. If the above criteria are not met, the item will then be sent to the **Classification Team** for assessment based on the recognized standards.

3. If the product is classified as Medical Device but it holds a Pharmaceutical HS code, the requirements of **Combined Medical devices** must be full filled prior to importation.
***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.***

## AUTHORIZED REPRESENTATIVE REGISTRATION

All Medical Devices Importers and Authorized Representatives in Kingdom of Bahrain should be registered with NHRA. The aim of this registration is to facilitate the importation process, all registered companies will be listed on NHRA website for marketing purposes and will be able to participate in national tenders.

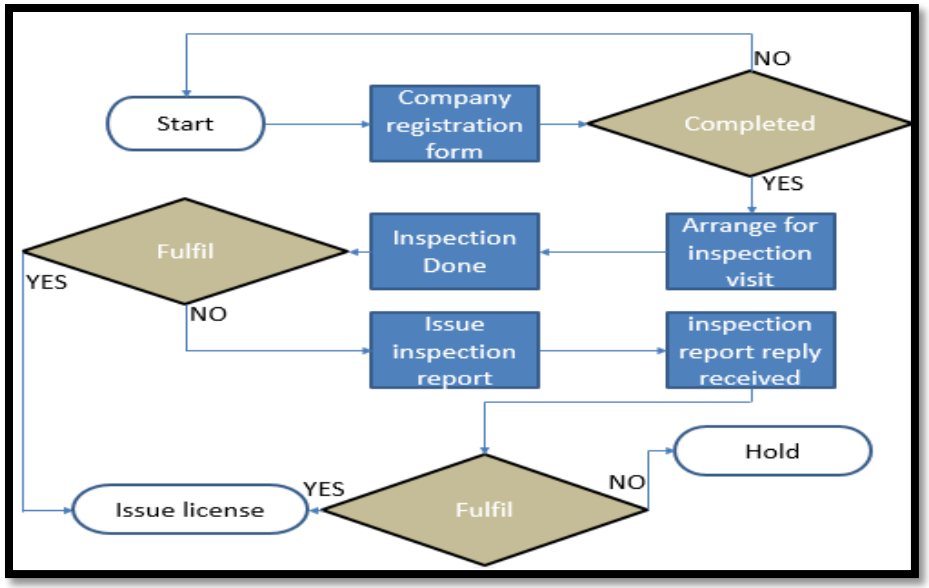
The required documents should be submitted manually are:

| No. | Required Documents |
|---|---|
| 1 | Registration Form. |
| 2 | Valid Commercial Registration (CR). |
| 3 | Authorization Letters OR Agreements, valid, signed and stamped by the manufacturer |
| 4 | To have a system (Software or Excel sheet) to monitor and trace the distribution of medical devices, maintenance, recall and adverse events. |
| 5 | Policy of the company including Distribution record, Maintenance, complain handling, Recall and Adverse event procedures and it should be mentioned that it is being reported to NHRA… |
| 6 | List of company staff with the CVs and qualifications and medical training certificates if any. |
| 7 | List of products with clear scope of service (ex: dental, lab, surgical, ortho…). |

## Commercial Registration Certificate (CR):

New importers who are planning to open new companies should obtain **NHRA approval** to have a commercial registration (CR) with an activity **"Sale/Trade in other machinery and equipment and parts-Medical Devices supplies and Related Parts"** that allow them to import medical devices.

Applicant should apply for new CR on **Sijilat website** and choose **code 4659 for medical devices importation activity**, the process is similar to the submission of company registration request but the requirements are minimized to:




| Required Documents | |
|---|---|
| **1** | Company Registration Form. |
| **2** | Policy of the company clarifying the procedures that should be implemented in medical devices importation including the distribution process, complaint handling, recall and adverse events. |
| **3** | System (software OR excel sheet) for tracing and monitoring the imported and marketed medical devices including device name, model, lot number, serial number, manufacturer name and end-user details. |

Applicant should submit the above requirements **manually**, if the requirements are full filed, an inspection visit to the company will be scheduled to check that NHRA requirements are implemented then the CR will be issued to **Sijilat** website.

# MEDICAL DEVICES REGISTRATION

Registration of medical devices is done after ensuring the compliance of medical devices with international standards of quality and safety. Only **NHRA registered authorized representative** are allowed to register their medical devices.

For harmonization purposes the SFDA certificate is considered by NHRA as a fast track to register the device, therefore medical devices that are already registered in SFDA can obtain the certificate in maximum 4 working weeks given that all requirements are provided as per NHRA regulations, otherwise if the device is not registered in SFDA the process will be done during 8 working weeks.

**There are two process for Medical Device Registration:**

| | |
|---|---|
| **SFDA** | Which means medical devices that are registered in Saudi Food and Drug Administration. (have **MDMA certificate**) |
| **Non-SFDA** | Medical devices that are **NOT** registered in Saudi Food and Drug Administration. |

***Each process has a checklist including the required documents and a form which should be submitted manually through an appointment.***

The **validity** of the medical device license is 3 years in case of SFDA medical devices and for Non-SFDA medical devices the validity will be according to the submitted quality assurance certificate expiry date.

***The renewal of medical device license should be 9 months before expiry date.***

## Variation

The medical device license can be amended during the validity period according to the type of variations done in device details which can be:

### Minor Variation

Any modification that does not affect safety or performance of a medical device which obtained a marketing authorization

### Major Variation

Any modification that does affect safety or performance of a medical device, such as changing the physical manufacture location, changing detailed specification of the device.

Minor changes can be amended via an official letter from the manufacturer, however Major changes means that medical devices registration form must be submitted and the previous license will be cancelled.

# MEDICAL DEVICE IMPORTATION

This guideline is intended to highlight the process and requirements to get the pre-approval of medical devices importation through OFOQ system. Starting from 2016 all medical devices with the HS code listed under ministry code **2251** must be granted with NHRA pre-approval by submitting the required documents on OFOQ system.

The required documents to be uploaded on OFOQ for medical device importation are:

| No. | Required Documents |
|---|---|
| 1 | Invoice including HS Code/ Manufacturer Name & Country of Origin. |
| 2 | Country of origin Certificate or (Free sale certificates / competent authority registration certificates. |
| 3 | Product quality assurance certificate, (example: SFDA, FDA, CE or ISO 13485), it should be verified and issued by a recognized certifying body. |
| 4 | Catalog and it should contain the imported item part number. |
| **Required documents must be provided in the following cases:** | |
| 1 | Authorization letter from the manufacturer to invoice issuer:<br>**If the invoice is issued from third party.** |
| 2 | Declaration of conformity issued from the manufacturer containing full details about shipment and stating it will be delivered to Bahrain market through a third party:<br>**In case the invoice is not issued from manufacturer or Authorized Representative.** |
| 3 | Relationship letter from QAC holder to the invoice issuer:<br>**In case the invoice is not issued from manufacturer.** |
| 4 | Samples sealed from customs:<br>**In case of importing contact lenses OR surgical instruments OR upon NHRA request.** |

**All documents must be in Arabic or English only.**

***If the medical device is registered in NHRA then only the medical device license with the invoice will be submitted on OFOQ to obtain pre-approval to clear the shipment from customs.***

## Process of OFOQ Application

For new applicants, In order to be able to use "OFOQ" it is required to have a user name and password, this is can be done by sending a form available on the website http://www.ofoq.gov.bh to the customs through the email: customs.licensing@customs.gov.bh

## Importation of Combined Medical Devices.

This guideline is intended to guide all importers through the process of getting combined medical device (CMD) importation pre-approval **manually, with pre-fixed appointment**.

The required documents to obtain the importation permit for combined medical devices:

| No. | Required Documents |
|---|---|
| 1 | Free Sale Certificate OR Registration Certificate from Regulatory 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, Holland, Belgium.) |
| 3 | Invoice with clear item description including HS Code/ Manufacturer Name & Country of Origin. |
| 4 | Importer valid commercial record (CR). |
| 5 | Authorization letter from the legal manufacturer to the authorized representative to market the device in the kingdom of Bahrain. |
| 7 | (GMP) certificates from the Regulatory Authority in the Country of origin to the legal manufacturer OR Quality management's system certificates (example: ISO 13485) from a recognized certifying body. |
| 8 | Quality assurance Certificates (example: FDA, CE Mark, ISO 13485) from a recognized certifying body along with a verification of its validity from the issuer. |
| 9 | Product intended use /Product Art work. |
| 10 | Device Classification based on level of Risk. (I, II, III…). |
| 11 | Product GMDNS Code Description. *Global Medical Device Nomenclature System.* |

## Quality Assurance Certificate

All Medical Devices that are being imported and marketed in the Kingdom of Bahrain should have a **Quality Assurance Certificate (QAC)** to ensure a good manufacturing process as per global standards and ensure patient safety and public health.

To check if your certificates are issued by a recognized please visit **"European Commission"** website for **CE certificate** and **"IAF"** website for **ISO certificate.**

**European Commission website**

http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.main

**IAF website**

https://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

***NHRA should be in the mailing loop if verification is done through mail, if not, a capture of certificate validity from certifying body website should be attached in the request.***

## Importation of Medical Devices with Biological Material

The process and requirements of importing medical devices made from biological materials differs from the active and combined medical device importation due to the fact of biological materials sources declaration needs and even the transportation and the use limitations.

The required documents to get the pre-approval for importation must be submitted manually:

| No. | Requirements |
|---|---|
| 1 | Official letter from the end-user stating the quantity needed for transplantation and not for storage. |
| 2 | Declaration of conformity issued from the manufacturer stating that the product is classified as a Bio-therapeutic medical device. |
| 3 | Invoice and LPO. |
| 4 | Country of Origin Certificate of the product issued from the competent authority. |
| 5 | Information about the imported medical device. |
| 6 | Country of origin registration certificate of the center exporting the biological materials, center should be recognized by international agencies. Or Registration Certificate issued from Saudi Center for Organ Transplantation. |

### Medical Devices Personal Importation

In order to obtain the pre-approval for importing personnel use medical devices (For example, contact lenses, blood pressure monitor, home use blood glucose meter…etc.), applicant should provide the following required documents either manual or through OFOQ system according to **HS Code**:

| No. | Requirements |
|---|---|
| 1 | Healthcare professional prescription to ensure that the purchased medical device suits health condition. |
| 2 | The invoice, and the quantity should not exceed 3 devices, or 3 months adequate supply. |
| 3 | The quality assurance certificate to ensure safety and good manufacturing as per international standards. |
| 4 | Medical device catalogue to ensure it is for personnel use and doesn't require to be used by a qualified person (when needed). |

## RECALL AND FIELD SAFETY NOTICE

Manufacturers or their representatives may sometimes need to undertake corrective or preventative action in relation to their medical devices. These include safety related field corrective actions taken by the manufacturer to reduce the risk of harm to patients, operators or others and/or to minimize the re-occurrence of the event.

When a Recall/ field safety notice is issued by a medical device manufacturer to the Kingdom of Bahrain market, NHRA seek confirmation from the local agent that the required action has been completed. Users of the affected medical devices should review the relevant information and follow the guidance provided.

# PERMISSION TO USE

All licensed Healthcare facilities should obtain the **Permission 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 required documents are:

| No. | Required Documents |
|---|---|
| 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. |

# GLOSSARY

| Terminology | Definition |
|---|---|
| **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:<br>• Diagnosis, prevention, monitoring, treatment or alleviation of disease,<br>• Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,<br>• Investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>• Supporting or sustaining life,<br>• Control of conception,<br>• Disinfection of medical devices,<br>• Providing information by means of in vitro examination of specimens derived from the human body;<br>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. |
| **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:<br>• Concerning a physiological or pathological state, or<br>• Concerning a congenital abnormality, or<br>• To determine the safety and compatibility with potential recipients, or<br>• To monitor therapeutic measures. |

| | |
|---|---|
| **Combined medical device** | Medical devices combined with pharmaceutical and/or chemicals and/or Biological materials and does not achieve its action by pharmacological, immunological or metabolic means, used for prevention of illness. |
| **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. |
| **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. |
| **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. |
| **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. |

| | |
|---|---|
| **FDA** | **Food and Drug Administration** , it is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs(medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products. |
| **EU** | European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. |
| **SFDA** | **Saudi Food and Drug Authority**, which regulates, oversee, and control food, drug, medical devices, as well as to set mandatory standard specifications thereof, whether they are imported or locally manufactured. |
| **WHO** | The World Health Organization (**WHO**) is a specialized agency of the United Nations that is concerned with international public health. |
| **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. |
| **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. |
| **ISO (International Organization for Standardization)** | Quality management systems – Requirements for regulatory purposes, is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. |
| **GMP** | Good manufacturing product certificate issued by the regulatory authority in the country of origin. |

Annex 1: Reference countries

| Reference Country | Regulatory Authority |
|---|---|
| Saudi Arabia | Saudi Food And Drug **SFDA** |
| USA | US Food and Drug **FDA** |
| Australia | Therapeutic Goods Administration **TGA** |
| Canada | Canada's Food and Drugs Act and Regulations |
| Japan | Pharmaceuticals and Medical Devices Agency **PMDA** |
| New Zealand | the New Zealand Medicine and Medical Devices Safety Authority **MEDSAFE** |
| Switzerland | **Swissmedic** |
| United Kingdom | Medicines and Healthcare products Regulatory Agency **MHRA** |
| France | **ANSM / CCI Paris** |
| Ireland | The Health Product Regulatory Authority **HPRA** |
| Netherland | The Dutch Healthcare Authority **NZa** |
| Denmark | Danish Medicines Agency |
| Belgium | Federal Agency for Medicines and Health Products **Famhp** |