Online Medical Device importation approval Guideline

(OFOQ)

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Definitions

- **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:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
3. Investigation, replacement, modification, or support of the anatomy or of a physiological process,
4. Supporting or sustaining life,
5. Control of conception,
6. Disinfection of medical devices,
7. Providing information by means of in vitro examination of specimens derived from the human body.
8. 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.

- **OFOQ:** It is a web-based software developed by Customs Affairs - Ministry of Interior (MOI) allowing all the governmental sector to grant pre-approvals of shipments requests submitted by importers, on one page to better monitor and control all shipments accessing the Kingdom of Bahrain ports**.**

2. Introduction

With reference to **Decision (48) 2020, Article (7)** "The device and medical product must be used in healthcare facilities licensed by the Authority, and it is not permissible to manufacture or introduce any medical device and product to the Kingdom or put it in its markets or use it, except after registering with the Authority and obtaining written permission to market from Authority, and it is not permissible to transfer, resell, dispose of or export any medical device and product without the written approval of the Authority".

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 (NHRA medical devices) must hold an online license to be cleared by customs. All medical devices with HS codes regulated by NHRA must be granted with pre-approval by first submitting the required documents on OFOQ system.

3. Requirements

The below required documents of medical devices importation should be uploaded on OFOQ system, where each document must be uploaded individually in PDF format and labeled as per the below checklist. Documents must be in Arabic or English language, Organized, readily searchable, and unambiguous manner.

N	Code	Description	Att	Reference
1	003	Invoice	☐	INVOICE
2	2251	National Health Regulatory Aut...	☐	CATALOG
3	2251	National Health Regulatory Aut...	☐	CE CERTIFICATE
4	2251	National Health Regulatory Aut...	☐	CE VERIVICATION

Main requirements should be submitted on OFOQ system for pre-approval

No.	Requirements
1	Invoice including HS Code/ Manufacturer Name & Country of Origin.
2	NHRA medical devices registration license, if not available please provide the below requirements:
A	Product quality documents, (example: foreign government USFDA, CE), it should be issued by a recognized certifying body.
B	Quality Management System (**ISO 13485**).
C	All certificates provided should be verified and a verification proof should be provided as a screenshot in the application
D	Catalog that should contain the imported product code / Ref No. of the product/s mentioned in the invoice.
E	Label of the medical device should include name of the legal manufacturer.

In some cases, as below NHRA might ask for submitting additional documents to clear the shipment:

	Cases	Required Documents
1	In case of legal manufacturer and Physical manufacturer are different:	• Quality Assurance Certificate **(CE)** / foreign government **FDA** should be provided for the Legal manufacturer. • Quality Management System **(ISO 13485)** should be provided for the physical manufacturer. • A Relationship letter includes the issuing date, and it must be with a minimum validity of 5 years. The letter should be provided from the Physical manufacturer.
2	For some of class I medical devices, provide:	• **DOC** for legal manufacturer. • **ISO 13485** for physical manufacturer.
3	If the Online Verification Database does not show the site (CoO) or/and the scope used in the application	The Verification must be done through an email.
4	If the invoice is issued from third party.	Authorization letter from the manufacturer to invoice issuer should be provided, and it must be with a maximum validity of 5 years.
5	In case of importing contact lenses OR surgical instruments OR upon NHRA request	Samples sealed from customs should be provided.
6	In case the product is single use medical device.	Classification letter including issued from NHRA MDR Department stating that the product is classified as a medical device.

4. 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- Importation of medical devices must be done through authorized representative from the legal manufacturer.

3- Applicant should have Commercial Registration (CR) with activity of importing Medical Devices **4659 "Sale/Trade in other machinery and equipment and parts-Medical Devices supplies and Related Parts"** This activity includes **importation, exportation, and sale in Bahrain market.**

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

5- Importation request should be submitted on OFOQ by the authorized representative **NOT** by the clearance agent.

6- In some cases, NHRA might request for additional documents not mentioned in this guideline for safety and quality assurance purposes.

7- If the medical device is already registered in NHRA, Pre-approval is granted by attaching valid NHRA license along with invoice.

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

9- Importation of used/refurbished medical device is prohibited.

10- In some cases, request maybe rejected with a comment please provide sealed samples to NHRA for evaluation, where approval cannot be granted until the shipment arrives to Bahrain port, in these cases the sample should match with document provided in order to clear the shipment

11- Medical devices manufactured for research purpose only, will be approved by providing local purchased order (LPO) from the university and Declaration of conformity to the international quality and safety standards issued by the manufacturer.

12- All certifying bodies issuing the quality assurance certificate should be recognized by the EU for CE certificate and IAF for ISO certificate, kindly refer to Quality Assurance Certificates and Verification Process Guideline for more information.

13- It is the responsibility of applicant to make sure all submitted docs are authentic and verified otherwise it will be recorded as a violation to the applicant leading to CR deactivation.

14- In some cases, where shipment is partially approved from NHRA due to noncompliance of some of the devices in the shipment with international standards, the importer could contact costumes headquarter, to clear the approved devices and export the rejected ones or destroy them.

15- In case of importing Cold chain products, i.e. (2-8 ℃), the temperature data logger must be provided to NHRA within 24 hours of receiving the shipment to ensure good storage conditions; from the port of shipping "the manufacturer", to Bahrain ports. Conditional Pre-approval 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.

16- If the medical device is intended for veterinary use, please highlight this in the information details & attach an official document from the manufacturer justifying that.

5. Product Classification

In case of importing products single use medical devices, OFOQ team will transfer the request to classification. Applicant should book an appointment through "Microsoft Bookings" system for submitting the required documents for product classification.

The submitted documents will be reviewed and studied, if the product falls under the medical device regulation, then a classification letter will be issued stating that the product is classified as a medical device.

For more information about classification process and requirements, please refer to "Classification Guideline" on NHRA website.

6. Samples

In case of importing surgical instruments or contact lenses, applicant is requested to provide sealed samples to NHRA once the shipment arrives to customs port. These samples will be checked and evaluated to make sure they are manufactured as per international safety and quality standards and match with the provided documents.

Applicant should submit the sealed samples along with "Sample Form" and required documents and as per "Section 3" in addition to a capture from OFOQ system stating the samples are requested.

The submission is from **9:00 am to 12:00 pm** any day during the week.

In case the samples are approved, OFOQ team will approve the request on OFOQ system.

In case the samples are rejected, a letter of rejection will be issued stating the rejection reasons and the request will remain rejected on OFOQ system.

7. Violations

Applicant must make sure that application contains authentic and valid certificates where all documents submitted by the importer to NHRA is under the full responsibility of the applicant, the moment a violation has been recorded:

- A written notice letter from NHRA will be sent to the importer.

- An official letter should be provided by the importer within **one week** of receiving the notice letter justifying reasons that led to the violation.

- If justification is accepted, violation will be dropped, and AR should sign an obligation.

Otherwise (justification is not accepted), the importer should take all necessary measures and corrective actions during **one month** of receiving the notice letter from NHRA to prevent future similar mistake.

On the fourth notice letter **Or** in case of continues occurrence of the same violation and ignorance to NHRA written notice the action taken by NHRA will be on SIJILAT system where CR activity will show the violation and the process following this action can be found in violation guideline for further references.

What to be considered violation?

- Invalid documents

- Using previously approved invoice to clear new shipment.

- Adding HS code and CoO not existing in the invoice.

- Providing misleading information.

- Falsified documents.

- In case of not complying with NHRA rules and regulations.

For more information, please refer to "Violation Guideline".

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

8. Process of OFOQ Application

For new applicants, In order to be able to use "OFOQ" it is required to have a username 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

First time user ? Please click here to get instructions	هل تستعمل الموقع للمرة الاولى؟ اضغط هنا لتحصل على ارشادات الاستعمال
To request OFOQ user fill this form and	لطلب حساب على نظام أفق فضلاً املئ هذه الاستمارة وارسلها إلى customs.licensing@customs.gov.bh
send it to customs.licensing@customs.gov.bh	
help phone number: +973 17359700	هاتف للمساعدة: 17359700 973+
email: ofoqsupport@customs.gov.bh	بريد الكتروني: ofoqsupport@customs.gov.bh

Then you can follow these steps to make a new request on OFOQ:

Step 1: open http://www.ofoq.gov.bh, click "OPEN WINDOW".

E-Mail: **medical_devices@nhra.bh**   Website: **www.nhra.bh** Tel.: **17113299** /P.O. Box: **11464**
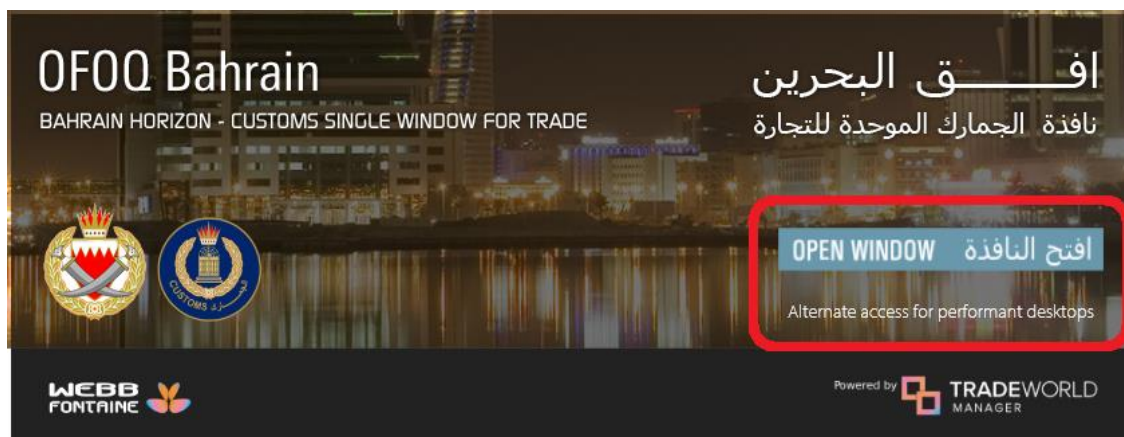
Step 2: enter your username and password. (That is sent to you from OFOQ support team)

Step 3: click on "Licensing" > right click on "License" > click "New".
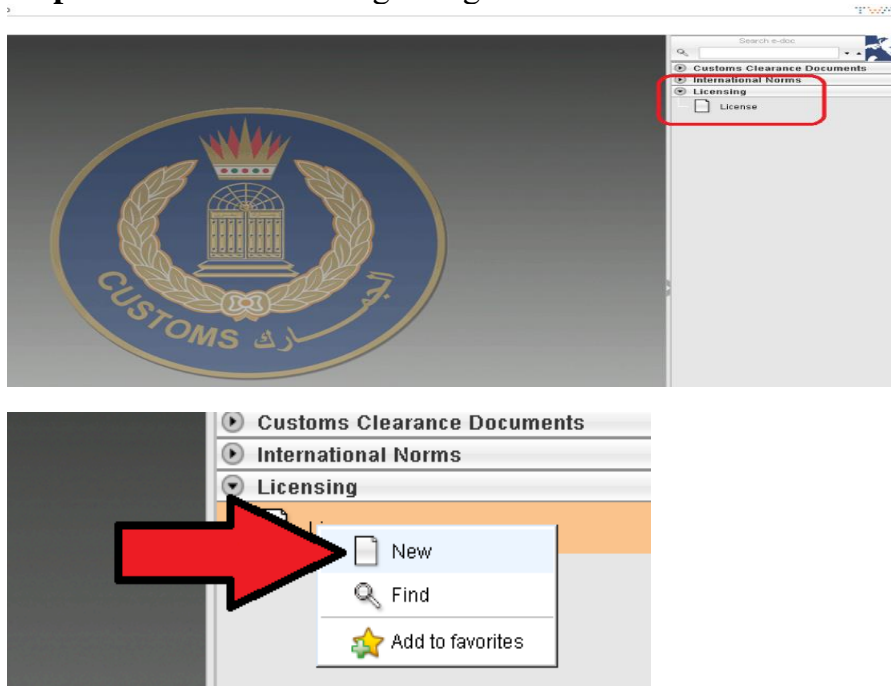
Step 4: make sure that you insert the correct ministry code "**2251**".

KINGDOM OF BAHRAIN
National Health Regulatory Authority -Medical Devices

Ministry		License No.	Issued Date
2251	National Health Regulatory Authority -Medical Devices		

Reference No.		Valid from	
License Type	Single Use	Valid to	
Consignee		Document Code	2251

Step 5: insert license type. (Choose single use only)

Ministry		License No.	Issued Date
2251	National Health Regulatory Authority -Medical Devices		

Reference No.		Valid from	
License Type	Single Use	Valid to	
Consignee		Document Code	2251
			National Health Regulatory Authority -Medical Devices
		License Status	

Step 6: insert the request date. (Validity is recommended to be entered for one year to avoid expiry before shipment arrive)

Step 7: choose "Item" in the bottom to move to the next page.

Step 8: insert the item HS code.

- Make sure that the tariff description matches the imported item by clicking F3 on the Tariff heading box twice, for farther assistance please contact customs tariff department.

- If you did not find the most suitable description for your item, choose "other".

Step 9: if there are more than one HS Code in the invoice for the same shipment you can add it from this icon in the top.
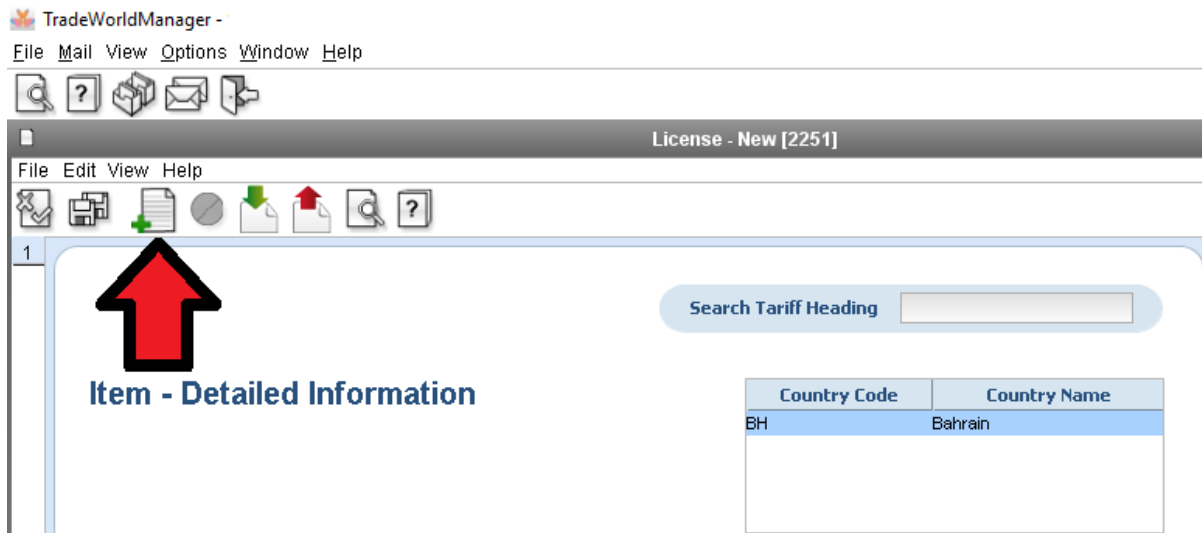
Step 10: insert the country-of-origin (CoO) in the country code box. (Make sure that you select the correct code that matching with the invoice details)
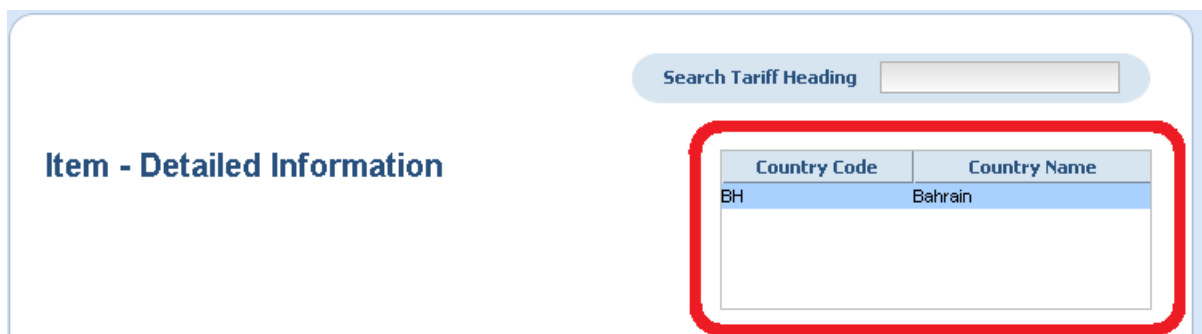
Step 11: please select "PRICE" and enter the correct amount of total price that covers your HS code in the invoice without any additional charges or discounts

Tariff Heading	90189020	000	0000	0000	Tariff Description	- - - Anaesthetic appliances and instruments

Spec. Code

Allowable Amount [ ] [10.000]   Remaining Amount [ ]

○ UOM [ ] [ ]   ○ Gross Mass   ○ Net Mass   ○ Value   ● Price

Item Category [Medical Device]

Item Type   Registered [1]   Unregistered [1]

Other Information [ ]

Step 12: enter the correct items type number (ether if its registered or unregistered), ***please check the fees video for mor information***.

Item Category [Medical Device]

Item Type   Registered [ ]   Unregistered [ ]

add comment, for example: item details, end-user, clarification, contact details or any other information.

Allowable Amount [ ]   Remaining Amount [ ]

○ UOM [ ] [ ]   ○ Gross Mass   ○ Net Mass   ○ Value

Other Information [ ]

N	Code	Description	Att	Reference	Date	Att Doc

Step 13: in this box you must attach the medical device documents as per explained in the guideline "section 3"

Step 14: store the request.
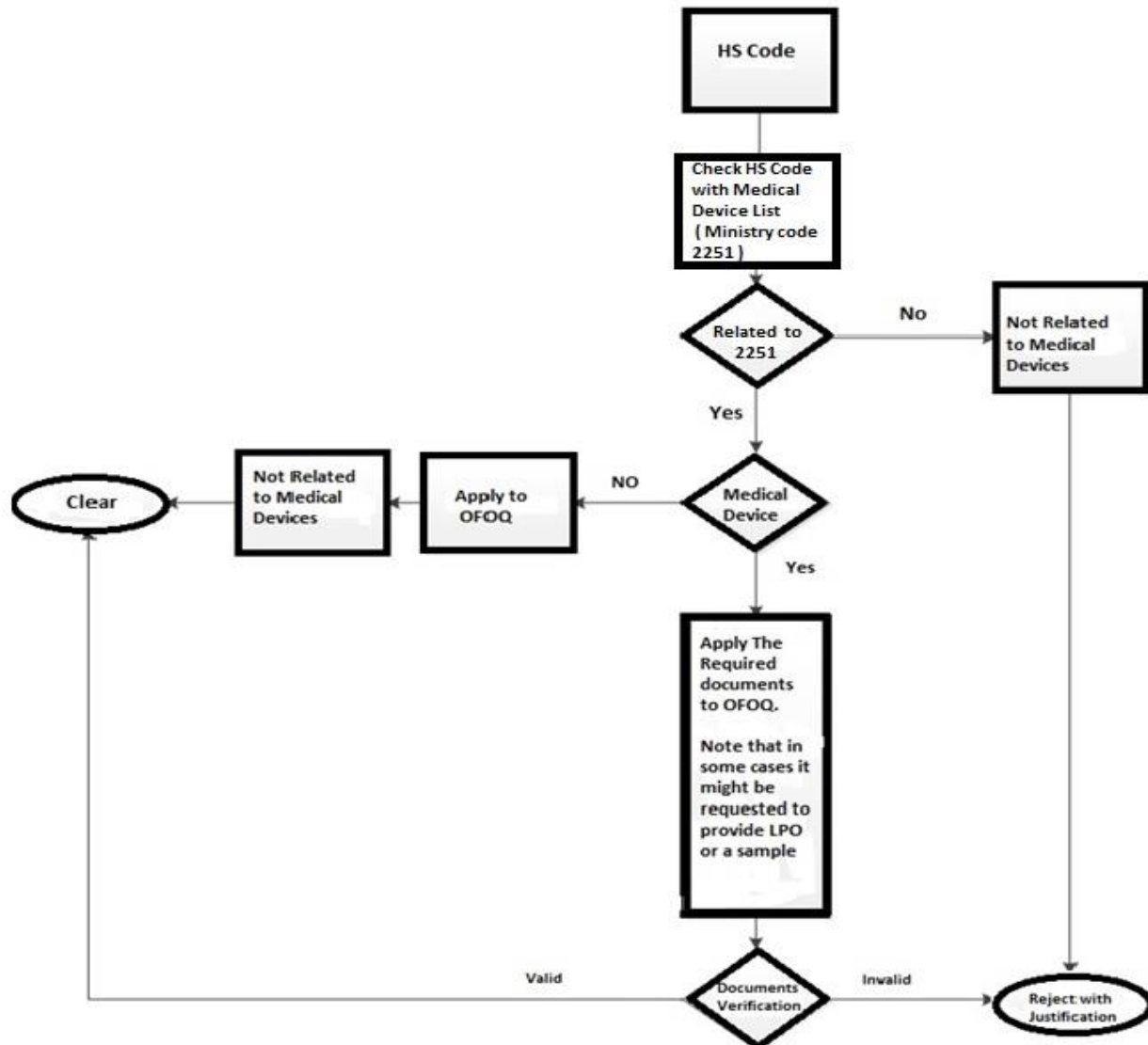

9. Fees Payment

- Create and store the application on OFOQ system with the required documents.
- Send an email to MDRFees@nhra.bh to request a payment notice and include The License reference number of the application, the commercial registration (CR) number of the company, the applicant contact information such as name and phone number.
- The Applicant will receive a notification by email or/and phone with a link to proceed with the payment via FAWATEER.
- After payment is done, the application status will be changed from "stored" to "requested" and will be reviewed and processed afterwards.

The process of applying on OFOQ can be simplified by the following flowchart:

10. Glossary

No.	Terminology	Definition
1	**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.
2	**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.
3	**HS code**	The Harmonized Commodity Description and Coding System generally referred to as "**Harmonized System**" or simply "HS" is a multipurpose international product nomenclature developed by the **World Customs Organization (WCO).** The Harmonized Commodity Description and Coding System (HS) is broad and is not structured for medical devices field.
4	**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, 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[4] and veterinary products.

No.	Terminology	Definition
5	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.
6	ISO 13485	**International Organization for Standardization** Quality management systems required for regulatory purposes is an (ISO) standard published for the first time in 1996; it represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
7	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.
8	Quality Assurance Certificate Verification	Means to check the validity of the quality assurance certificate by contacting the notifying body either by sending an email or online through the website of the notifying body.

No.	Terminology	Definition
9	**Notifying Body (Certifying Body)**	The role of the Notified Body is to conduct a conformity assessment under the relevant EU Directives. The conformity assessment usually involves an audit of the manufacturer's quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device. Once the Notified Body has determined a manufacturer has conformed to the relevant assessment criteria, it issues a certificate to show that the products assessed meet the requirements.

11. Annex

Please visit NHRA website for more information about Medical Device importation (OFOQ) requirements and approval process.

Medical Device Importation checklist

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/Checklists/Ofoq%20Documents%20Requested%20Checklist%20updated-%20MD0100%20nov%202021.pdf

Classification checklist

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Classification%20form%209%20JUNE.pdf