



**Online Medical Device importation approval
Guideline
(OFOQ)**

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Version 9.0



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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	<input type="checkbox"/>	INVOICE
2	2251	National Health Regulatory Aut...	<input type="checkbox"/>	CATALOG
3	2251	National Health Regulatory Aut...	<input type="checkbox"/>	CE CERTIFICATE
4	2251	National Health Regulatory Aut...	<input type="checkbox"/>	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 <u>Legal manufacturer</u> . Quality Management System (ISO 13485) should be provided for the <u>physical manufacturer</u> . 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 <u>Physical manufacturer</u> .
2	For some of class I medical devices, provide:	DOC for <u>legal manufacturer</u> ISO 13485 for <u>physical manufacturer</u>
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- Health care facilities, Importer, clearance agents, regulatory affairs can apply on OFOQ.
- 5- Importers should initially have a user name and a password from the customs headquarter, by contacting them by email.
- 6- Request submission on “OFOQ” must be before shipping the item in order to grant pre-approval before shipment arrives at Bahrain port.
- 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 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, all certificates must be verified from the issuing body; By contacting the notifying body either by email where NHRA should be included in the mailing loop or a copy of verification email should be attached with the request, OR the verification can be done online through the website of the notifying body and a capture of the validity should be attached with the request.

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://iaf.nu/en/accreditation-bodies/>

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- 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.

15- 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.

16- All documents must be in Arabic or English with readable font.

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



17- In case of importing Cold chain products, i.e. (2-8 °C), 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.

18-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.

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

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 be 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 to 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”.

8. Fees Payment

- First, Create the application on Ofoq system with the requested documentation.
- Second, Save the application in store after verifying the information such as phone number, email and notify NHRA to issue the receipt via email.
- Then, Send an email - via to Fatima.alderazi@nhra.bh for request a payment notice .
- Payment details will be entered in Fawateer system by NHRA in addition application number that has been entered in Ofoq system and issue payment notice.
- The Applicant will receive notification and will start payment process through the system.
- Final, Paid application will be reviewed by the engineer (Paid application only), and transform it from store status to requested status and accordingly will accept it Or reject it.

The applicant is required to attach the following in the e-mail :-

- 1- Attach the receipt was paid by (Fawateer) device including the barcode to Fatima.alderazi@nhra.bh for complete the receipt process .
- 2- The license reference number.
- 3- Commercial registration number.
- 4- The applicant's name and contact numbers.

In case the application has been transferred to requested status directly and the payment has not done, the application will be cancelled.

9. 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

First time user ? Please click here to get instructions

To request OFOQ user fill this form and

send it to customs.licensing@customs.gov.bh

help phone number: +973 17359700

email: ofosupport@customs.gov.bh

هل تستعمل الموقع للمرة الاولى؟ اضغط هنا لتحصل على ارشادات الاستعمال

لطلب حساب على نظام أوفو ق فضلاً املئ هذه الاسمارة وارسلها إلى customs.licensing@customs.gov.bh

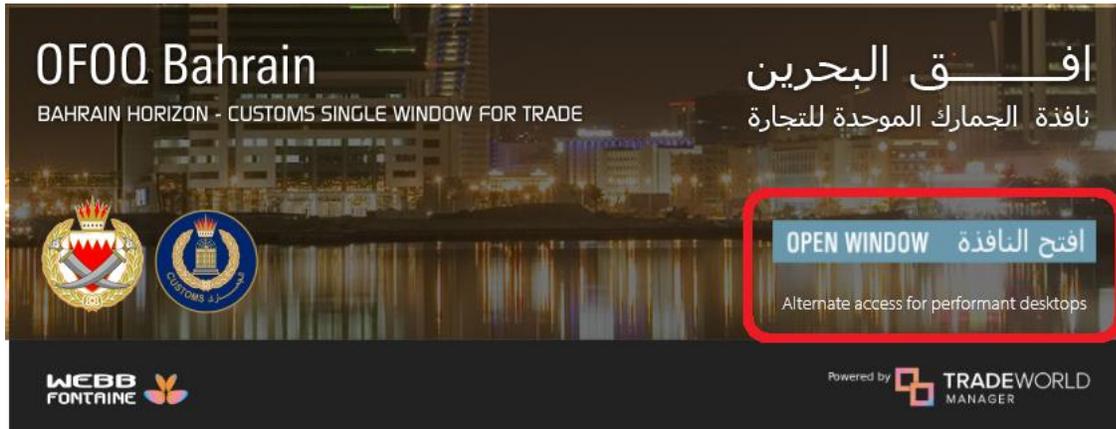
هاتف للمساعدة: +973 17359700

بريد الالكتروني: ofosupport@customs.gov.bh

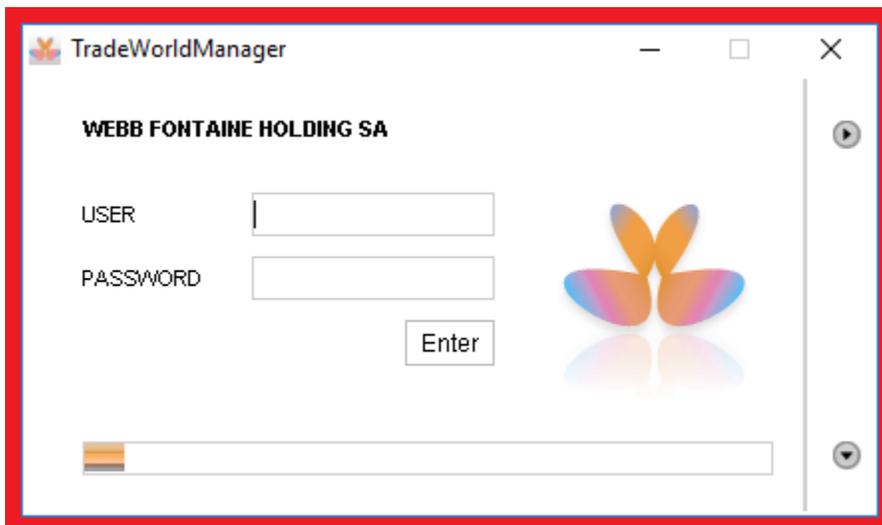


Then you can follow these steps to make a new request on OFOQ:

Step 1: open <http://www.ofoq.gov.bh>, click “OPEN WINDOW”.



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.	<input type="text"/>	Valid from	<input type="text"/>
License Type	Single Use	Valid to	<input type="text"/>
Consignee	<input type="text"/>	Document Code	2251

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

Ministry	<input type="text" value="2251"/>	<input type="text" value="National Health Regulatory Authority -Medical Devices"/>	License No.	<input type="text"/>	Issued Date	<input type="text"/>
Reference No.	<input type="text"/>		Valid from	<input type="text"/>		
License Type	<input type="text" value="Single Use"/>		Valid to	<input type="text"/>		
Consignee	<input type="text"/>		Document Code	<input type="text" value="2251"/>		
<input type="text"/>			<input type="text" value="National Health Regulatory Authority -Medical Devices"/>			
<input type="text"/>			License Status	<input type="text"/>		

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

Ministry	<input type="text" value="2251"/>	<input type="text" value="National Health Regulatory Authority -Medical Devices"/>	License No.	<input type="text"/>	Issued Date	<input type="text"/>
Reference No.	<input type="text"/>		Valid from	<input type="text"/>		
License Type	<input type="text" value="Single Use"/>		Valid to	<input type="text"/>		
Consignee	<input type="text"/>		Document Code	<input type="text" value="2251"/>		
<input type="text"/>			<input type="text" value="National Health Regulatory Authority -Medical Devices"/>			
<input type="text"/>			License Status	<input type="text"/>		

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

Main Page	<input type="text" value="Item"/>	Fees
		
<input data-bbox="535 1522 1015 1606" type="text" value="License - New [...]"/>		

Step 8: insert the item HS code.

Item - Detailed Information

Country Code	Country Name
BH	Bahrain

Tariff Heading **Tariff Description**

Allowable Amount **Remaining Amount**

UOM Gross Mass Net Mass Value

Other Information

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

Tariff Heading **Tariff Description**

- If you did not find the most suitable description for your item chose “other”.

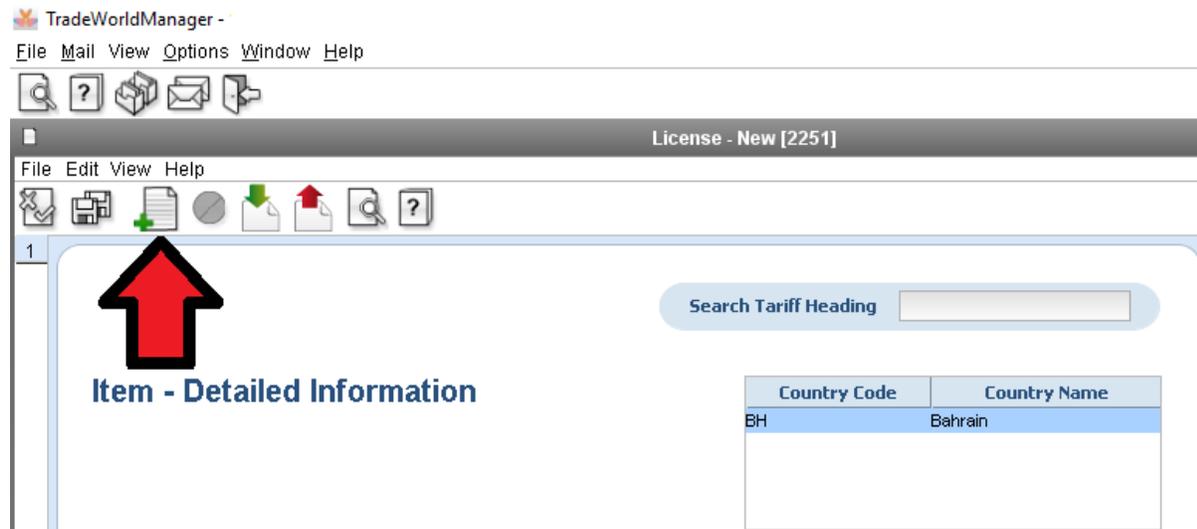
National Tariff finder of License - Validate [2251]

3 documents found! Please select a document and select an action from the local menu

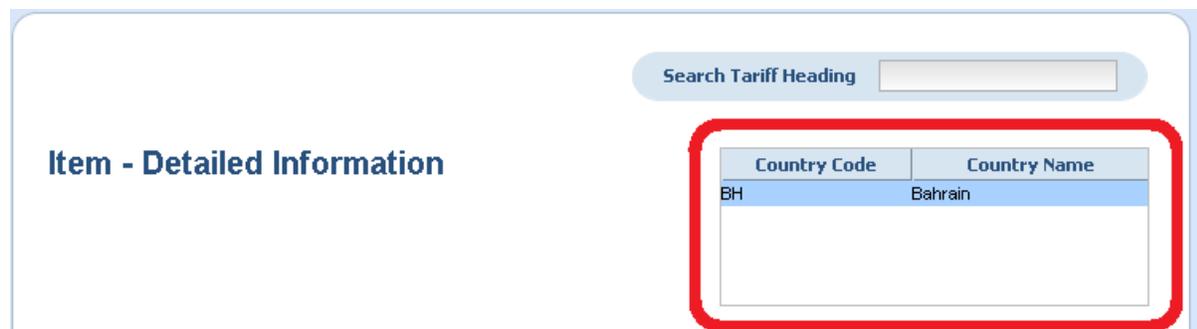
HS6 co...	PR1 c...	PR2 c...	PR3 co...	PR4 co...	Tariff description
901850	20	000	0000	0000	--- Sight examination instruments and equipment (for testing sight sharpness, retina .
901850	90	000	0000	0000	--- Other
901850	10	000	0000	0000	--- Diagnostic appliances (ophthalmoscope, ophthalmic hemopiezometer..etc.)

- Make sure that the medical device for human use, not for veterinary use.

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 code in the country of origin 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 units 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”

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NATIONAL HEALTH REGULATORY AUTHORITY

N	Code	Description	Att	Reference	Date	Att Doc
1	003	Invoice	<input type="checkbox"/>			
2	2251	National Health Regulatory Aut...	<input type="checkbox"/>			

POWERED BY 

Step 14: storing the request.



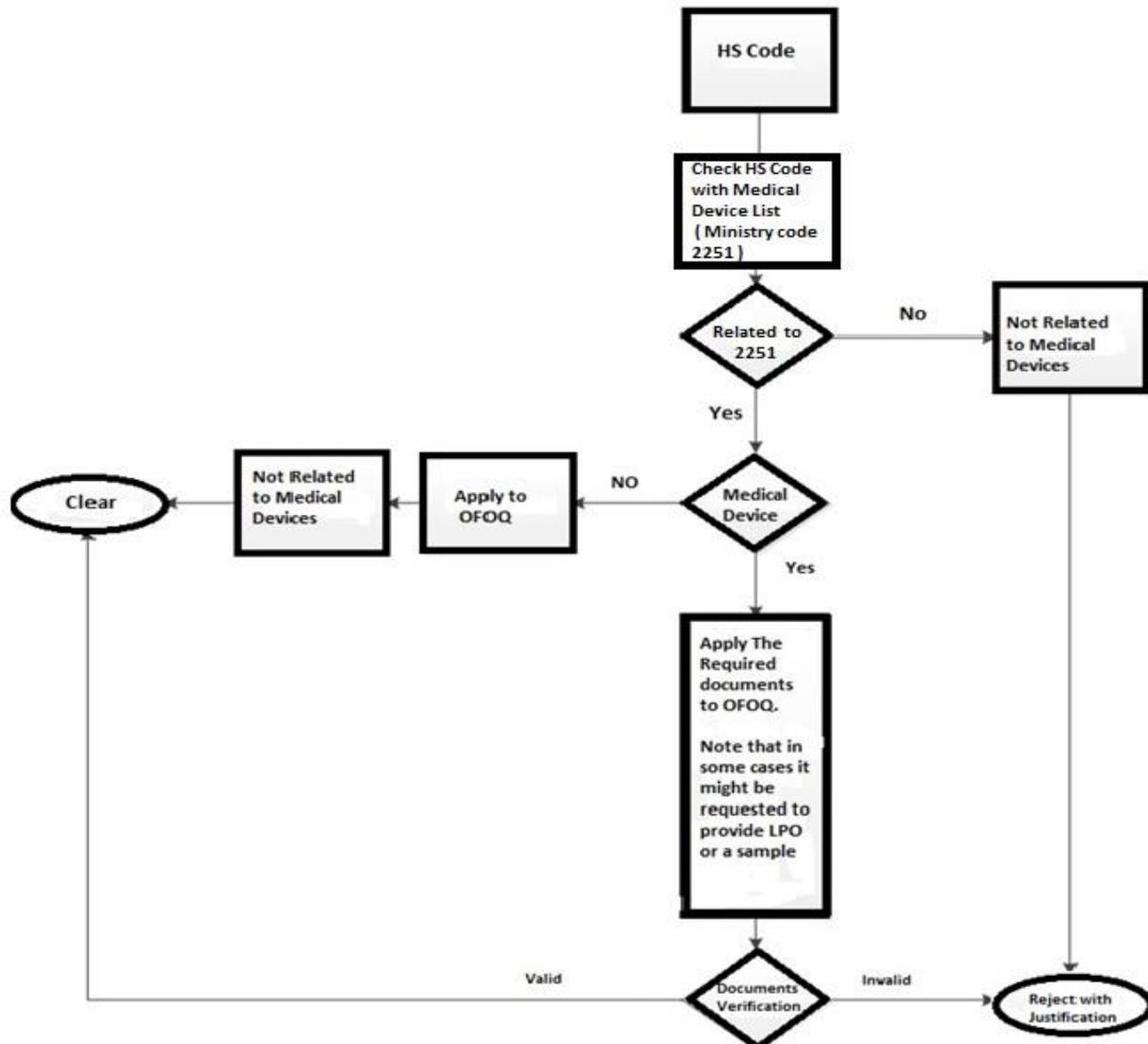
After storing the request, the license applicant should pay the fees through (TAM) device, then an email to be sent from the applicant to the cashier employee at the port, in order to complete the payment process on the License.

The applicant is required to attach the following in the Email: -

- 1- Attach the receipt was paid by (TAM) device including the barcode.
- 2- The license reference number.
- 3- Commercial registration number.
- 4- The applicant's name and contact numbers.

To check if your request's get approved or not, you can search by request reference number or the company commercial registration number (CR).

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





10. Glossary

<u>No.</u>	<u>Terminology</u>	<u>Definition</u>
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	<p>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).</p> <p>The Harmonized Commodity Description and Coding System (HS) is broad and is not structured for medical devices field.</p>
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.



<u>No.</u>	<u>Terminology</u>	<u>Definition</u>
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.



<u>No.</u>	<u>Terminology</u>	<u>Definition</u>
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/Ofq%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>