الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref. 2023-MDGUD-Q1-001

Online Medical Device importation approval Guideline (OFOQ)

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Version 11.0

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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. General Rules

1- NHRA mostly regulates the importation of medical devices Class II and III, 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 requests is recommended to be submitted on OFOQ by the authorized representative.

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

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

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

9- 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.

10- 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.

11- 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.

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

13- 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.

14- 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.

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

4. Requirements

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

No.	Requirements
1	Invoice including HS Code, Manufacturer Name and Country of Origin.
2	Authorized Representative certificate.
3	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.

Each document must be uploaded individually in PDF format and labeled as per the checklist. Documents must be in Arabic or English language, Organized, readily searchable, and unambiguous manner.

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, a nd 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 legal 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.
7	In case of importing devices under HS codes that start with 28, 29, 30, 32, 33, 38, 84.	Authorization letter from the manufacturer to the distributor to distribute their product in the Kingdom.
8	In case of repair and return shipments.	A signed detailed service report of the maintenance done for the device issued by the Legal manufacturer, or an entity authorized by the legal manufacturer.

5. 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

To request OFOQ user fill this form and

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

help phone number: +973 17359700

email: ofoqsupport@customs.gov.bh

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

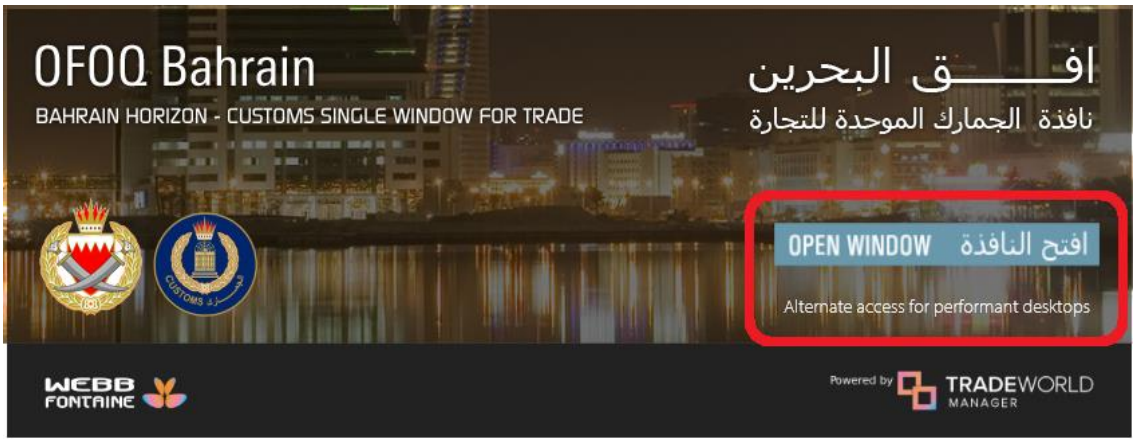
لطلب حساب على نظام أفق فضلاً املئ هذه الاستماره وارسلها إلى customs.licensing@customs.gov.bh

هاتف للمساعدة: +973 17359700

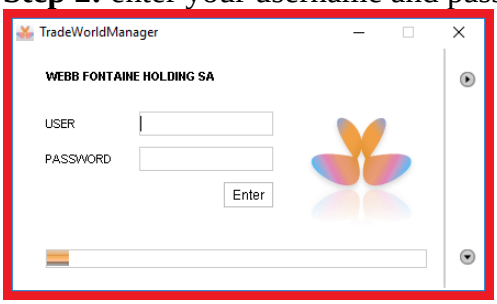
بريد الكتروني: ofoqsupport@customs.gov.bh

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

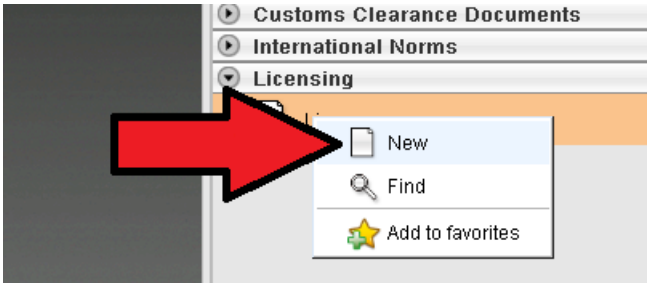
Step 1: open http://www.ofoq.gov.bh, click "OPEN WINDOW".



Step 2: enter your username and password. (That is sent to you by OFOQ support team)

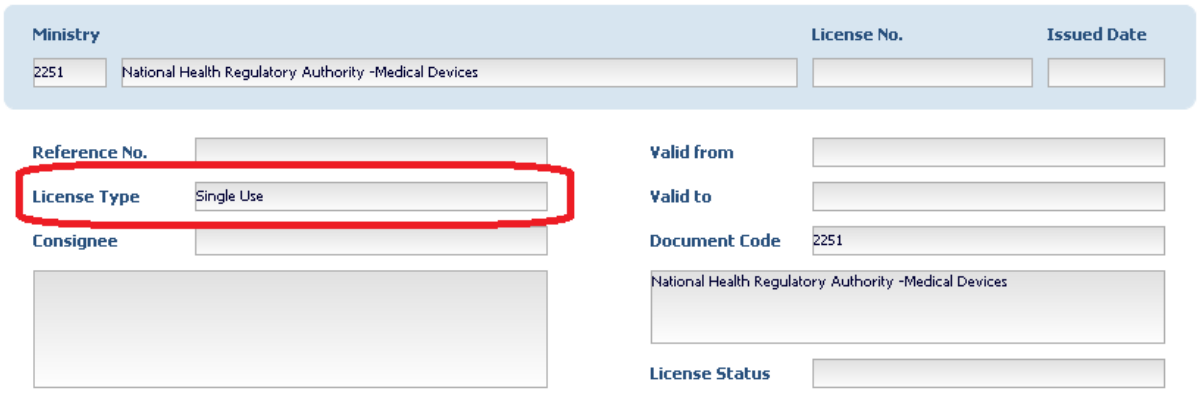


Step 3: click on "Licensing" > right click on "License" > click "New".

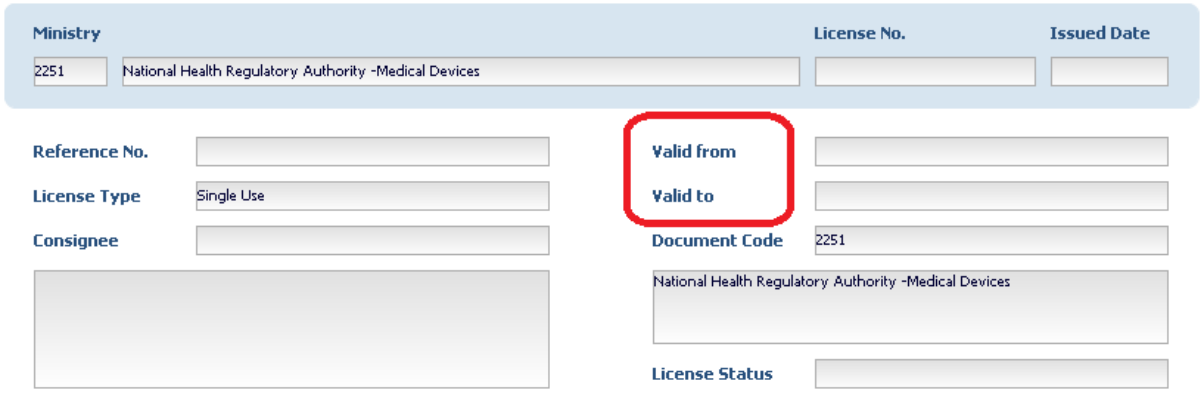


Step 4: make sure that you insert the correct ministry code "**2251**".

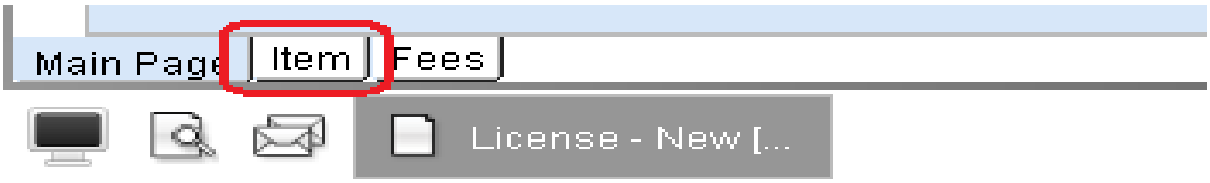
Step 5: insert license type. (Choose single use only)



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

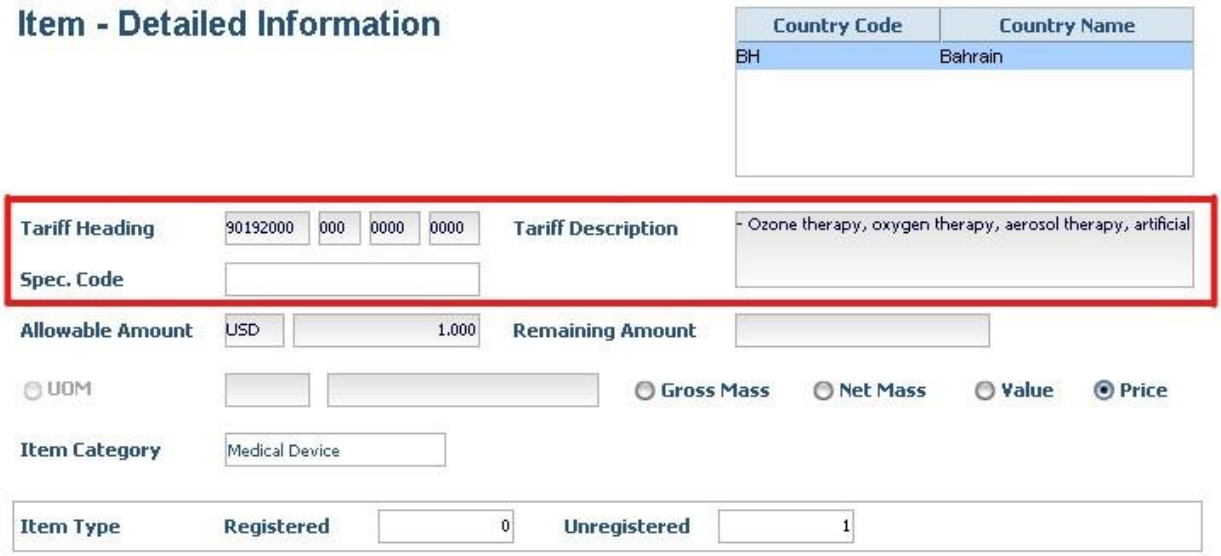


Step 7: move to the next page by choosing "Item" in the bottom.

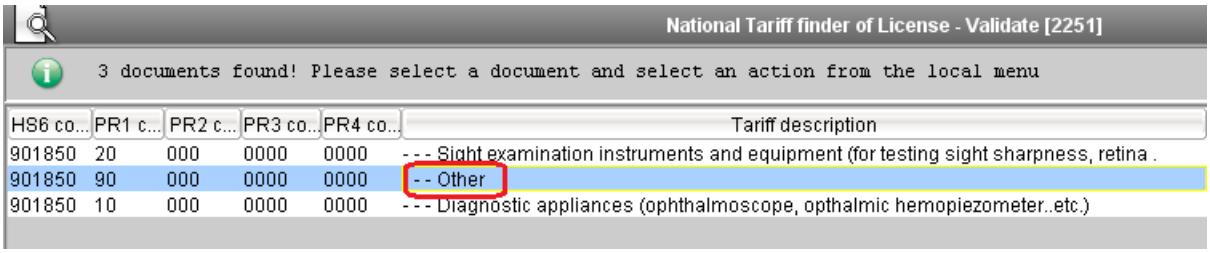


Step 8: insert the HS code for your item(s).

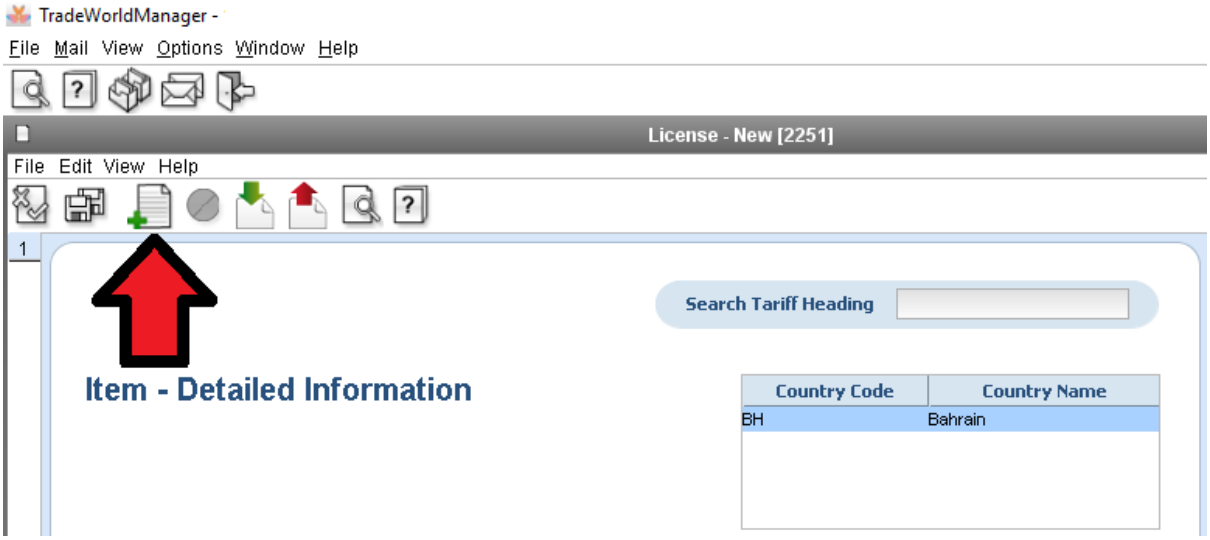
- Make sure that the tariff description matches the imported item by clicking F3 on the Tariff heading box twice, for farther assistance please contact customs tariff department.



- If you did not find the most suitable description for your item, contact customs to classify your product.

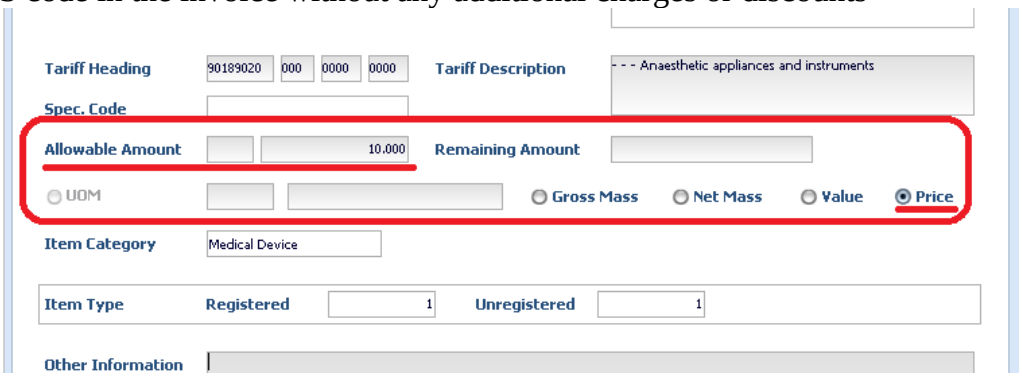


Step 9: if there are more than one HS Code in the invoice for the same shipment you can add it from this icon in the top.

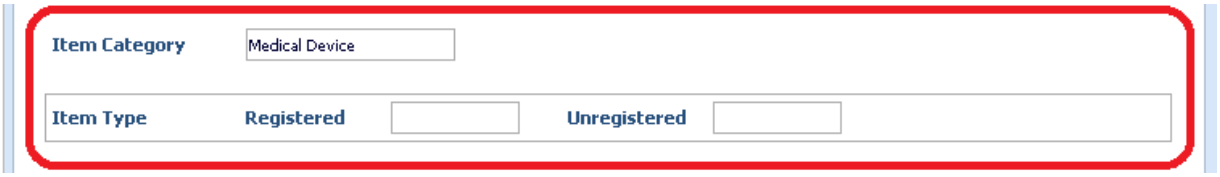


Step 10: insert the country-of-origin (CoO) in the country code box. (Make sure that you select the correct code that matches with the invoice details)

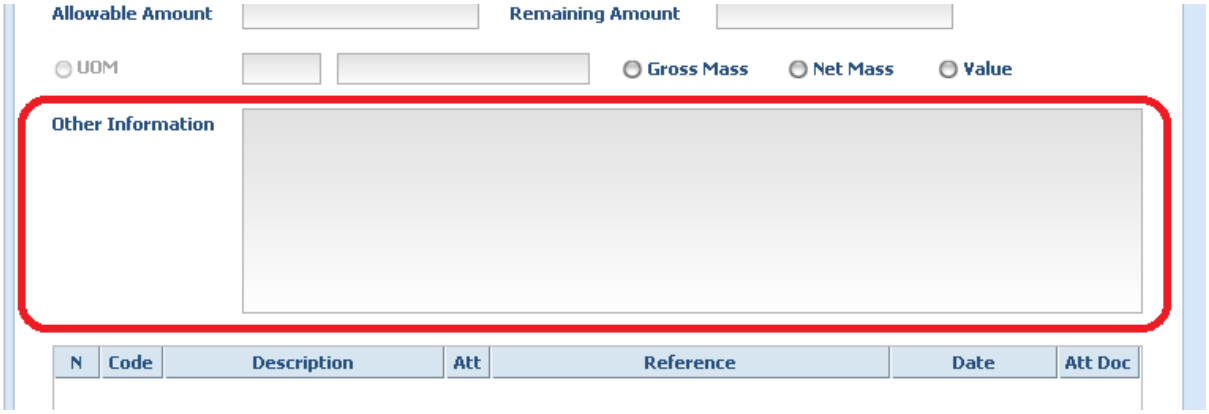
Step 11: please select "PRICE" and enter the correct amount of total price that covers your HS code in the invoice without any additional charges or discounts



Step 12: enter the correct items type number (ether if its registered or unregistered), ***please check suction (6) for mor information***.



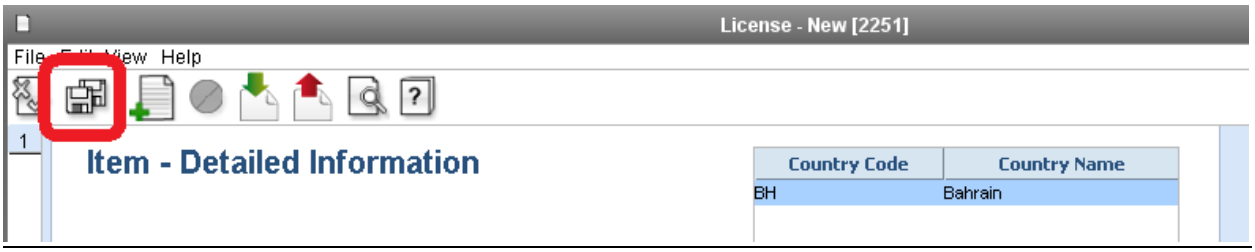
add comment if needed.



Step 13: in this box you must attach the medical device documents as per explained in the guideline "section 4"

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

Step 14: store the request.



6. Fees calculation and payment.

The applicant must calculate the types of medical devices in the invoice.

Depending on the products if it is registered or unregistered the applicant must fill the boxes in the request with the correct number of types for each box.

A Type is considered as one when a group of products falls under all of the criteria below:

- Same device.
- Intended Use.
- Matching Brand names.
- Covered by the same Quality Assurance Certificate. ***(DoC Not applicable)***
- Same physical manufacturer.

There are some exceptions such as:

- Each consumable will be considered as a different type. (e.g., IVDs)
- Each spare part\accessory will be considered as different type.

(Unless the products have the same name and/or identification number (e.g., reference, model, …ETC) then it will be considered as one type.)

- Bundled Products consider as one type ***(e.g., Procedure pack)***

Examples:

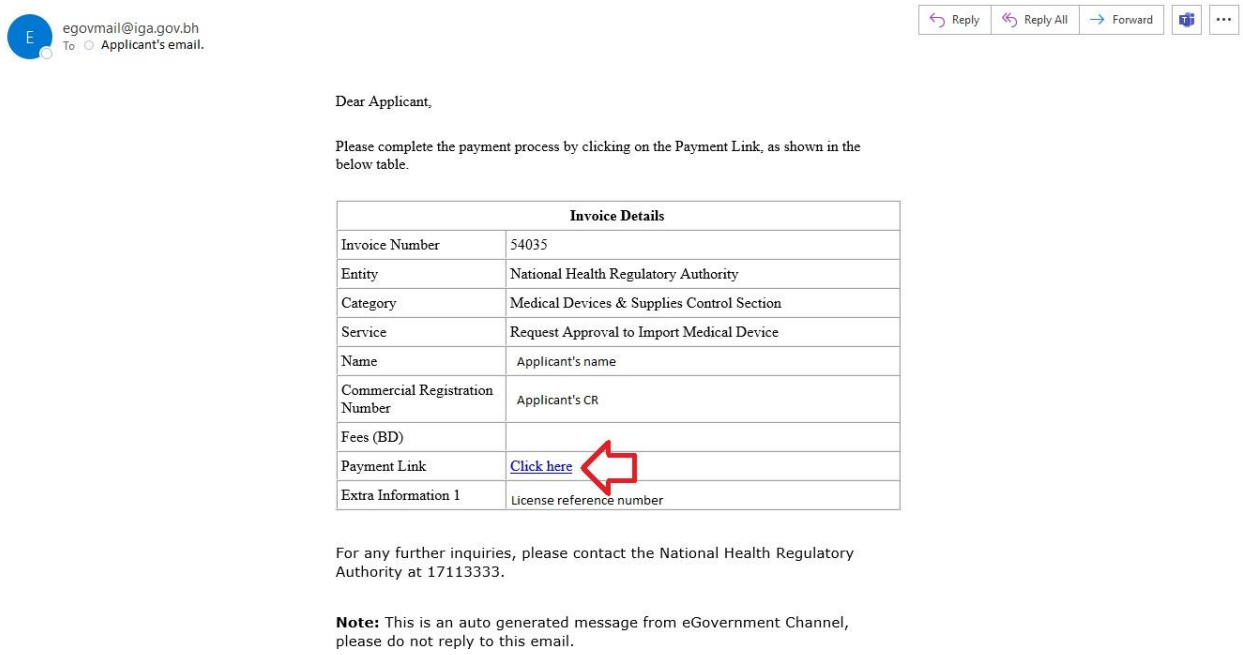
- A group of surgical instruments that consists of different sizes of scissors that holds the same brand name, covered by the same CE certificate, and manufactured by the same Physical manufacturer is considered **1**.
- A group of surgical instruments that consists of different sizes of scissors and blades that holds the same brand name, covered by the same CE certificate, and manufactured by the same Physical manufacturer is considered **2**.

After following the steps of submission and creating the application on OFOQ system with the required documents mentioned above, store your application then send an email to MDRFees@nhra.bh to request a payment notice and include in the email the following information:

1. The License reference number of the application
2. The commercial registration (CR)
3. The applicant contacts information such as
    - Name.
    - Phone number.
    - Email.

The Applicant will receive a notification by email and phone with a link to

proceed with the payment via FAWATEER.



egovmail@iga.gov.bh
To Applicant's email.

Reply | Reply All | Forward

Dear Applicant,

Please complete the payment process by clicking on the Payment Link, as shown in the below table.

Invoice Details	
Invoice Number	54035
Entity	National Health Regulatory Authority
Category	Medical Devices & Supplies Control Section
Service	Request Approval to Import Medical Device
Name	Applicant's name
Commercial Registration Number	Applicant's CR
Fees (BD)	
Payment Link	Click here
Extra Information 1	License reference number

For any further inquiries, please contact the National Health Regulatory Authority at 17113333.

Note: This is an auto generated message from eGovernment Channel, please do not reply to this email.

After payment is done, the application status will be changed from “stored” to

“requested” and will be reviewed and processed by NHRA afterwards.

7. 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".

8. 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 the requirements listed in the sample form.

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

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.

please refer to "Sample form". Hyperlink of form to be added once updated.

9. Violations

Applicant must make sure that applications contain authentic and valid certificates since all documents submitted to NHRA are under the full responsibility of the applicant.

Below you can find examples of what is considered a violation but not limited to:

- Invalid documents
- Using previously approved invoice to clear new shipment.
- Adding HS code and/or CoO not existing in the invoice.
- Providing misleading information.
- Falsified documents.
- Repetition of wrong submissions without complying with the rejection reason of previous application.

After receiving a violation, the applicant can justify within a week the reason that led to this error. If the justification is accepted, the violation will be dropped.

In case the justification is not accepted, the violation will be registered. After several violations, the company will receive their First Notice and will be subjected to provide an obligation letter which must be issued and signed by the owner of the CR; stating his acknowledgement of the violations. The applicant must issue this letter once only but attach it in every OFOQ application.

After getting the first notice, if the applicant repeats the same actions that led to receiving it, the applicant will get the Second Notice. Upon getting the second notice, an official meeting with the CR owner will be scheduled to discuss the situation with the company and hear their corrective actions plan.

On the Third notice letter **Or** in case of continues occurrence of the same violation and ignorance to NHRA written notices, 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.

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

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 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.
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 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.