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 al 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

This guideline is intended to highlight the process and requirements to get the preapproval 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 preapproval by first submitting the required documents on OFOQ system.

3. Requirements

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

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.

All documents must be in Arabic or English only.

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

3- All importers should initially have a user name and a password from the customs headquarter, by contacting them by email.

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

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

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

7- In some shipments sample will be requested for evaluation, where approval cannot be granted until the shipment arrives, in these case the sample should match with document provided in order to clear the shipment.

8- When importing artificial limbs, due to the fact of its being classified as CLASS I, importation permit can be granted without Quality Assurance Certificate.

9- 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://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

10- NHRA should be in the mailing loop if done through mail, if not a capture of its validity from certifying body website should be attached in the request.

11- 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.

12- 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 .

13- For combined medical device, importation permit is currently granted manually, a separate document is available for this subject; another guideline is available clarifying the process of pre-approval.

14- List of (HS cods) used for medical device online approval is available on NHRA website.

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

16- Shipments imported for researches and will not be used on patients, will be approved without Quality assurance certificate if the LPO from the university is provided.

17- 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.

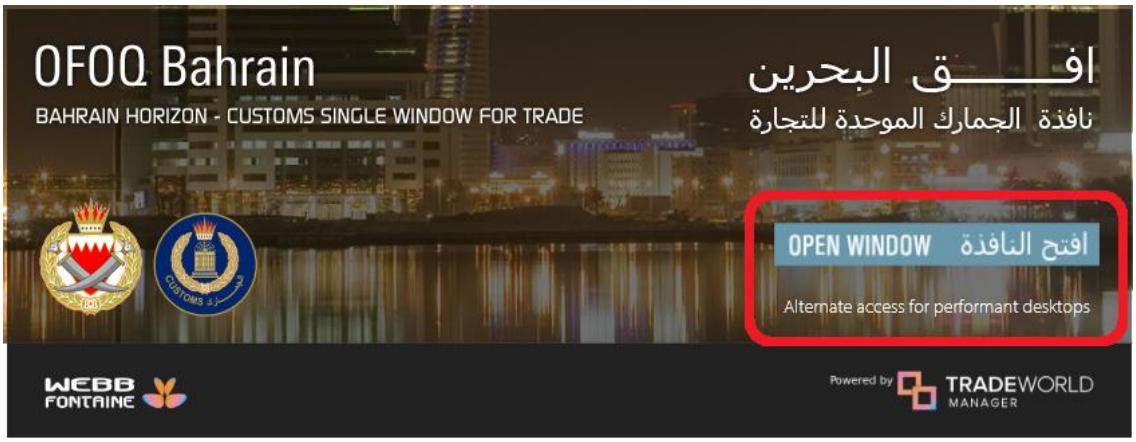
18- In order to avoid frequent rejection of the requests, please note that the **Relationship Letter** requested from NHRA to get medical device importation approval , should be issued from the legal manufacturer relating the other party to it.

5. 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

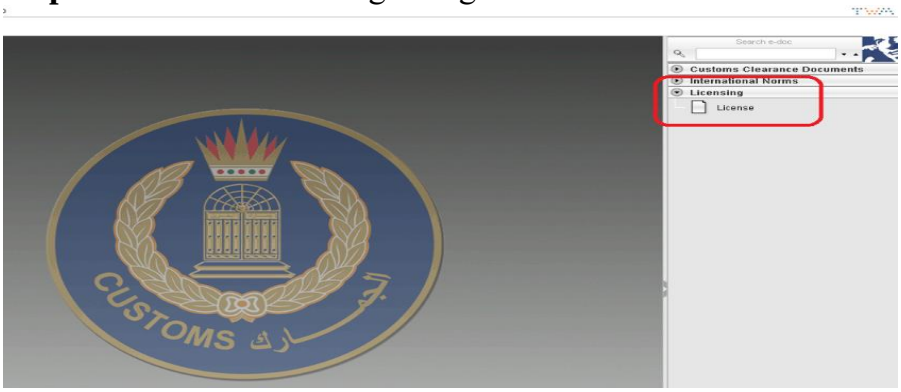
Then you can follow these steps to make a new request on OFOQ:

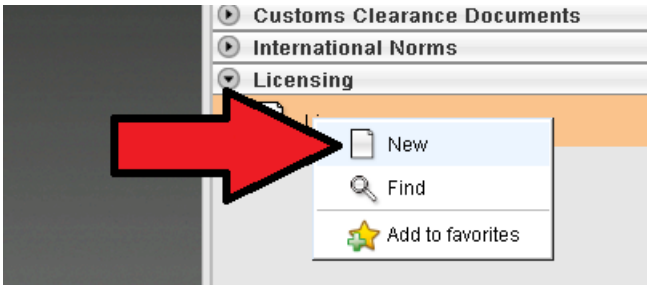
Step 1: open http://www.ofoq.gov.bh, click "OPEN WINDOW".



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

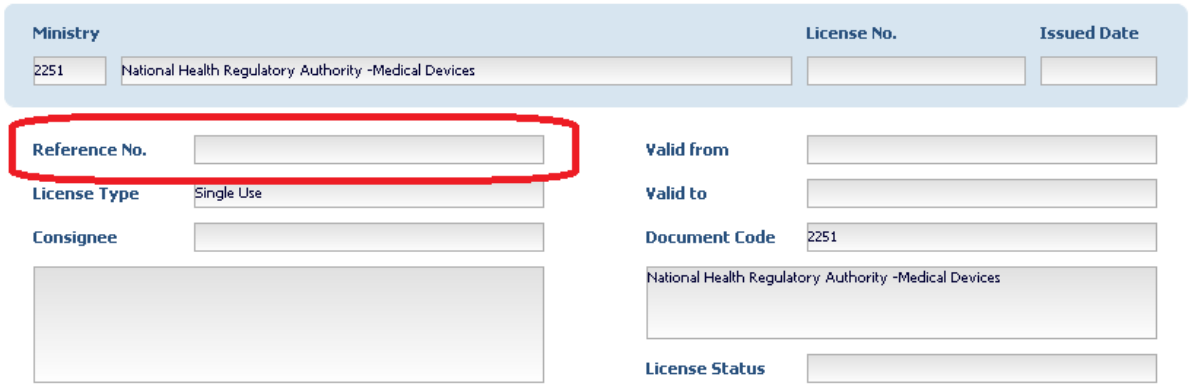
Step 3: click on “Licensing” > right click on “License” > click “New”.



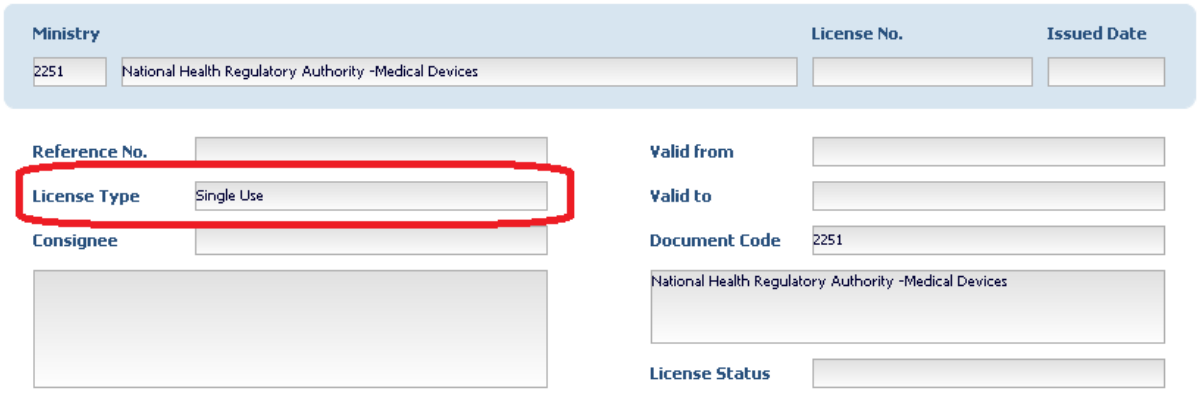


Step 4: make sure that you insert the correct ministry code “**2251**”.

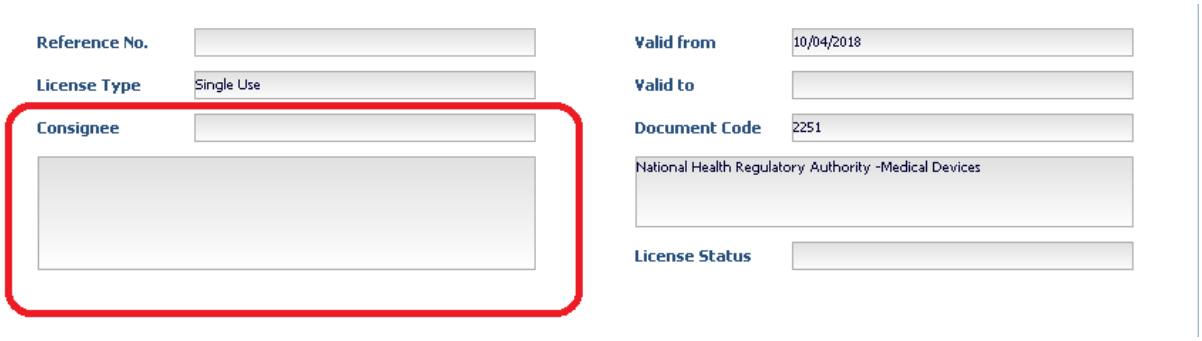
Step 5: reference number will be generated automatically



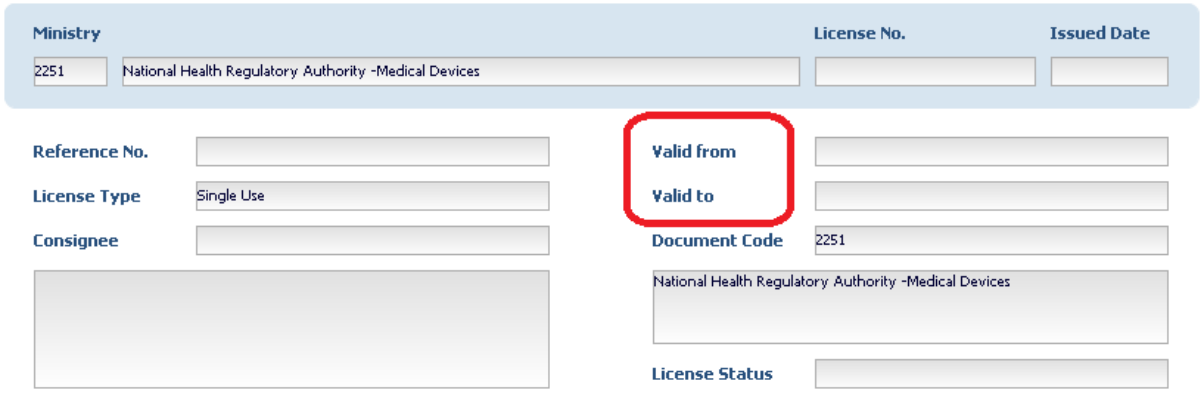
Step 6: insert license type. (**Chose single use only**)



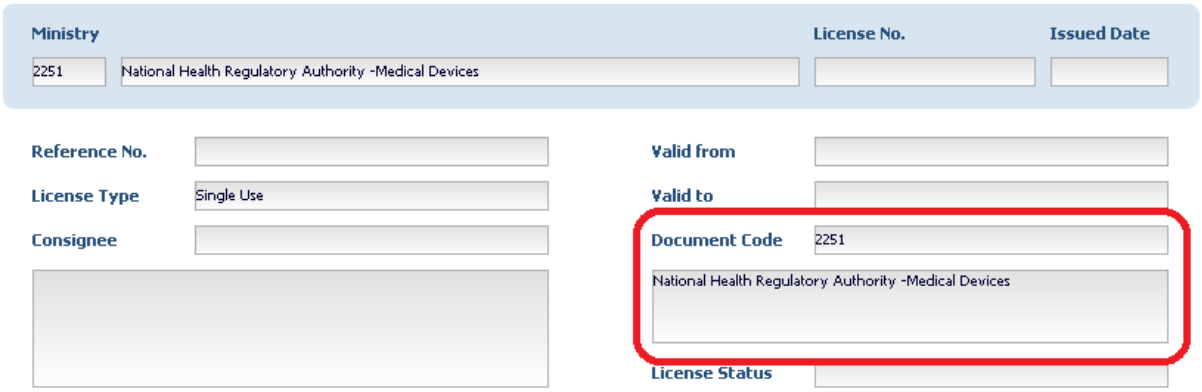
Step 7: CR number will be generated automatically.



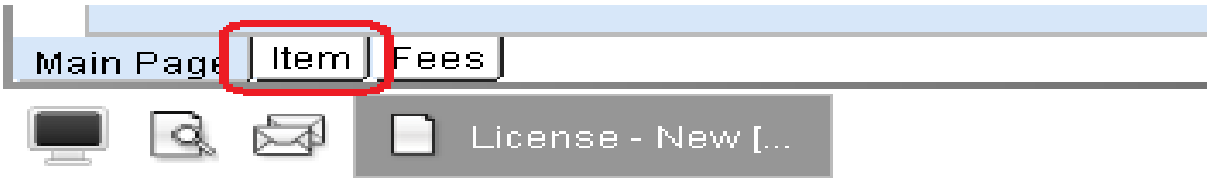
Step 8: insert the request date. (Validity is recommended to be entered for one year to avoid expiry before shipment arrive)



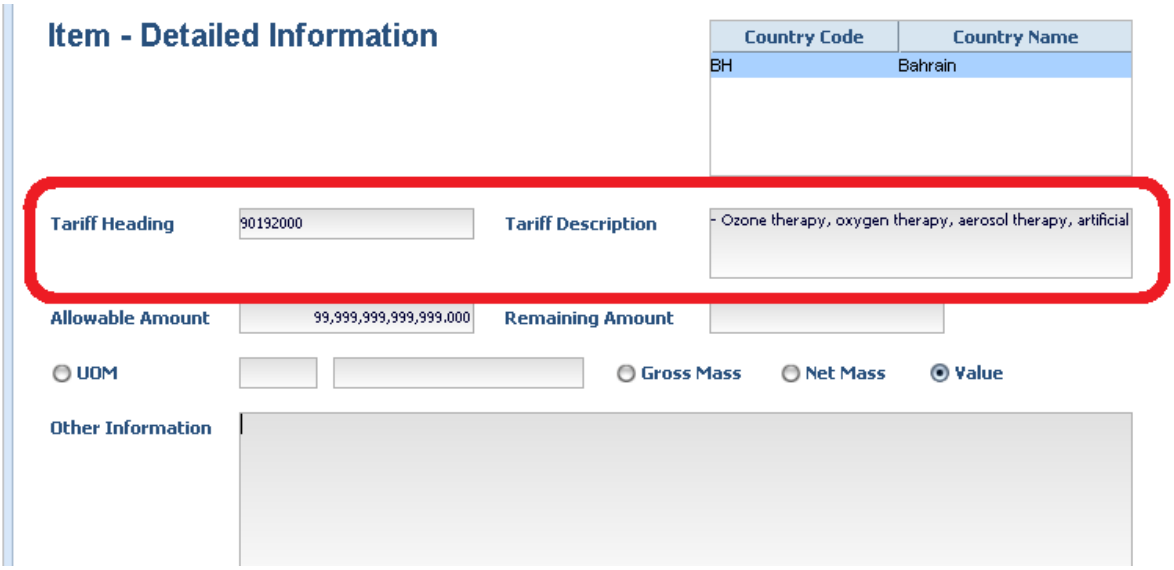
Step 9: "document code" the code will generate automatically when you do (step 4)



Step 10: chose "Item" in the bottom to move to the next page.

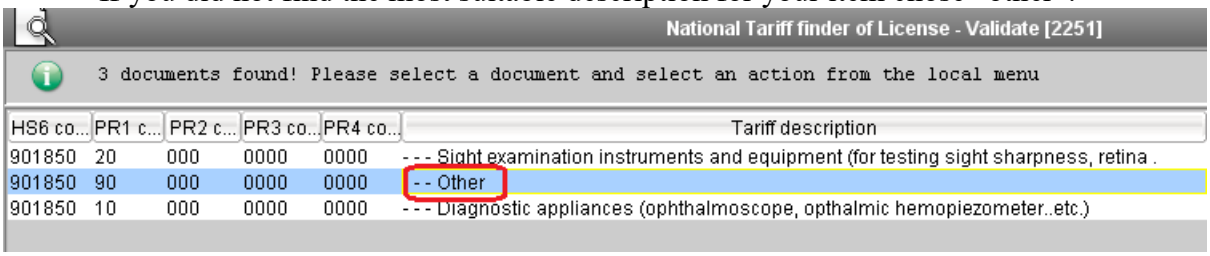


Step 11: insert the item HS Code.



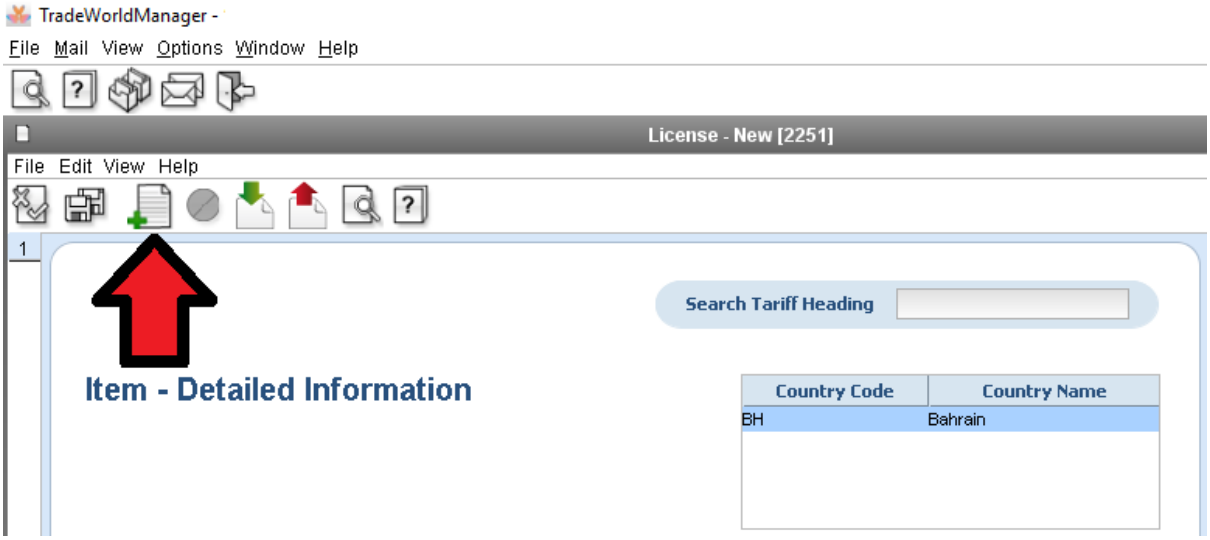
- Make sure that the tariff description match the imported item by clicking F3 on the Tariff heading box two time, for farther assistance please contact customs tariff department.

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



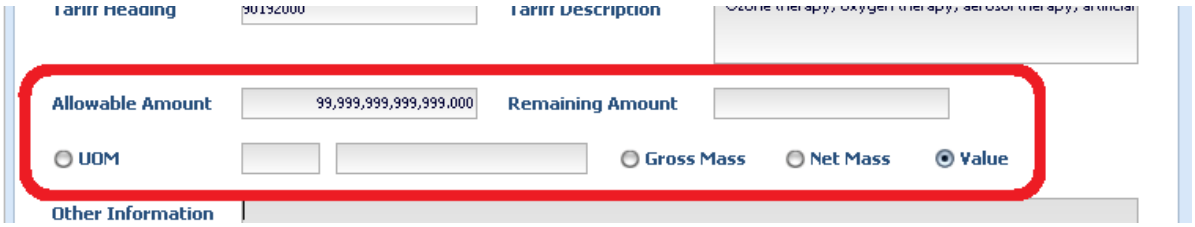
- Make sure that the medical device for human use, not for veterinary use.

Step 12: 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.

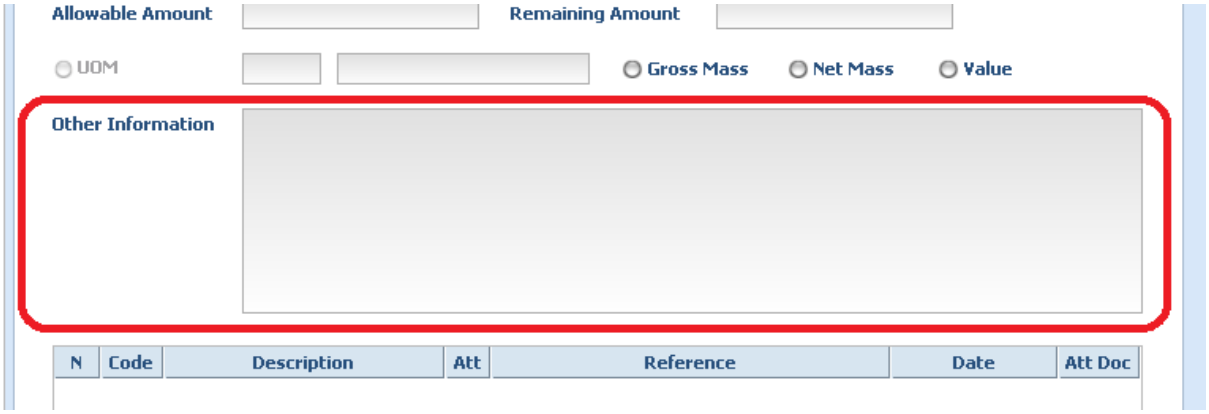


Step 13: insert the country code in the country of origin box. (Make sure that you select the correct code that matching with the invoice details)

Step 14: always chose "Value" and insert infinite number of nine.

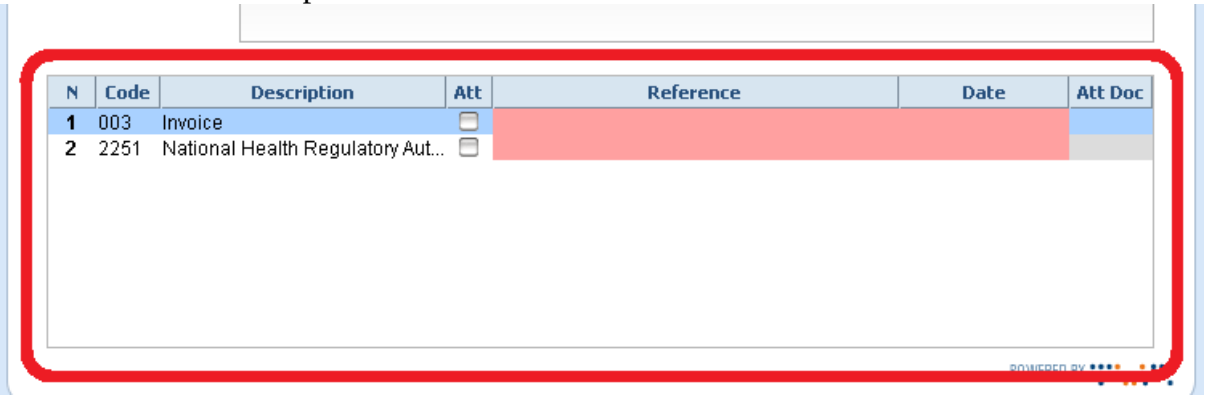


Step 15: add comment, for example: item details, end user, clarification, contact details or any other information.



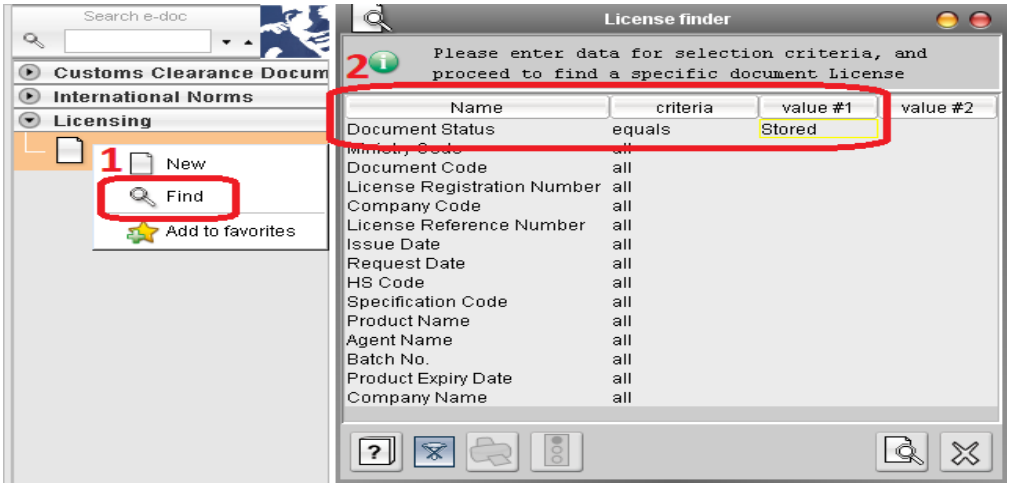
Step 16: in this box you have to attach the medical device documents, as follows:

1- Invoice (contains a clear item description, HS Code, the country of origin and the name of the manufacturer).
2- Medical device certificate from 3rd party (country of origin, quality assurance certificate and quality management system certificate) **or Saudi FDA certificate "MDMA"**.
3- Catalog, technical details of the device.
4- Verification capture.



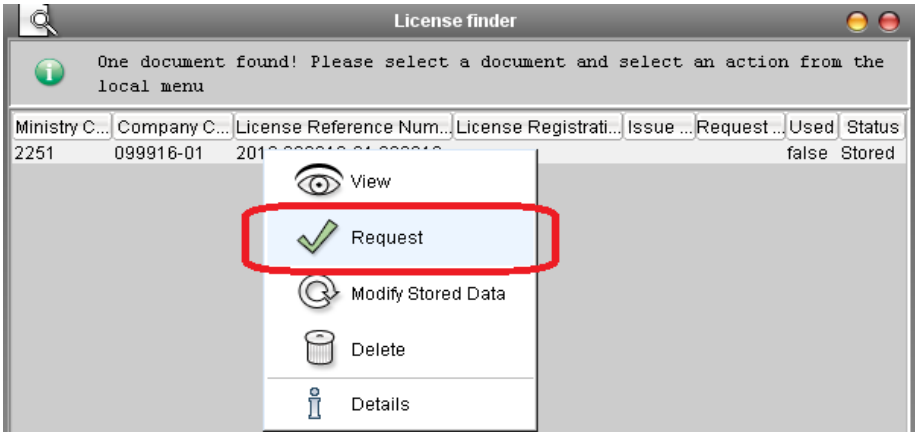
Step 17: store your request.

Step 18: find your request.



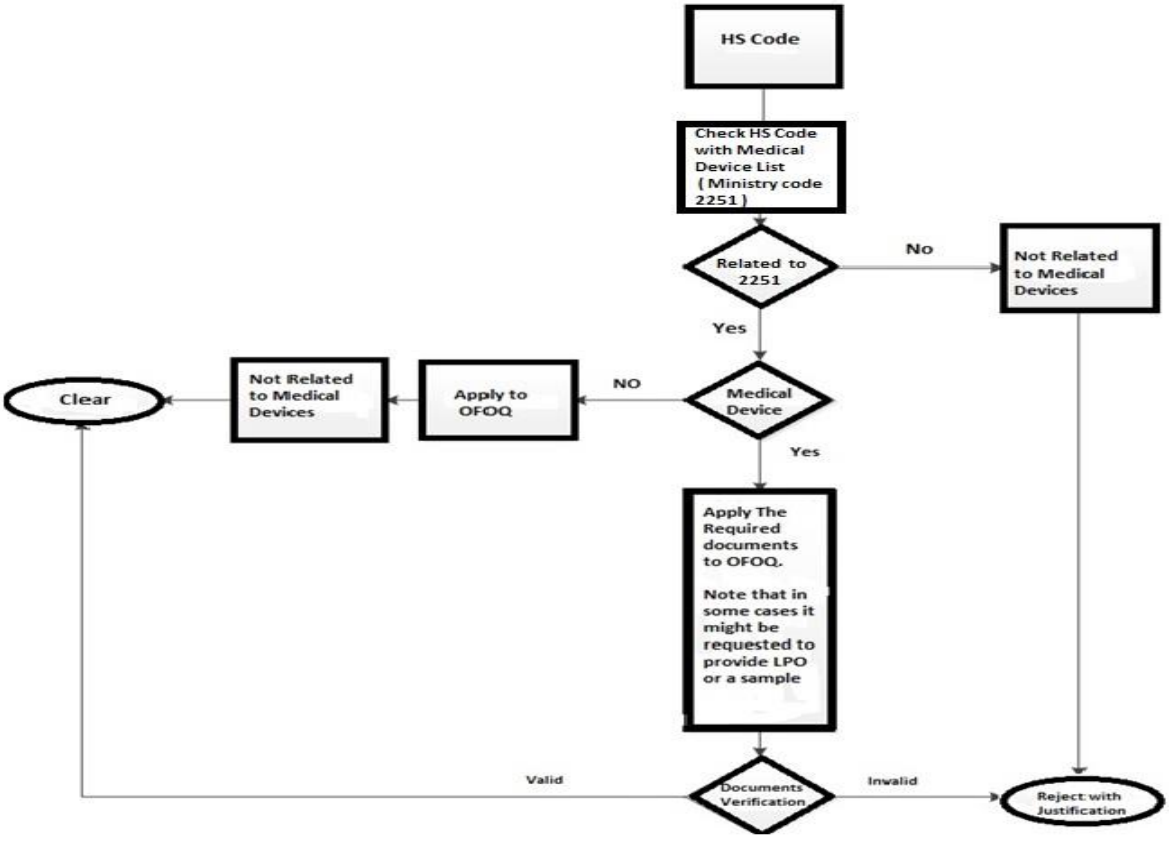
Step 19: after finding your request

1. Right click on the request.
2. Click “Request”.
3. Click the



To check if your request's get approved or not you can search for the request in the same way as the step 18, 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:



6. 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, blo od 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.

7. Annex

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

http://www.nhra.bh/files/files/2018/MD%20doc/Forms/Ofoq%20Documents%20Requested%20Checklist.pdf

http://www.nhra.bh/files/files/Healthcare%20Facilities/MD/MDR_Medical%20Device%20Importation%20Approval%20Process.pdf