



Non-Medical Importation Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction.....	3
2. General Rules.....	3
3. Requirements	3



1. Introduction

The guideline's purpose is to address and ease importation applications (OFOQ) for those shipments that are not under the Medical Devices and Supplies Control Section but fall within the regulated medical device's HS code list. This guideline will focus on research use only (RUO), spare parts, veterinary, and industrial devices.

This guideline documents the current practice, aiming towards NHRA policy in terms of transparency and clarity in regulation enforcement.

2. General Rules

1. The OFOQ application must be submitted as per the guideline of importation (refer to Section 5 in the mentioned guideline).
2. Documents must be in Arabic or English, organized, and searchable.
3. Ensure that the provided documents contain all necessary details and sufficient information to support your case.
4. Providing the requirements as per the cases listed below does not guarantee approval, as NHRA might request additional documents not mentioned in this guideline for safety and quality assurance purposes.

3. Requirements

- **Research Use Only (RUO):**

1. Invoice
2. Local Purchase Order (LPO) from a university or a Governmental Hospital only.
3. A Letter from the LPO issuer stating their acknowledgement and confirming the use of the device/s for research purposes only and not for diagnostic or therapeutic purposes.
4. A clear description of the device's use (Catalogue, IFU, or any official document from the manufacturer)
5. Label.



- **Spare parts:**

For “core” parts which will be covered by the main device quality documents, applicant must refer to the guideline of importation and apply accordingly, as it is considered as medical device.

Other spare Parts can be approved with the following documents:

1. Invoice
2. A clear description of the part’s use and where it belongs in the device.
(Catalogue, IFU, or any official document from the manufacturer)

- **Veterinary and Industrial:**

1. Invoice
2. A clear description of the device’s use (Catalogue, IFU, or any official document from the manufacturer).
3. A letter from the supplier stating the use of the device and confirming that it cannot be used for human healthcare.