Medical device Importation for Personal use Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction

This guideline is intended to guide all individuals that import personal-use medical devices. For example, contact lenses, blood pressure monitor, home use blood glucose meter…etc.

Different brands and models may vary in terms of their design, function, operation, price, quality, and user-friendliness. This guideline ensures that the imported medical device is safe, effective, and appropriate to an individual's need.

As NHRA aim to ensure the safety of end-users, this guideline aims to prevent any harm to patients or users and to avoid the rejection of import permits, which could result in significant time and financial losses for importers

2. Selections Parameters

1. Consulting a healthcare professional is important to ensure that the purchased medical device suits importers health condition.
2. Medical devices imported by for personal use non-authorized personal must be designed and approved for personal use and not intended to be used by professional health workers.
3. Medical devices imported for personal use must have a claim that is suitable for home use medical devices and no contraindications.
4. The quality of imported medical devices should be guaranteed by asking for a quality assurance certificate from the manufacturer or the seller before purchasing.
5. Importation should be from a reputable supplier, as medical devices require after-sales service from the supplier.
6. Ensure the supplier/manufacturer will provide instruction/user manual in proper language.
7. Check medical device warranty to ensure after-sale service.

3. Requirement

In order to grant the pre-approval for importing personal use medical devices, applicant should provide the following required documents through OFOQ system according to HS Code (please refer to OFOQ importation guideline):

1. Healthcare professional prescription to ensure that the purchased medical device suits health conditions.
2. An Invoice where the device quantity should not exceed 3 devices, or 3 months adequate supply.
3. A Quality Assurance Certificate to ensure safety and quality as per international standards.
4. Medical device catalogue to ensure it is for personal use and doesn't require to be used by a qualified Healthcare professional (when needed).

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