Personal Medical device Importation Guideline

National Health Regulatory Authority (NHRA)

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1. Introduction

This guideline is intended to guide all individuals that import personnel use medical devices for different purposes of diagnosis, prevention, treatment, or monitor of diseases. 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, functioning and appropriate to individual's need.

Use of unsafe medical devices or improper use of medical devices may not only cost money, but more importantly it affects the user health.

2. Selections Parameters

1. Consulting a healthcare professional is important to ensure that the purchased medical device suits health condition.
2. Quality of imported medical device should be guaranteed by asking for quality assurance certificate before purchasing.
3. Importation should be from reputable supplier, as medical devices require after sales service from the supplier.
4. Ensure the supplier/ manufacturer will provide instruction/user manual in proper language.
5. Check medical device warranty to ensure after-sale service.

3. Requirement

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

1. Healthcare professional prescription to ensure that the purchased medical device suits health condition.
2. The invoice, and the quantity should not exceed 3 devices, or 3 months adequate supply.
3. The quality assurance certificate to ensure safety and good manufacturing as per international standards.
4. Medical device catalogue to ensure it is for personnel use and doesn't require to be used by a qualified person (when needed).