MDS – G15

# GUIDANCE ON IMPORTATION REQUIREMENTS FOR PERSONAL USE AND CUSTOM-MADE MEDICAL DEVICES

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# DEFINITIONS & ABBREVIATIONS

## Definitions

| | |
|---|---|
| Medical Device | means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:<br>A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:<br>- diagnosis, prevention, monitoring, treatment or alleviation of disease,<br>- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,<br>- investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>- supporting or sustaining life,<br>- control of conception,<br>- disinfection of medical devices,<br>- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;<br>and<br>B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. |
| Custom-Made Medical Device | means any medical device specifically made in accordance with a healthcare professional's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. Custom-made medical devices exclude those devices which are generally available from a dispenser such as orthotics or glasses. |
| Home-Use Medical Device | is a medical device labeled for use in any environment outside of healthcare facility. This includes but not limited to home, office environments, schools, and vehicles. If the medical device is intended to be used in healthcare facilities and outside those facilities, it meets this definition. |
| Lay Person | is any individual that does not have formal training in a specific field or discipline. Note: Medical personnel in healthcare facilities are not considered to be lay persons. |

## Abbreviations

| | |
|---|---|
| KSA | Kingdom of Saudi Arabia |
| SFDA | Saudi Food and Drug Authority |
| MDS | Medical Devices Sector |
| MDIL | Medical Devices Importation License |

# INTRODUCTION

## Purpose

The purpose of this guidance is to provide requirements on obtaining an importation license and shipment clearance for importing personal use and custom-made medical devices which are not frequently imported.

## Scope

This document applies to who wish to import the following:

- personal use medical devices, or
- custom-made medical devices which are not frequently imported.

## Background

Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Medical Devices Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization.

Devices that may access KSA for the purpose of personal use and custom-made medical devices are exempt from marketing authorization requirements according to the requirements specified in this guidance document.

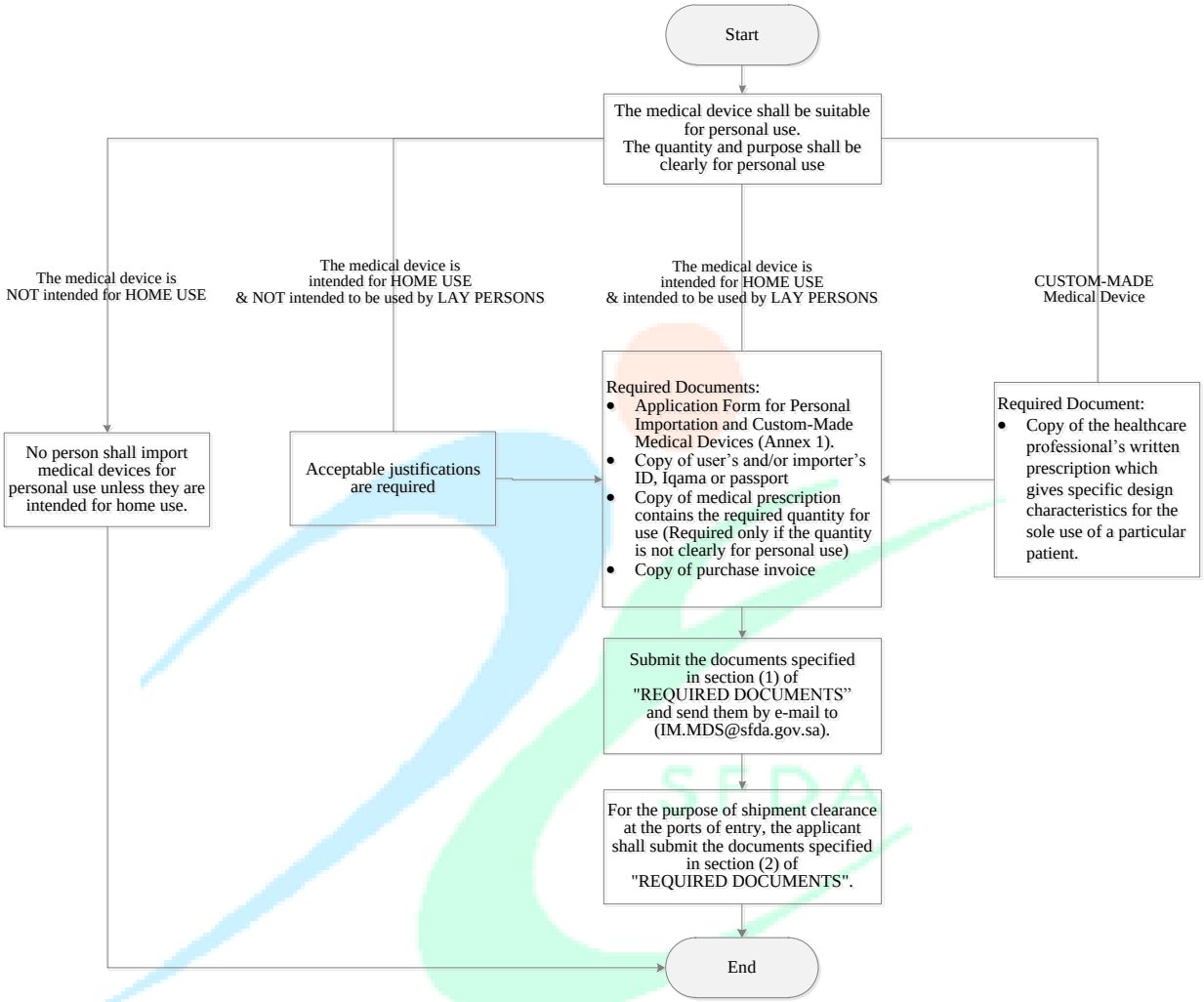
# REQUIREMENTS

| | | |
|---|---|---|
| General | 1 | Importing personal use and custom-made medical devices may access KSA only if a written approval is obtained from SFDA/MDS. |
| | 2 | Importation will be considered personal when the quantity and purpose are clearly for personal use and not for any other purpose. SFDA reserves the right to reject the request if the medical devices are not suitable for personal use. |
| | 3 | No person shall import medical devices for personal use unless they are intended for home use. |
| | 4 | For the purpose of personal importation, no person shall import home-use medical devices not intended to be used by lay persons, unless acceptable justifications are provided. |
| Imported Quantity | 5 | Each shipment shall not exceed the quantity needed for three months, according to a medical prescription. The total imported shipments shall not exceed five shipments per year. |
| Submitting to SFDA | 6 | Applicants shall submit the documents specified in section (1) of "REQUIRED DOCUMENTS" and send them by e-mail to (IM.MDS@sfda.gov.sa). Once satisfied, SFDA will send the MDIL to the applicant's email. |
| Shipment Clearance at the Ports of Entry | 7 | For the purpose of shipment clearance at the ports of entry, the applicant shall submit the documents specified in section (2) of "REQUIRED DOCUMENTS". |
| Declaration | 8 | The user and/or importer shall abide by the provisions of "Application Form for Personal Importation and Custom-Made Medical Devices" (Annex 1) |

# REQUIRED DOCUMENTS

| | Required Documents | Sample | Note |
|---|---|---|---|
| | (1) Required Documents for MDIL | | |
| 1 | Application Form for Personal Importation and Custom-Made Medical Devices | See Annex 1 | • See "Point (6) of Requirements" in this document. |
| 2 | Copy of medical prescription | - | • ***Required only if the quantity is not clearly for personal use***<br>• The prescription shall contain the required quantity for use. |
| 3 | Copy of the healthcare professional's written prescription which gives specific design characteristics for the sole use of a particular patient | - | • ***Required only in case of custom-made medical devices*** |
| 4 | Copy of user's and/or importer's ID, Iqama or Passport | - | - |
| 5 | Copy of purchase invoice | - | • Required only if the devices are purchased |
| | (2) Required Documents for Shipments Clearance at the Ports of Entry | | |
| 1 | Copy of MDIL | - | • It shall be valid |
| 2 | Original Purchase Invoice | - | - |

# FLOWCHART


Start
The medical device shall be suitable for personal use.
The quantity and purpose shall be clearly for personal use
The medical device is NOT intended for HOME USE
The medical device is intended for HOME USE & NOT intended to be used by LAY PERSONS
The medical device is intended for HOME USE & intended to be used by LAY PERSONS
CUSTOM-MADE Medical Device
No person shall import medical devices for personal use unless they are intended for home use.
Acceptable justifications are required
Required Documents:
Application Form for Personal Importation and Custom-Made Medical Devices (Annex 1).
Copy of user's and/or importer's ID, Iqama or passport
Copy of medical prescription contains the required quantity for use (Required only if the quantity is not clearly for personal use)
Copy of purchase invoice
Required Document:
Copy of the healthcare professional's written prescription which gives specific design characteristics for the sole use of a particular patient.
Submit the documents specified in section (1) of "REQUIRED DOCUMENTS" and send them by e-mail to (IM.MDS@sfda.gov.sa).
For the purpose of shipment clearance at the ports of entry, the applicant shall submit the documents specified in section (2) of "REQUIRED DOCUMENTS".
End

# ANNEXES

# Annex 1
# Application Form for Personal Importation and Custom-Made Medical Devices

## نموذج طلب استيراد الأجهزة والمنتجات الطبية المستوردة أو المُصنّعة بالطلب للاستخدام الشخصي

| | | | | | |
|---|---|---|---|---|---|
| **بلد الشحن**<br>Source of Shipment | | **رقم بوليصة الشحن**<br>(في حال تم الشحن)<br>Number of Bill Of Lading (BOL)/ Air Waybill (AWB)<br>(if the shipment is shipped or arrived) | | | |
| **الشركة الناقلة**<br>Carrier | | | | | |
| | **اسم الجهاز/المنتج الطبي**<br>Medical Device Name | | **الكمية**<br>Quantity | **الشركة المصنعة**<br>Manufacturer | **الغرض من الاستخدام**<br>(بشكل مختصر)<br>Intended Use |
| **الأجهزة/ المنتجات الطبية المراد استيرادها**<br>Medical Devices Intended to be Imported | 1 | | | | |
| | 2 | | | | |
| | 3 | | | | |
| | 4 | | | | |
| | 5 | | | | |
| | 6 | | | | |
| | 7 | | | | |
| **طريقة الشراء**<br>Purchasing Method | ☐ عن طريق الانترنت<br>(يكتب موقع الشراء باللغة الانجليزية)<br>By Internet<br>(Please write the website address) | | ☐ أخرى (يرجى ذكرها)<br>Other (Please specify) | | |
| | www. | | | | |
| **مسوغات الشراء**<br>Justification for purchasing from outside Saudi Arabia | | | | | |

| | | | |
|---|---|---|---|
| **التعهد**<br>Declaration | أتعهد بأن الأجهزة والمنتجات الطبية المذكورة أعلاه هي للاستخدام الشخصي فقط وليست للاستخدام لأي غرض آخر. كما اقر بأني على علم أن الهيئة العامة للغذاء والدواء لا تضمن سلامتها أو كفاءتها أو جودتها، لذا أتحمل كامل المسؤولية في حال نتج عن استخدامها أي مخاطر. كما اقر بأن جميع المعلومات المقدمة صحيحة. | | I declare that above medical device/s are for personal use only, and not intended to be used for any another purpose. I also understand that the Saudi Food & Drug Authority (SFDA) can give no guarantee as to the safety, effectiveness, or quality of the above medical devices. Therefore, I will take full responsibility for all hazards or risks due to usage. I also declare all provided information is correct. |
| | اسم المستورد | Importer Name | |
| | رقم الجوال | Mobile Number | |
| | رقم الهوية الوطنية/الإقامة/ الجواز | Saudi ID /Iqama ID/Passport No. | |
| | البريد الإلكتروني | E-mail | |
| | العنوان | Address | |
| | التاريخ | Date | |
| | التوقيع | Signature | |
| | **في حال اختلاف المستفيد عن المستورد تملأ الحقول الآتية:** | | |
| | اسم المستفيد | Beneficiary Name | |
| | رقم الجوال | Mobile Number | |
| | رقم الهوية الوطنية/الإقامة/ الجواز | Saudi ID /Iqama ID/Passport No. | |
| | البريد الإلكتروني | E-mail | |
| | العنوان | Address | |
| | التاريخ | Date | |
| | التوقيع | Signature | |