MDS-G8

Guidance on
Importation Requirements of Medical Devices Intended for Demonstration or Training Purposes Only

Version Number: 3.0
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Introduction

Purpose

The purpose of this document is to specify the requirements for obtaining an importation license for medical devices intended for demonstration or training purposes only.

Scope

This document is applicable to:

- Medical devices establishments wishing to import medical devices intended for demonstration or training purposes only.
- Establishments organizing exhibitions and other establishments wishing to import medical devices intended for demonstration purposes at exhibitions.

Background

SFDA/MDS has issued this guidance document in reference to Article Four of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by Saudi Food and Drug Authority Board of Directors decree No. (4-16-1439) dated 27/12/2017 stipulating that "medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization. The SFDA may exempt any medical device and shall announce the exempt medical devices on its website taking into consideration the public interest".

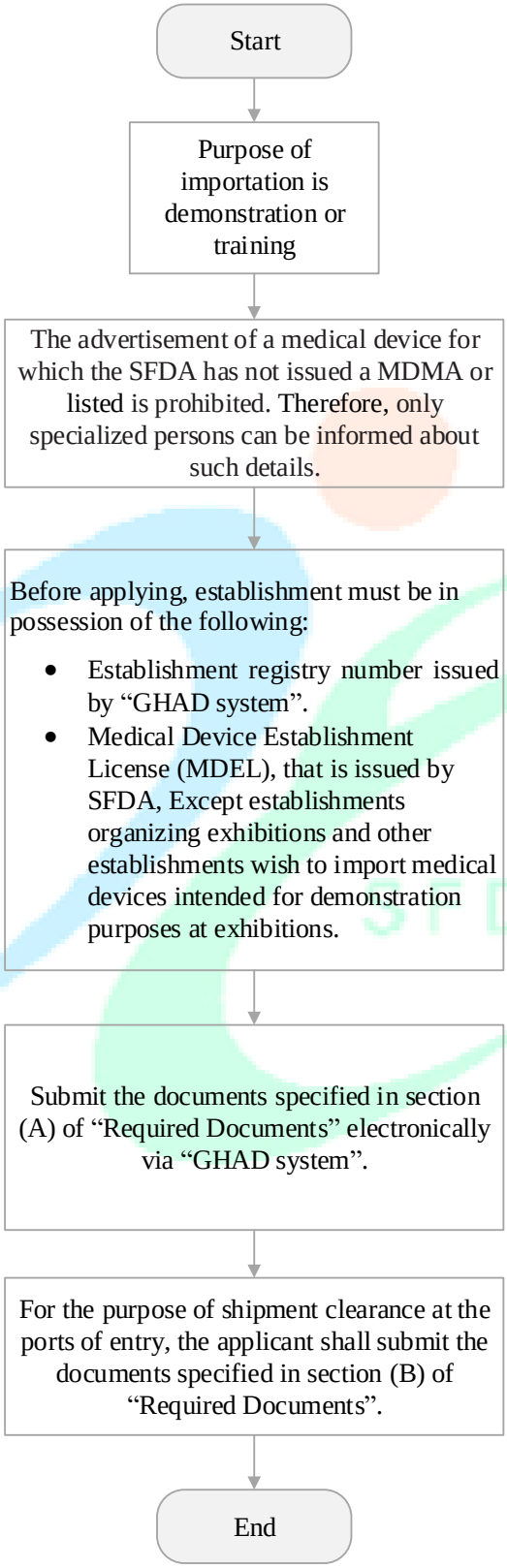
Requirements

General	1	Medical devices intended for demonstration or training purposes only are exempt from SFDA requirements for registeration or Medical Device Marketing Authorization (MDMA).
	2	No person shall import a medical device (intended for demonstration or training purposes only) unless the SFDA has issued an importation license.
	3	The advertisement of a medical device for which the SFDA has not registered or issued a Medical Device Marketing Authorization (MDMA) is prohibited. Therefore, only specialized persons can be informed about such details.
Pre-requisite	4	Before applying for an importation license, the establishments shall be in possession of: - Establishment registry number issued by "GHAD system". - Medical Device Establishment License, for importation activity, that is issued by SFDA. Except establishments organizing exhibitions and other establishments wishing to import medical devices intended for demonstration purposes at exhibitions accompaniying conferences and events held in KSA.
Submitting to SFDA	5	Applicant shall submit "Application Form of Medical Devices Intended for Demonstration or Training Purposes Only" in Annex (1) electronically via "GHAD system", and provide "Required Documents".
Clearance at the Ports of Entry	6	For the purpose of shipment clearance at the ports of entry, applicant shall submit documents specified in section (B) of "Required Documents" according to "Guidance on Requirements of Shipments Clearance (MDS-G21)".

Required Documents

S/N	Name of documents	Note
A. Required Documents for Importation License (MDIL)		
1	Proof that the device is classified as medical devices	– Such as classification certificate, proof of marketing outside KSA or declaration of conformity (DOC)
2	User Manual/Catalogue/ Brochure	– If applicable
3	Copy of the device label indicating that the device intended for demo or training only and not for sale	– The label shall contain a statement to indicate the intended purpose like: For Demo ONLY For Training ONLY NOT for sale
4	Copy of the invoice	
5	Copy of the Bill Of Lading (B/L) or the Air WayBill (AWB)	– If applicable
6	Attestation	– See Annex (2), click here for printable and editable version – It shall be signed by the authorized person of importer (who is defined in GHAD system)
B. Required Documents for Shipment Clearance		
7	Copy of Purchase Invoice	– It shall be authenticated by the chamber of commerce in the country of origin or country of exporting – It shall contain the invoice number, manufacturer's name and address, products name, quantity, and unit price – Model/part numbers and lot/serial numbers shall be indicating in the invoice or packing list – Beneficiary name
8	Bill Of Lading (B/L) or the Air Waybill (AWB)	
9	Copy of Customs Declaration	
10	Copy of Importation Licence	

Flowchart


Start
Purpose of importation is demonstration or training
The advertisement of a medical device for which the SFDA has not issued a MDMA or listed is prohibited. Therefore, only specialized persons can be informed about such details.
Before applying, establishment must be in possession of the following:
Establishment registry number issued by "GHAD system".
Medical Device Establishment License (MDEL), that is issued by SFDA, Except establishments organizing exhibitions and other establishments wish to import medical devices intended for demonstration purposes at exhibitions.
Submit the documents specified in section (A) of "Required Documents" electronically via "GHAD system".
For the purpose of shipment clearance at the ports of entry, the applicant shall submit the documents specified in section (B) of "Required Documents".
End

Annexes

Annex (1): Application Form of Medical Devices Intended for Demonstration or Training Purposes Only

(This is for reference only. Valid version is incorporated into GHAD system)

1. Manufacturer
Manufacturer Name:
Country:
City:
Postal Code:
Address Details
Email Address:
Telephone Number:
Mobile Number:
2. Shipments Information
Product Type:
Section 1: Shipments details
Purpose of Importing:
Shipment Country:
Shipment Company:
Arrival Port:
3. Purchase Invoices
Invoice Number:
Invoice Date:
Serial Number:
4. Product
General Name:
Trade Name:
Intended Use:
Quantity:
Unit of Quantity:
Total Price/Weight:
5. Documents
Certificate of Conformity
Letter from applicant indicating that the device intended for demo or training only

Annex (2): Attestation for Importers of Medical Devices Intended for Demonstration or Training Purposes Only

Click here for printable and editable version

يطبع على الورق الرسمي للمستورد التاريخ: / / هـ

نحن شركة / مؤسسة /مستودع ..... سجل تجاري رقم .....

وبغرض طلب إذن استيراد الأجهزة/المنتجات الطبية التالية:

م	رقم الفاتورة	تاريخ الفاتورة	عدد البنود	الشركة المصنعة	بلد الصنع
1					

والقادمة عن طريق منفذ ..... ، نتعهد بالآتي:

1. مطابقة بنود الشحنة الواردة في الفاتورة مع الشروط والمعايير الدولية والمتطلبات الواردة في لائحة رقابة الأجهزة والمنتجات الطبية بالهيئة العامة للغذاء والدواء .
2. مراعاة شروط النقل والتخزين حسب اشتراطات ومتطلبات الهيئة العامة للغذاء والدواء والشركة الصانعة مع إيضاح مكان التخزين بعد فسح الشحنة.
3. الأجهزة/المنتجات الطبية المستوردة لن تستخدم على المريض وإنما يقتصر استعمالها على مجال العرض والتدريب فقط، بغض النظر عن كفاءة الأجهزة للاستخدامات العلاجية أو التشخيصية.
4. إحضار أصل الفاتورة وشهادة المنشأ لدى منفذ الوصول.
5. استخدام المواد المطلوب استيرادها في الأغراض الموردة من أجلها بالإضافة إلى عدم تداولها في غير الأماكن المخصصة لذلك وتحمل جميع الأضرار الناجمة عن سوء استخدام المواد المذكورة في طلب إذن الاستيراد أو استخدامها في غير الغرض الذي وردت من أجله.
6. الأفراد القائمين بالعمل مؤهلون علمياً وعملياً
7. وضع البطاقة التعريفية على الجهاز/المنتج الطبي والتي تتضمن بأن الجهاز/المنتج الطبي سيستخدم لغرض العرض أو التدريب فقط وليس للبيع.
8. أن يتم إعادة تصدير الأجهزة/المنتجات الطبية بتاريخ ..... (ستة أشهر كحد أقصى) أو إتلافها وإخطار الهيئة بذلك مع إحضار ما يثبت ذلك.
9. بنود الشحنة الواردة في الفاتورة المذكورة أعلاه تحتوي على:

9-1 مواد مشعة ☐نعم ☐لا

اسم المادة المشعة:..... (إذا كانت الإجابة بنعم)

9-2 مواد كيمائية خاضعة لرقابة الأمن العام ☐نعم ☐لا

اسم المادة الكيمائية::..... (إذا كانت الإجابة بنعم)

9-3 مواد مخدرة ☐نعم ☐لا

اسم المادة المخدرة::..... (إذا كانت الإجابة بنعم)

ولكم جزيل الشكر والتقدير ،،،

اسم الشخص المسؤول :

المسمى الوظيفي :

التوقيع :

التاريخ :

الختم

Annex (3): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: 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: 1. Diagnosis, prevention, monitoring, treatment or alleviation of disease, 2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, 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 for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and 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.
Advertising of medical devices	means any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.
Labelling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers.

	B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.

Annex (4): List of Changes on the Pervious Versions

Number & Date of the Pervious Version	Changes Description
1.1 1/5/2016	- Changing in the text of the “Scope”. - Changing in the text of the “Background”. - Changing in the text of section (4) of "Requirements".
2.0 11/9/2018	- Changing in the text of sections (1-5) of “Requirements”. - Adding sections (1-3) and (9-10) of “Required Documents”. - Changing in the text of section (7) of “Required Documents”. - Changing in “Flowchart” - Changing in Annex (1), Annex (2) and Annex (3).