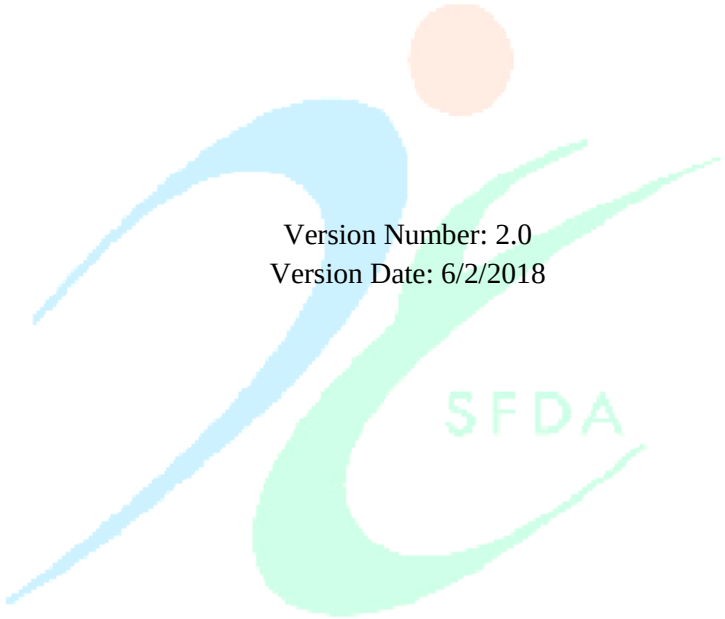
MDS-G21

Guidance on Requirements of Shipments Clearance at Ports of Entry



Version Number: 2.0
Version Date: 6/2/2018

This guidance document has been published after being distributed for public comments dated on 1/5/2017 for 30 days.

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Introduction

Purpose

The purpose of this guidance is to clarify the requirements to obtain shipment clearance for products subject to SFDA/MDS regulation at the KSA POEs.

Scope

This guidance is applicable to any importer wishes to clear shipments containing products subject to SFDA/MDS regulation at the KSA POEs.

Background

In accordance with "The Law of Saudi Food and Drug Authority" issued by the Royal Decree No.(M/6) issued on 25/1/1428 H, SFDA/MDS undertakes the responsibility of issuing shipment clearance for products subject to its regulation according to the requirements specified in this guidance document.

Requirements

General	1	Regulated products included in this guidance shall NOT be imported unless shipment clearance is obtained from the SFDA/MDS.
	2	No person shall import used medical devices.
	3	For products containing materials subject to the MOI's control (such as IVDs and chemicals) require MDIL from SFDA/MDS before the referral to MOI.
	4	Importers may request a classification for the products intended to be imported, in order to know whether they are subject to SFDA/MDS regulation or not. For more information, refer to the SFDA's website.
Registration & Licensing Requirements for Medical Devices Imported for Marketing Purposes	5	Importers of medical devices, for marketing purposes, shall have: o establishment National Registry Number that is issued through MDNR. o MDEL for importing medical devices for marketing purposes. Healthcare facilities importing for their own use are not required to have MDEL with condition that the shipment quantity is not commercial.
	6	Medical devices imported for marketing purposes shall have MDMA. However, low-risk medical devices that are non-sterile and not having measuring function require either listing in the MDNR or having MDMA.
Product Shelf Life	7	If the shelf life of the product is: o more than three years, it shall NOT be less than one-third of its shelf life at the POE. o between one and three years, it shall NOT be less than half of its shelf life at the POE. o less than one year, it shall NOT be less than two-thirds of its shelf life at the POE.
Storage and Transportation	8	• Importers shall comply with the manufacturer's instructions for the storage, handling, and transport of products they import. • Each shipment that requires specific temperature for transportation and/or storage, according to the manufacturer instructions, shall contain data logger (digital temperature indicator) activated from the time of shipping.
Samples Withdrawal	9	SFDA/MDS withdraws random samples of imported shipments at POEs in order of assessment or examination according to risk-based studies and for testing and scientific evaluation purposes or suspension

		cases (e.g. misleading medical claims, sterilization and labeling malfunctioning, inappropriate environment conditions, or counterfeit… etc.). However, SFDA neither bear any costs of those samples nor costs of their testing in private labs.
Submitting to the SFDA	10	Importers shall submit the documents specified in "REQUIRED DOCUMENTS" below for each shipment at any of the following POEs: 1. King Khaled International Airport – Riyadh (RAP) 2. Riyadh Dry Port (RDP) 3. King Abdulaziz International Airport – Jeddah (JAP) 4. Jeddah Islamic Seaport – (JSP) 5. King Abdullah Seaport – Rabigh (RSP) 6. King Fahd International Airport – Dammam (DAP) 7. King Abdulaziz Seaport – Dammam (DSP) 8. King Fahd Causeway – Khobar (DBP) 9. Batha Port - Al Ahsa (BBP) 10. Haditha Port - Al Qurayyat (HBP).

Required Documents

	Required Documents	Sample	Note
1	Copy of Purchase Invoice	-	• It shall be authenticated by the chamber of commerce in the country of origin • It shall contain the invoice number, manufacturer's name, products name, quantity, and unit price • Model/part numbers and lot/serial numbers shall be indicating in the invoice or packing list
2	Bill Of Lading (B/L) or the Air Waybill (AWB)	-	-
3	Declaration of Conformity to SFDA Medical Devices Interim Regulation	Annex 1	• Required only for medical devices imported for marketing purpose that are having MDMA and/or listed in the MDNR. • This declaration is different than the declaration of conformity to the regulation of one of the GHTF countries (Australia, Canada, Japan, the USA and the EU/EFTA)
4	Copy of MDIL	-	• Required only for the following products: ○ Medical devices imported for: ▪ Demonstration or training purpose only. (For more information, refer to guidance document MDS-G8) ▪ Clinical investigations purpose. ▪ Personal use. (For more information, refer to guidance document MDS-G15). ▪ National emergency situations. (For more information, refer to guidance document MDS-G14)

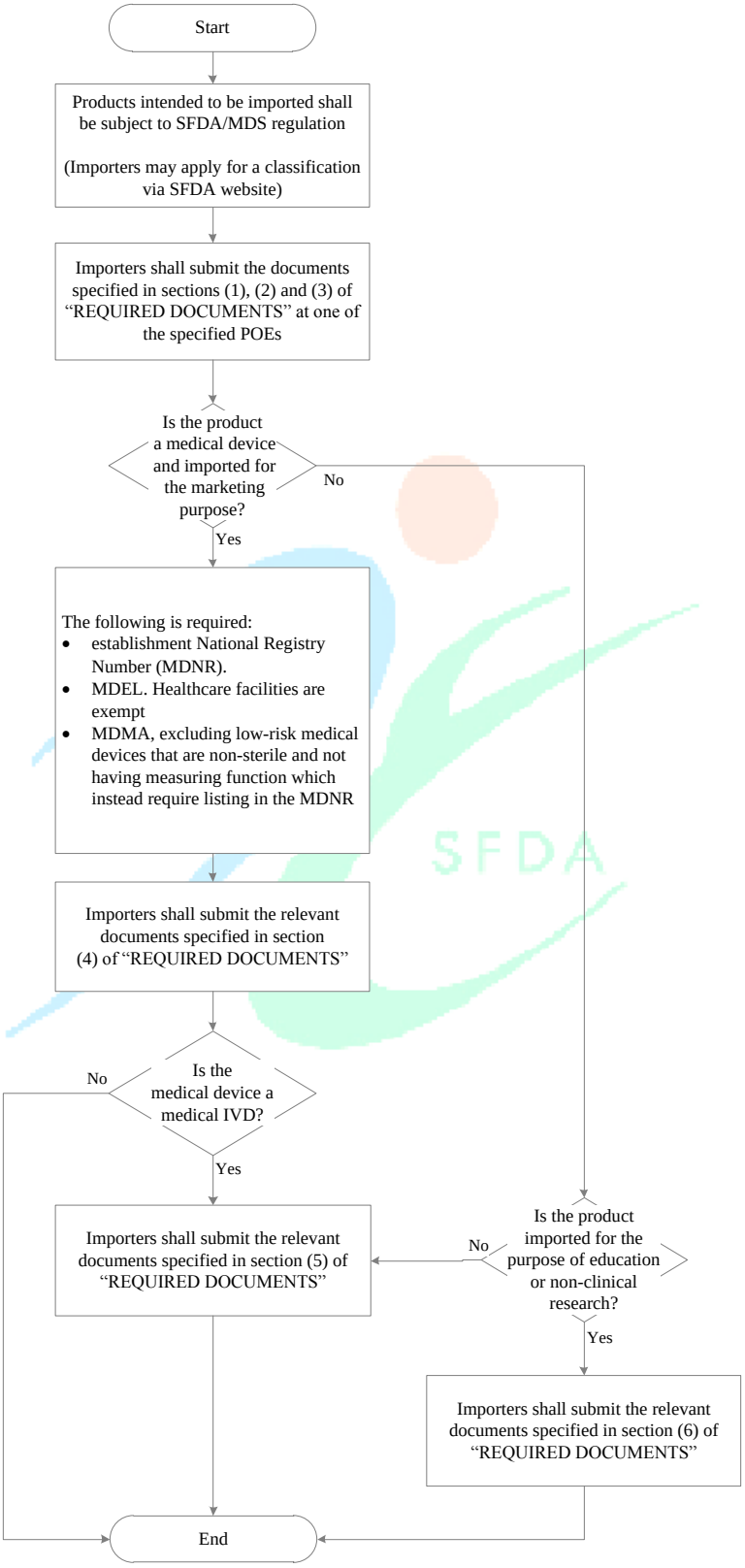
			○ Custom-made medical devices not frequently imported. (For more information, refer to guidance document MDS-G15) ○ Finished medical devices imported for the purpose of local manufacturing. ○ Medical IVDs ○ Non-medical IVDs. (For more information, refer to guidance document MDS-G16) ○ Biological therapeutic products ○ International quality and efficiency samples. (For more information, refer to guidance document MDS-G9) ○ Distillation apparatuses imported for healthcare providers or medical educational facilities . (For more information, refer to guidance document MDS-G19) ○ Chemicals (finished products) used in medical applications. (For more information, refer to guidance document MDS-G12)
6	Research Products Importation License	-	• Required only for medical devices and non-medical IVDs intended for educational or non-clinical research purposes (For more information, refer to guidance document MDS-G18)
Notes:			

1. Labeling (affixed on the product itself or the instruction for use) for medical devices imported for marketing purpose shall:
    - correspond to the submitted labeling in MDMA system
    - contain a barcode for home-use medical devices and correspond to the registered barcode in MDMA
    - be available in Arabic for medical devices intended for use by lay person.
    - not include the SFDA logo nor the Establishment National Registry Number issued by the SFDA
    - not include logo for any governmental body, unless the purchase order requires that, except conformity marks (such as qulaity mark of SASO, GCC conformity marking).

    For more information about labeling requirements, please refer to guidance document MDS-G10 entitled "Guidance on Labeling Requirements for Medical Devices".

2. Dvices intended to be connected to an a/c power supply and imported for marketing purpose shall operate at a frequency of 60 Hz.
3. Importers have two weeks for correction from the issuance date of the notice letter, issued from the port.
4. In case the shipment requires specific temperature for transportation and/or storage according to the manufacturer instructions, serial number of data logger (digital temperature indicator) shall be indicated in the invoice, (B/L)/(AWB), packing list or letter from the invoice issuer. The delivery of data logger (digital temperature recorder) to the SFDA office at the POE, especially the air ports, speeds up the shipments clearance process.
5. Shipments that meet certain criteria may be cleared faster and without inspection. These criteria are related to the shipment storage requirements and the importer's record of compliance with the shipments clearance requirements (annual assessment).
6. Importer have the right to object within two weeks from the date of shipment rejection by providing an objection letter to the POE Department at SFDA/MDS.

Flowchart


Start
Products intended to be imported shall be subject to SFDA/MDS regulation
(Importers may apply for a classification via SFDA website)
Importers shall submit the documents specified in sections (1), (2) and (3) of "REQUIRED DOCUMENTS" at one of the specified POEs
Is the product a medical device and imported for the marketing purpose?
No
Yes
The following is required:
establishment National Registry Number (MDNR).
MDEL. Healthcare facilities are exempt
MDMA, excluding low-risk medical devices that are non-sterile and not having measuring function which instead require listing in the MDNR
Importers shall submit the relevant documents specified in section (4) of "REQUIRED DOCUMENTS"
Is the medical device a medical IVD?
No
Yes
Importers shall submit the relevant documents specified in section (5) of "REQUIRED DOCUMENTS"
Is the product imported for the purpose of education or non-clinical research?
No
Yes
Importers shall submit the relevant documents specified in section (6) of "REQUIRED DOCUMENTS"
End

Annexes

Annex (1): Declaration of Conformity for the Shipment to Saudi Food and Drug Authority Medical Devices Interim Regulation

[To be printed on Manufacturer Letterhead]

Manufacturer Name: .....
Manufacturer Identification Number Assigned by the SFDA: .....
Manufacturer Address: .....
Invoice Number (optional): .....

I hereby declare that the medical device(s) identified below complies with the Medical Devices Interim Regulation and its associated Implementing Rules and has been authorized by the SFDA to be placed on the KSA market.

Authorized Representative Name: .....
(Note: Not applicable for low-risk medical devices that are non-sterile and not having measuring function)

Importer Name: .....

#	Medical Device Trade Name[1]	Quantity	Serial Number/ Batch Number	Medical Device Listing National Registry Number (issued by MDMA system)[2] or MDMA Application Number	Medical Device Listing National Registry Number (issued by MDNR system)[3]
1					
2					
…					

[1] Medical device trade name shall match the names mentioned in the invoice, the MDMA and the MDNR.
[2] Not applicable for low-risk medical devices that are non-sterile and not having measuring function.
[3] Applicable for low-risk medical devices that are non-sterile and not having measuring function.
Note: Additional devices may be attached as a list.

Authorised Signatory (on behalf of the manufacturer)
Name:
Position:
Date:
Signature:

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MOI	Ministry of Interior
GCC	Gulf Cooperation Council
SASO	Saudi Standards, Metrology and Quality Organization
AR	Authorized Representative
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: ○ Diagnosis, prevention, monitoring, treatment or alleviation of disease, ○ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, ○ Investigation, replacement, modification, or support of the anatomy or of a physiological process, ○ Supporting or sustaining life, ○ Control of conception, ○ Disinfection of medical devices, ○ 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.
Labeling	means written, printed or graphic matter A. Affixed to a product or any of its containers or wrappers. B. Information accompanying a product, related to identification, technical description. C. Information accompanying a product, related to its use, but excluding shipping documents.
MDMA	Medical Devices Marketing Authorization
MDEL	Medical Devices Establishment License
MDIL	Medical Devices Importation License
POE	Port of Entry

Annex (3): List of Changes on the Pervious Version

Number & Date of the Pervious Version	Changes Description
1.0 17/9/2017	• Changing in the text of sections (6), (7) and (8) of "Requirements". • Changing in the text of section (3) of "Required Documents". • Adding sections (4) and (5) to "Notes" of "Required Documents". • Changing in Annex (1).