MDS-REQ 5

Requirements for Shipments Clearance of Medical Devices at Ports of Entries

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Introduction

Purpose

The purpose of this document is to determine and clarify the requirements for SFDA approval to release imported or exported medical devices at the KSA port of entries.

Scope

This document applies to those wishing to obtain the SFDA approval to release at port of entries for products subject to the provisions of the Medical Devices Law and its Executive Regulations.

Notes:

1. Accessories of medical device are treated as medical devices except spare parts.
2. A classification request for the products intended to be imported or exported may be submitted through services of products classification , in order to know whether they are subject to SFDA/MDS regulation or not.

Background

SFDA has issued this document in reference to the following:

A. Article Eleven of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H.

B. Announcement No. (47084) dated 12/6/1440 H regarding to keeping the original required documents of Shipment Clearance.

Requirements

General	1	Products included in this document shall not be released, at port of entries, without the SFDA approval.
	2	The following products are prohibited from importation: A. Used medical devices, unless where the purpose of importing them is: • Maintaining or renewing them within the KSA and then re-exporting them. • Return them to the KSA after they have been maintained, calibrated, displayed as marketing samples, corrected according to a field safety notice (FSN) that requires it, or tested outside the KSA. B. Surgical gloves containing powder, patient examination gloves containing powder, and absorbable powder used to facilitate the wearing of medical gloves. C. Products bearing phrases indicating that they are intended for other than the KSA (e.g., For sale only in US) D. Following electrical medical devices: – intended to be operated to an a.c. power supply other than (230) or (400) volts, – intended to be operated with frequency other than (60) hertz, or – fitted with a/c power connector not compatible with part 401 of SBC or the Saudi standard entitled "Plugs and socket-outlets for household and similar purposes-safety requirements and test methods 250 V/13 A (SASO-2203)". E. Any medical device appears to the SFDA that may endanger the health or safety of patients and users, even if it has a MDMA from the SFDA.
Storage, Transportation, Product Shelf Life and Labeling	3	A. Storage and Transportation of Product: Manufacturer's instructions for the storage, handling, and transport of products they import shall be complied, and when transportation or storage requires specific temperatures or humidity, an electronic data logger (sensor/reader/indicator) for temperature and humidity shall be available in each parcel for each shipment, and: • the data logger shall be activated from the time of shipment.

		• the data logger shall be readable, in detail without the need for a program to run it, at the POE. • the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice (B/L)/ (AWB) or bill of lading). • in the case of importing medical IVDs, the data logger shall be readable online (through the website of the service provider), as follows: – The SFDA shall be granted access (by providing it with the necessary data, such as data logger data, website, user name, password), on this website to view the data logger readings, without restricting access to a limited number of times, and – the SFDA shall not incur any financial compensation for that. B. Product Shelf Life: If the shelf life of the product is: • less than (1) year, the remaining shelf life, at the POE, shall not be less than 40%. • more than (1) year, the remaining shelf life, at the POE, shall not be less than (7) months. C. Labeling: Labeling of imported prodcucts shall be complied with the requirements of SFDA and correspond to the labeling previously submitted to the SFDA, if applicable.
Samples Withdrawal	4	SFDA 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 labs.
Submitting to the SFDA	5	Importers and exporter, for each shipment, shall submit the "Required Documents", specified in paragraph (9) below, electronically (with keeping the original documents for five years from the date of shipment clearance and provide them to the SFDA when requested) through the "FASAH" platform before the shipment arrives at one 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).
	6	The SFDA takes one of the following actions: • Release of the shipment, when the requirements are met. • Conditional release of the shipment and notify the importer of the notes to be corrected. • Rejection of the shipment, and the importer has the right to object within (60) days from the date of shipment rejection by submitting an objection letter according to the "objection procedure to the refusal of releasing the shipment" published on the SFDA website.

7. Required Document		Note
Required Licenses to Release the Products to be Imported		
7-1	Medical Devices Marketing Authorization (MDMA)	– Automatically verified without the need to provide it in the application – Not required from the following: 1) Medical devices: – Custom-Made – Used for Personal Use – Used in National Emergency Situations. – Used for Non-Clinical Research or Educational – Used for Clinical investigations. – Used as Samples in Exhibitions or worksops for (Demonstration) 2) Minimally manipulated biological products intended for human application 3) Imaging products. 4) Particle accelerators used in the formation of radioisotopes for dignostice medical applications – The MDMA shall be valid, noting that it can be renewed 90 days before its expiration – See "Medical Devices Marketing Authorization (MDS-REQ 1)" for information on the MDMA
7-2	Establishment License for importing medical devices	– Automatically verified without the need to provide it in the application – Not required form individuals and establishments that do not have activities related to medical devices and who have an importation licesne. – It shall be valid, noting that it can be renewed 60 days before its expiration
7-3	Importation License	– Required from the following: 1) Medical devices: – Contain chemicals, restricted gases, or radioactive medical materials – Custom-Made – Used for Personal Use – Used in National Emergency Situations.

		– Used for Non-Clinical Research or Educational – Used for Clinical investigations. – Used as Samples in Exhibitions or worksops for (Demonstration) – Used, mentioned in section (2-A) of "Requirements" 2) Minimally manipulated biological products intended for human application 3) Imaging products. 4) Particle accelerators used in the formation of radioisotopes for dignostice medical applications – See Annex (2) for requirements of Importation License
Other Required Documents to Release the Products to be Imported		
7-4	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 – In case the shipment requires data logger (sensor/reader/indicator) according to manufacturer instructions, the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice (B/L)/ (AWB) or bill of lading)
7-5	Bill Of Lading (B/L) or the Air Waybill (AWB)	– In case the shipment requires data logger (sensor/reader/indicator) according to manufacturer instructions, the serial number of the data logger shall be indicated in any of shipment documents (such as an invoice (B/L)/ (AWB) or bill of lading)
7-6	Customs Declaration	–
7-7	Declaration of Conformity to Medical Devices Law and its Regulation	– See Annex (1) – Required only for medical devices have MDMA. – This declaration is different than the declaration of conformity provided for pourpose of obtaining MDMA
Required Documents to Release the Products to be Exported		

7-8	Exportation Licesnse	– Required only for medical devices exporation

Annexes

Annex (1): Declaration of Conformity for the Shipment to Medical Devices Law and its Executive 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 Law and its Executive Regulation 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 (mentined on the MDMA certificate)
1				
2				
…				

[1] Medical device trade name shall match the names mentioned in the invoice and the "SFDA E-Services (Ghad)".

Note: Additional devices may be attached as a list.

Authorised Signatory (on behalf of the manufacturer)

Name:

Position:

Email:

Date:

Signature:

Annex (2): Relevant Requirements

	Product Type/Purpose	Relevant Requirements		
Requirements of Imporation License				
1	Requirements of Importation of Medical Devices Intended for Demonstration or Training Purposes Only	Guidance on Importation Requirements of Medical Devices Intended for Demonstration or Training Purposes Only	MDS-G8	
2	Requirements of Importation of Medical Devices Intended for Educational or Non-Clinical Research Purposes	Guidance on Importation Requirements for Medical Devices and Non-Medical IVDs Intended for Educational or Non-Clinical Research Purposes	MDS-G18	
3	Requirements of Importation of Medical Devices for Personal Use	Guidance on Importation Requirements for Personal Use and Custom-Made Medical Devices	MDS-G15	
4	Requirements of Importation of Custom-Made Medical Devices	Guidance on Importation Requirements for Personal Use and Custom-Made Medical Devices	MDS-G15	
5	Requirements of Importation of Medical Devices in National Emergency Situation	Guidance on Importation Requirements of Medical Devices in National Emergency Situation	MDS-G14	
6	Requirements of Importation Preliminary Products Importation for the Purpose of Local Manufacturing of Medical Devices	Guidance of Requirements for Preliminary Products Importation for the Purpose of Local Manufacturing of Medical Devices	MDS-G26	
7	Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application	Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application	-	
8	Requirements of Importation of Chemicals Used in Medical Devices Applications	Guidance on Importation Requirements for Chemicals Used in Medical Devices Applications	MDS-G12	
9	Requirements for the Import of Medical Imaging Materials and Particle Accelerators Used in	Requirements for the Import and Clearance of Medical Imaging Materials and	MDS-REQ 4	

	Radioisotopes Formation for Medical Applications	Particle Accelerators Used in Radioisotopes Formation for Medical Applications		
Requirements of MDMA				
10	Requirements of Medical Marketing Device Authorization (MDMA)	Requirements for Medical Devices Marketing Authorization	MDS-REQ1	
Other Requirement				
11	Requirements of Products Classification	Saudi FDA Products Classification Guidance	-	
12	Requirements of Storage, Handling and Transportation of Medical Devices	Guidance on Requirements for Storage, Handling and Transportation of Medical Device	MDS-G25	

Annex (3): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MOI	Ministry of Interior
AR	Authorized Representative
MDMA	Medical Devices Marketing Authorization
POE	Port of Entry

Annex (4): List of Changes on the Previous Version

Number & Date of the Previous 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).
2.0 6/2/2018	- Changing in the text of section (7) of “Requirements”.
3.0 26/7/2018	- Changing in the text of sections “Product Shelf Life” - Reformatting some sections
4.0 20/10/2020	- Genertal changing in the text of sections “Introduction” and Annex (1) for complying with Medical Devices Law and its regulation - Changing from “Guidance on Requirements of Shipments Clearance at Ports of Entry (MDS-G21) to “Requirements for Shipments Clearance Medical Devices and Other Releavent Products (MDS-REQ5)” - Changing on points (3-A) and (3-B) - Adding Annex (2)