

MDS – G21

GUIDANCE ON SHIPMENT CLEARANCE  
AT PORTS OF ENTRY



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# INTRODUCTION

## Purpose

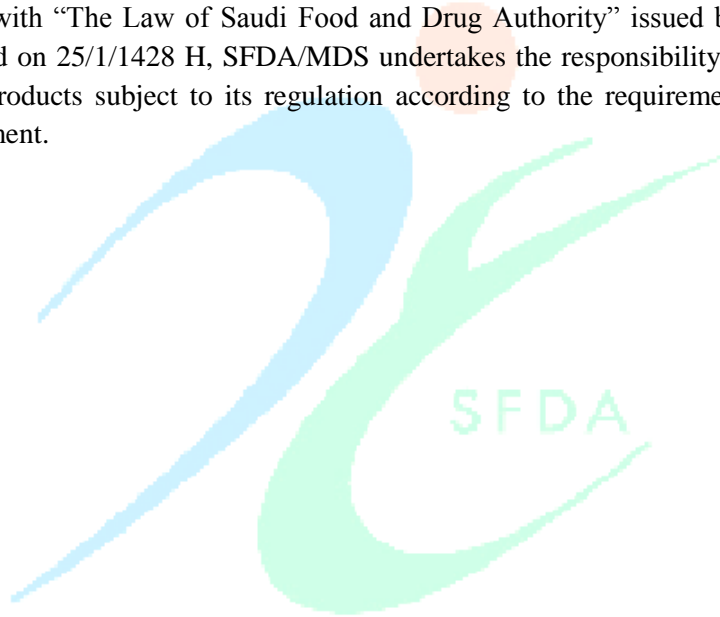
The purpose of this guidance is to clarify the requirements to obtain shipment clearance for products subject to SFDA/MDS regulation at the KSA POEs.

## Scope

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

## Background

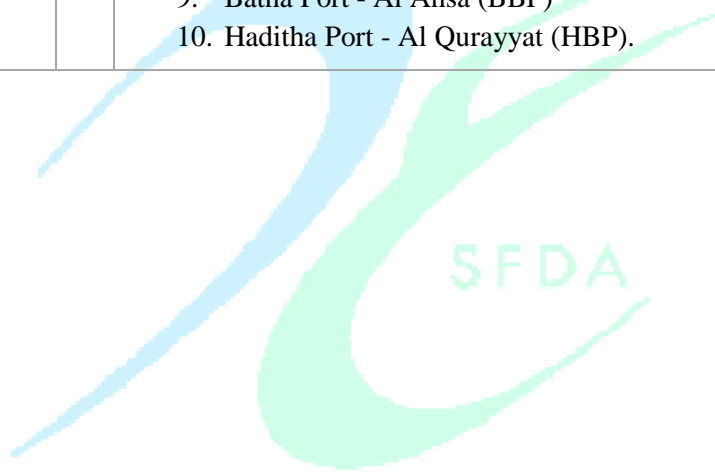
In accordance with “The Law of Saudi Food and Drug Authority” issued by the Royal Decree No.(M/6) issued on 25/1/1428 H, SFDA/MDS undertakes the responsibility of issuing shipment clearance for products subject to its regulation according to the requirements specified in this guidance document.



## REQUIREMENTS

<b>General</b>	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.
<b>Registration &amp; Licensing Requirements for Medical Devices Imported for Marketing Purposes</b>	5	Importers of medical devices, for marketing purposes, shall have: <ul style="list-style-type: none"> <li>○ establishment National Registry Number that is issued through MDNR.</li> <li>○ 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.</li> </ul>
	6	Medical devices imported for marketing purposes shall have MDMA excluding low-risk medical devices that are non-sterile and not having measuring function which instead require: <ul style="list-style-type: none"> <li>○ Listing in the MDNR</li> <li>○ AR certificate for its manufacturer.</li> </ul>
<b>Product Shelf Life</b>	7	If the shelf life of the product is: <ul style="list-style-type: none"> <li>○ more than three years, it shall NOT be less than one-third of its shelf life at the POE.</li> <li>○ between one and two years, it shall NOT be less than half of its shelf life at the POE.</li> <li>○ less than one year, it shall NOT be less than two-thirds of its shelf life at the POE.</li> </ul>
<b>Storage and Transportation</b>	8	<ul style="list-style-type: none"> <li>● Importers shall comply with the manufacturer's instructions for the storage, handling, and transport of products they import.</li> <li>● Each shipment that requires specific temperature for transportation and/or storage, according to the manufacturer instructions, shall contain digital temperature indicator activated from the time of shipping.</li> </ul>
<b>Samples Withdrawal</b>	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	<p>Importers shall submit the documents specified in “REQUIRED DOCUMENTS” below for each shipment at any of the following POEs:</p> <ol style="list-style-type: none"> <li>1. King Khaled International Airport – Riyadh (RAP)</li> <li>2. Riyadh Dry Port (RDP)</li> <li>3. King Abdulaziz International Airport – Jeddah (JAP)</li> <li>4. Jeddah Islamic Seaport – (JSP)</li> <li>5. King Abdullah Seaport – Rabigh (RSP)</li> <li>6. King Fahd International Airport – Dammam (DAP)</li> <li>7. King Abdulaziz Seaport – Dammam (DSP)</li> <li>8. King Fahd Causeway – Khobar (DBP)</li> <li>9. Batha Port - Al Ahsa (BBP)</li> <li>10. Haditha Port - Al Qurayyat (HBP).</li> </ol>



## REQUIRED DOCUMENTS

	Required Documents	Sample	Note
1	Copy of Purchase Invoice	-	<ul style="list-style-type: none"> <li>It shall be authenticated by the chamber of commerce in the country of origin</li> <li>It shall contain the invoice number, manufacturer's name, products name, quantity, and unit price</li> <li>Model/part numbers and lot/serial numbers shall be indicating in the invoice or packing list</li> <li>In case the shipment requires specific temperature for transportation and/or storage according to the manufacturer instructions, number of digital temperature indicator shall be indicating in the invoice, (B/L)/(AWB), packing list or letter from the invoice issuer</li> </ul>
2	Copy of Certificate of Origin	-	<ul style="list-style-type: none"> <li>Required only for products manufactured in non-GCC countries</li> <li>It shall be stamped by the concerned authority for trade in the country of origin</li> </ul>
3	Bill Of Lading (B/L) or the Air Waybill (AWB)	-	<ul style="list-style-type: none"> <li>In case the shipment requires specific temperature for transportation and/or storage according to the manufacturer instructions, number of digital temperature indicator shall be indicating in the invoice, (B/L)/(AWB), packing list or letter from the invoice issuer</li> </ul>
4	Declaration of Conformity to SFDA Medical Devices Interim Regulation	<a href="#">Annex 1</a>	<ul style="list-style-type: none"> <li>Required only for medical devices imported for marketing purpose that are having MDMA.</li> <li>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)</li> </ul>

5	Copy of MDIL	-	<ul style="list-style-type: none"> <li>• Required only for the following products: <ul style="list-style-type: none"> <li>○ Medical devices imported for: <ul style="list-style-type: none"> <li>▪ Demonstration or training purpose only. (For more information, refer to guidance document <a href="#">MDS-G8</a>)</li> <li>▪ Clinical investigations purpose.</li> <li>▪ Personal use. (For more information, refer to guidance document <a href="#">MDS-G15</a>).</li> <li>▪ National emergency situations. (For more information, refer to guidance document <a href="#">MDS-G14</a>)</li> </ul> </li> <li>○ Custom-made medical devices not frequently imported. (For more information, refer to guidance document <a href="#">MDS-G15</a>)</li> <li>○ Finished medical devices imported for the purpose of local manufacturing.</li> <li>○ Medical IVDs</li> <li>○ Non-medical IVDs. (For more information, refer to guidance document <a href="#">MDS-G16</a>)</li> <li>○ Biological therapeutic products</li> <li>○ International quality and efficiency samples. (For more information, refer to guidance document <a href="#">MDS-G9</a>)</li> <li>○ Distillation apparatuses imported for healthcare</li> </ul> </li> </ul>
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			<p>providers or medical educational facilities . (For more information, refer to guidance document <a href="#">MDS-G19</a>)</p> <ul style="list-style-type: none"> <li>○ Chemicals (finished products) used in medical applications. (For more information, refer to guidance document <a href="#">MDS-G12</a>)</li> </ul>
6	Research Products Importation License	-	<ul style="list-style-type: none"> <li>● Required only for medical devices and non-medical IVDs intended for educational or non-clinical research purposes (For more information, refer to guidance document <a href="#">MDS-G18</a>)</li> </ul>

Notes:

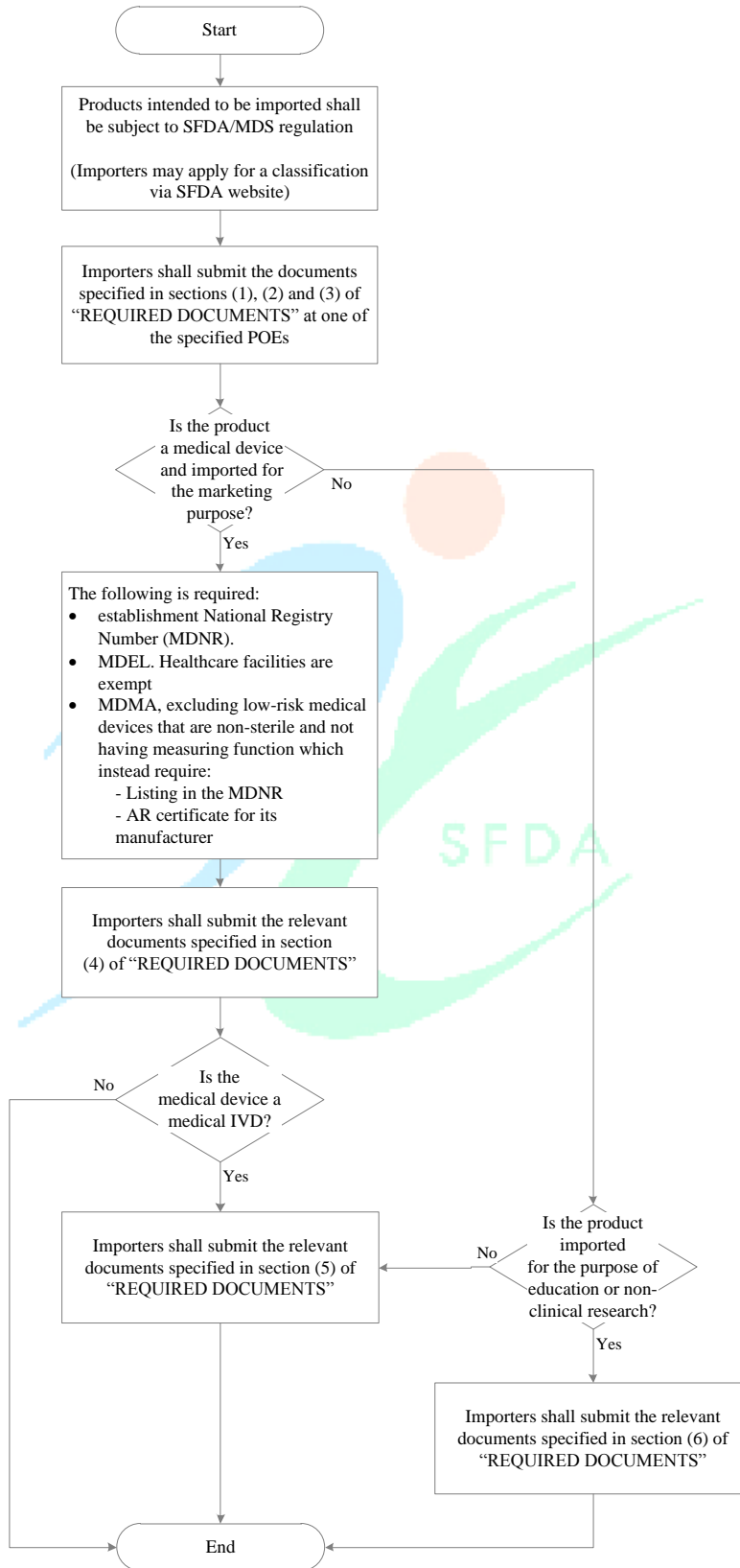
1. Labeling (affixed on the product itself or the instruction for use) for medical devices imported for marketing purpose shall:
  - correspond to the submitted labeling in MDMA system
  - contain a barcode for home-use medical devices and correspond to the registered barcode in MDMA
  - be available 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 quality 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. Devices 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. 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



ANNEXES



## Annex (1): Declaration of Conformity 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: .....

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: .....

Importer Name: .....

#	Medical Device Marketing Authorization (MDMA) Number/ MDMA Application Number	Medical Device Description	Quantity	SFDA Listing Number	Serial Number(s) / Batch Number(s)
1					
2					
..					

Note: Additional devices may be attached as a list.

Authorised Signatory (on behalf of the manufacturer)

Name:  
Position:  
Date:  
Signature:

## Annex (1): Definitions

Medical Device	<p>means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:</p> <p>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:</p> <ul style="list-style-type: none"><li>○ Diagnosis, prevention, monitoring, treatment or alleviation of disease,</li><li>○ Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,</li><li>○ Investigation, replacement, modification, or support of the anatomy or of a physiological process,</li><li>○ Supporting or sustaining life,</li><li>○ Control of conception,</li><li>○ Disinfection of medical devices,</li><li>○ Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;</li></ul> <p>and</p> <p>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.</p>
Labeling	<p>means written, printed or graphic matter</p> <p>A. Affixed to a product or any of its containers or wrappers.</p> <p>B. Information accompanying a product, related to identification, technical description.</p> <p>C. Information accompanying a product, related to its use, but excluding shipping documents.</p>

## Annex (2): 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
MDEL	Medical Devices Establishment License
MDIL	Medical Devices Importation License
POE	Port of Entry
GCC	Gulf Cooperation Council
SASO	Saudi Standards, Metrology and Quality Organization

