Draft for comment purposes (Not for implementation)

Project of Guidance of Import / Re-export Requirements for Medical Imaging Materials

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Introduction

Purpose

This guidance is intended to clarify SFDA requirements of importation and re-exportation of medical imaging materials.

Scope

This guidance applies to:

- Imaging materials used in medical applications (diagnostic/therapeutic).
- Importers and exporters of these materials and health service providers.

Background

In accordance with "The Law of Saudi Food and Drug Authority" issued by the Royal Decree No. (M/6) dated on 25/1/1428 H, which entrusted the Saudi Food & Drug Authority to regulate and monitor the food, drug and medical devices & supplies. The SFDA/MDS issued this guide to determine its requirements for importing and re-exporting medical imaging materials in order to ensure the safety and protection of patients, end-users and related parties of the potential hazards resulting to the use of these materials.

٧٥ Requirements

General	1	• Obtain permission from the SFDA to import or re-export of imaging materials used in medical applications. • SFDA studies the requests and verifies that the applicant fulfills the requirements.
SFDA Prerequisite	2	• Importers and exporters shall create an account in the unified system of the SFDA "Ghad System". • Facility shall have a medical device establishment license (MDEL) by the SFDA. • Providing all application documents stated in the required documents.
Submitting to the request	3	• Applicant shall submit the request of importing or re-exporting of imaging materials used in medical applications through the unified system of the SFDA "Ghad System" with the documents specified in "Required Documents", in order to take appropriate decision with regard to agreeing to clear the shipment or not.
Clearance at ports of entry	4	• Submit the manufacturer invoice. • Ensure the correct packaging and appropriate identification card for each product. • Adherence to marking packages with identification of either the consignee or the recipient, or both. • Shall follow the guidelines of ports clearance requirement, Available at: https://www.sfda.gov.sa/sites/default/files/2020-10/MDS-G21e.pdf
Written procedures for transporting	5	• Commitment to the guidelines for storage, transportation and handling of medical devices and products published on the SFDA's website: 1) https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G17)ar.pdf • Commitment to the guidelines for storage, transportation and handling of drugs and pharmaceuticals published on the SFDA 's website:

		1) https://sfda.gov.sa/ar/drug/resources/DocLib2/Drug-SupervisionCustomsPorts.pdf 2) https://sfda.gov.sa/ar/drug/resources/DocLib2/Drug-resource-5456.pdf 3) https://sfda.gov.sa/ar/drug/resources/DocLib2/PHWGuidelines1.pdf
Responsibility of importers and exporters	6	• Importers and exporters shall comply with the provisions of the "Application form for Requesting Permission to Import or Export Imaging Materials Used in Medical Applications" Appendix (1),

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٨١ Required Documents

	Required Documents	Notes
1	Copy of the MDEL for importation or distribution activities (issued by SFDA).	• It is required for importers and exporters. • Healthcare providers are excluded.
2	Copy of the MDMA for imaging material classified as a medical device (issued by the SFDA). Or the device registration number if it is registered as a low-risk device.	• It is required only if the imaging material classified as a medical device.
3	Bill of Lading (BoL).	• If applicable.
4	Copy of manufacturer's invoice or profoma invoice.	It shall include: - Shipment description (item names) - Marketing / Scientific names. - Quantity (total / detailed). - Unit weight of each item and gross. Weight of each package. - Unit price of each item. - Production and expiration date. - Batch/lot number.
5	The original certificate of origin.	It must be stamped by the trade reference in the country of origin.
6	Endorsing that the shipment conforms to the SFDA regulations for controlling medical devices and products in relation to the identification card and the conditions of supply and / or use.	In addition to an endorsement of conformity to comply with the supervision requirements of one of the countries of the Global Harmony Team (Australia, Canada, Japan, the United States of America and European Union countries).
7	Copy of the manufacturer Quality Management System (QMS) certificate in addition to the Good Manufacuerer Practice (GMP) certificate.	
8	Purchase order (PO) or award issued by the beneficiary or customer (in case of importing).	

9	Official letter or free sell certificate proving that the materials are sold in the country of origin.	
10	Application form of importation/ re-exportation of medical imaging materials	• See Annex (1), • It should be filled out electronically via Ghad system through the following link: https://ghad.sfda.gov.sa/en/
11	• Fill out the disclosure form. • Fill out the pledge.	• See Annex (2), • Link to guidelines, requirements and fees: https://www.sfda.gov.sa/ar/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx • Link to Disclosure Form of Radioactive Materials, Narcotic Substance or Chemicals Subject to Public Security Control: https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MD-DisclosureForm.docx
12	Special requirements for re-export	• Request letter for the export of medical imaging materials. • Attach the import permit previously granted for the material.

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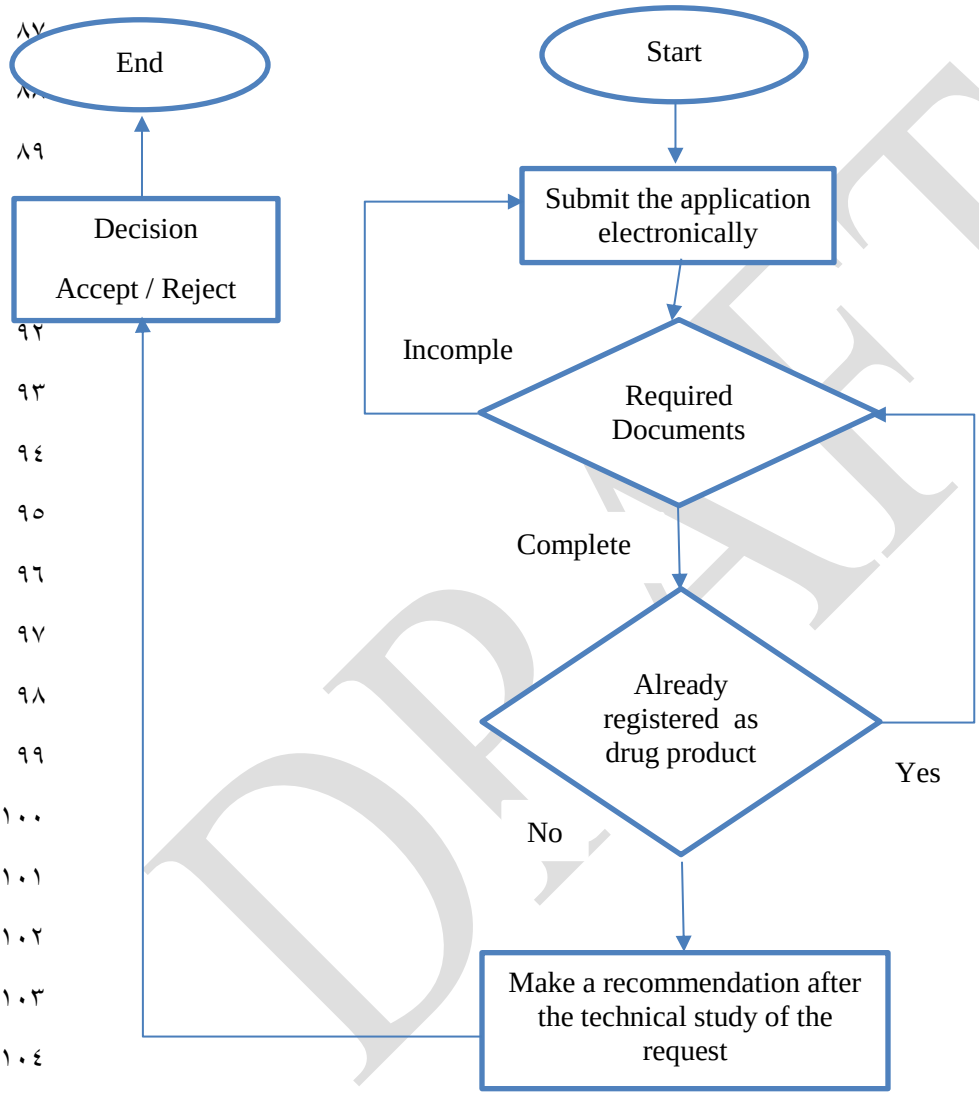
Flowchart



Operations Sector
Management of import and export permissions

Drug Sector
Medicines Import Department

Medical Devices & Products Sector
Radiation Health Executive

Annexes

Annex (1):
Application form for permission to import and re-export electronic medical imaging materials in the unified system

All fields must be filled with descriptive and relevant information in the request for permission to import into the unified system (GHAD) through the following link:

https://ghad.sfda.gov.sa/ar

Annex (2):
Disclosure Form of Radioactive Materials, Narcotic Substance or Chemicals Subject to Public Security Control

All fields with descriptive and relevant information must be selected and filled out in the disclosure form via the following link:

https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MD-DisclosureForm.docx

Attestation

☐	I certify that the information provided in this document are complete, accurate and correct.
☐	I pledge not to import any of the mentioned products to the non-beneficiary party of the order.
☐	I pledge that all items included in the request are in accordance with international requirements and specifications, as well as the requirements for the SFDA.
☐	I pledge to abide by the guidelines issued by the SFDA related to storage, transport and handling.
☐	I certify that the shipment does not contain: radioactive materials, drugs, explosives or any other prohibited material in accordance to the regulations of public security.
☐	I hereby declare that the contents of this shipment are fully and accurately described in the name of the appropriate shipping, classified, packed, labeled and placed identification card / installed card on the device. Materials in all respects are in a suitable condition for transporting in accordance with national and international requirements and government regulations.

Are all or one of the products classified as a medical device / product?		
Yes ☐		No ☐
If yes, product name:	……	
Classification type:	☐ High risk	……
	☐ Low risk	……

_____	_____	_____
Applicant name	**Applicant Signature**	**Date**

Annex (3): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDEL	Medical Device Establishment License
MDMA	Medical Devices Marketing Authorization
Facility file number in the unified system	Number issued by the SFDA to the entity in accordance with the Medical Devices Interim Regulation.
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.
Drug product	Any product manufactured in a pharmaceutical form that contains one or more substances which are used, externally or internally, to treat human or animal diseases or prevent them.