MDS-REQ 12

Requirements on Transporting and Storage for Medical Devices

Version Number: 3.0
Version Date: 17/07/2023

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Table of Content

Introduction

Purpose

The purpose of this document is to specify and clarify the requirements of storage and transportation of medical devices/supplies.

Scope

This document applies to the following:

1. Manufacturers.
2. Importers and Distributors.
3. Warehouses of Medical Devices.
4. Service Providers of Medical Devices.

Background

SFDA has issued this document in reference to the following:

- Item (6) in (Article 41) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH.
- Articles (10/12) and (10/14) of the "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 AH.

Requirement

General Requirements	1	– all mandatoriy licenses from other authorities shall be obtained. – Any establishment participate in storing activities for medical shall obtain a warehouse license or a storage license with third parties in accordance with "Requirements for Licensing of Medical Devices Establishments (MDS-REQ9)", and for sales centers, it is possible to suffice with a storage area within the establishment. – The Medical devices that will be stored or transported shall have medical device marketing authorization (MDMA). – All documents related to storage and transportation listed in annex (1) shall be kept for a period of at least (3 years). – Obligation/ Adhere to all circulars, conditions or requirement related to storage and transportation from SFDA.
Storage Area	2	The storage area shall be: • Designed or suitable for the purpose of medical devices storage. • Clean with enough space to allow for cleaning and inspection. • Provided/ Equipped with electronic temperature and humidity measuring instruments to monitor changes and adjust values according to manufacturer's instructions (sales centers are excluded), these instruments shall be: – Linkable and readable to specialized electronic systems. – Installed at different places and heights according to the effective temperature mapping. – Subject to regular calibration and monitoring. – The SFDA shall be notified in case of modification in the design or a storage area. Note: The list of Eligible facilities that provide temperature and humidity management and tracking service can be browsed on the SFDA website, note that the service is not limited to these establishments.

		• Providing a sufficient lighting to enable clear vision of the medical device/supply data and the instructional panels. • Providing an adequate ventilation. • Provide all personal protection equipment (protective clothing, gloves, etc.). • Providing proper equipments for handling inside the storage area - when needed. • Surfaces and shelves made of or covered by an impermeable material to enable proper and safe cleaning, pallets can be used. • Providing a separate area for keeping damaged, expired, rejected, fake or recalled medical devices. This area shall be clearly labeled and monitored until a final decision is made regarding these medical devices. • In case there are medical devices requiring cooling in fridge or freezer, according to manufacturer instructions, an emergency plan shall be arranged or a backup electrical generator wich automatically operated in case of an electricity shutdown.

Traceability in the Storage Area	3	• The establishment shall be able to trace the stored, sold, expired and damaged medical devices by its lot/batch/serial number; and be able to specify the quantity still available and the storage location for each item of the stored medical devices. Note: Annex (2) shows an example of a traceability record. • Establishments shall monitor/ follow up the expiry dates of the stored medical devices through periodic inventories.
Transportation	4	Establishment shall ensure that the vehicles used to transport medical devices: • Clean and suitable for transportation. • Designed and prepared to ensure protection from different environmental and weather conditions. Uncovered vehicle shall not be used at all. • Equipped with electronic temperature and humidity measuring instruments to monitor changes and adjust values according to manufacturer's instructions, these instruments shall be: – Linkable and readable to specialized electronic systems. – Installed at different places and heights according to the effective temperature mapping. – Subject to regular calibration and monitoring. – Activated from the beginning until the shipment has been delivered. – The SFDA shall be notified in case of modification in type or size vehicles. Note: (Eligible facilities that provide temperature and humidity management and tracking service can be browsed on the SFDA website), note that the service is not limited to these establishments

Manufacturer's Instructions	5	Establishments shall store and transport their medical devices under conditions specified by the manufacturer's instructions to prevent deterioration. These conditions might be related to one or more of the following: • Temperature • Moister and humidity • Exposure to light • The direction the package should face • The maximum number of packages stacked above each other. Notes: – If the label does not include information about the required storage and transportation conditions of a medical device, establishments shall obtain this information by submitting a request to manufacturer or authorized representive in the KSA. – If the manufacturer does not clarify information about the required storage and transportation conditions of a medical device within the label of medical devices, refer to annex (3).
Sterile Medical Devices	6	In addition to manufacturer's instructions for sterile medical devices, establishments shall store and transport it in a manner that protects its packaging from: - exposure to moisture. - direct sun-light. - dirt and non-clean environment. Note: Sterilized medical devices shall be considered unsterile if packaging loses its integrity.
Staff	7	Staff involved in the storage, handling and transport of medical devices shall: • Sufficient information and experience to perform tasks related to these activities.

		• Appropriate clothing and equipment to perform tasks related to these activities. • The ability to deal with medical devices that have different storage and transportation requirements/ conditions.
Written Procedures	8	Establishments shall have a written procedure that describes the practices taken to ensure that the medical devices are stored and transported based on the manufacturer's instructions. These written procedures are usually part of the quality system. For more details about writing procedures, see Annex (4).
Adverse events/ Incident Reporting	8	SFDA shall be immediately informed via National Centre for Medical Device Reporting (NCMDR) in case of any adverse events related to stored or transported medical devices according to "Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11)".

Final Provisions

Whoever commits any violation of the provisions of these requirements shall be penalized according to the "Table of the Classifications of Violations and Penalties According to the Medical Devices Law and its Implementing Regulation".

Annexes

Annex (1): Required Documents

#	Required Decuments	Notice
1	A warehouse license or storage license with third parties issued by the SFDA	For the sales centers, it is possible to suffice with a storage area within the establishment
2	Medical devices AR License issued by the SFDA	If applicable
3	The necessary licenses from other authorities	
4	Medical Device Marketing Authorization (MDMA) for stored medical devices	
5	Shipment Clearance Letters (Issued by SFDA)	
6	IFU Accompany Medical Device	- Applicable for all medical devices in the storage area. - It shall be in Arabic if the user of the medical device is a lay person (Home Use Medical Devices)
7	Quality Management System (QMS) Certificate.	If applicable.
8	Writing Procedures for transporting and storing medical devices .	
9	Traceability Documentation.	It may be in electronic format.
10	Records for Storage Conditions (e.g. Temperature and Humidity) included "Temperature Mapping" documents.	These documents shall be kept for a minimum one year.
11	Record for recalled and/or damaged medical devices.	If applicable.
12	Employees Qualifications.	Includes educational qualifications, training and experience certificates.
13	Purchase Invoices for Local represantative or distributors and Clients.	

Annex (2): Example of Traceability Record

#	Medical Devices Name	Manufacturer Name	Lot#/ Batch#/ Serial Number# Catalogue#	Customer Information	Expiry Date	Quantity	Remaining Quantity	
							Quantity	Location

Annex (3): Deffenitions of Temperature Range and conditions of transportation and/or storage

Temperature Range and conditions of transportation and/or storage	Instructions on Label
Temperatures between -20 and -10 °c	Freezer
Temperatures between 2 and 8 °c	Refrigerator
Temperatures does not exceed 8 °c	Cold Place
Temperatures between 8 and 15 °c	Cool Place
Temperatures between 15 and 30 °c	Room Temperature
Temperatures between 30 and 40 °c	Warm Place
Temperature should not exceed 40 °c	Excessive Heat
Temperatures between 2 and 8 °c	Do not store over 8 °C
Temperatures between 2 and 15 °c	Do not store over 15 °C
Temperatures between 2 and 25 °c	Do not store over 25 °C
Temperatures between 2 and 30 °c	Do not store over 30 °C
Temperatures between 8 and 25 °c	Do not store below 8 °C
Humidity does not exceed 60% under normal storage conditions. Delivered to the user, It should be kept in a Wet-proof packaging	Protect from moisture
It should be kept in light proof containers	Protect from light

Annex (4): Written Procedure on storage and transportation of medical devices

The written procedure of storage, transportation and handling the medical devices should be:

- A part of the quality management system, including the controls and records requirements
- Identify a member of staff responsible for ensuring the manufacturer's instructions for the storage, handling and transporting of its medical devices are identified and properly implemented; and that all personnel involved in such activities have the appropriate experience and training to undertake the duties assigned to them;
- Identify the range of different requirements and accommodate them all within the procedure, whether the establishment imports or distributes medical devices from more than one manufacturer,;
- Provide evidence that the medical devices are stored apart from other goods and under conditions that complies with the manufacturer's instructions, in particular, concerning ambient humidity, temperature and light exposure conditions;
- Ensure that storage and transport conditions, including those in the receiving bay
- specify the action to be taken in the event of deviations from the required storage or transport conditions;
- Describe the storage area, and the method used to include a secure area(s) within it for the purpose of storing separately:
    - any quarantined medical devices or, where necessary
    - devices incorporating dangerous and/or hazardous substances;
- Incorporate a system to ensure the medical device inventory is properly rotated (i.e. either 'first in first out' or 'expiration date' driven) and that any device exceeding its expiry date, or shelf life, is quarantined;
- incorporate a procedure to quarantine medical devices subject to a recall and/or field safety corrective action or to identify non-defective devices that have been returned from a user or other organization from other inventory until a decision on further action has been reached in cooperation with the manufacturer;
- Ensure that medical devices are properly packed and stored for transportation as well as transported in a suitable vehicle, taking into account the manufacturer's instructions with respect to temperature, humidity, vibrations and the risk of physical damage. Ensure that these factors are properly monitored and, where appropriate, recorded during transportation.
- Indicate the used vehicles for transportation from the port of entry to the storage area/warehouse and from the warehouse to the customer, if applicable. And indicate the transport company, if applicable.

Annex (5): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Medical Devices Law
Regulation	Executive Regulations of the Law
Medical Devices	Any instrument, apparatus or implement or implant or in vitro reagent or calibrator or software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis or prevention or monitoring or controlling or treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Supply	A medical material or product used in diagnosis, treatment, replacement, or correction/ straightening; or in disability cases or other medical uses for humans, including medical gases.
Fraudulent Medical Device or Supply	A device or supply the identity or source of which is deliberately altered with the intent to defraud. A medical device or supply shall be deemed fraudulent if its components have been altered in a manner that compromises its safety and efficacy, or if it is packed in counterfeit containers.
Establishment	A legal entity engaged in an activity related to medical devices and supplies.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulation.
License	A document issued by the SFDA to engage in any of the activities subject to this Law.

Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Quality Management System	A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device or supply in accordance with the latest version of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.
Warehouse	A building or part of it licensed by the SFDA and designated for medical device storage.
Temperature Mapping	It is the study of the temperature distribution for a specific area with three dimensions (length, width, height), to record and set the regions of the highest and lowest temperature in the selected area

Annex (6): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
2.0 21/06/2021	- Replacing the “Guidance on Requirements for Storage, Handling and Transportation of Medical Devices (MDS-G25)”. - Updating and amending baclground according to Medical Device Law and its Implementing Regulation. - Adding "General Requirements" item. - Adding the "Final Provisions" item. - Update and add definitions in accordance with Medical Device Law and its Implementing Regulation.