MDS – REQ 12

Requirements on Transporting and Storage for Medical Devices

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements on transporting and storage of medical devices.

Scope

This document applies to the following:

- Manufacturers
- Authorized Representatives
- Importers
- Distributors
- Warehouses of Medical Devices
- Other establishments that carry out transportation and storage of Medical Devices

Background

SFDA has issued this document in reference to the following:

- "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH through:
    - Article (41) Paragraph (6) that states "A person shall be deemed in violation of this Law if he: 6. Transports or stores medical devices or supplies in violation of the SFDA's transportation and storageconditions determined by the SFDA".

- "Implementing Regulation of Medical Devices Law" issued by the Saudi Food and Drug Authority Board of Directors decision No. (3-29-1443) dated 19/2/1443 AH through:
    - Article (10/11) Paragraph (3) that states "Importers and distributors of medical devices shall fulfill the requirements below to obtain a License from the SFDA: 3. Submit a documented procedure for the storage and transportation of the medical device in accordance with the requirements of the Manufacturer. Submit an undertaking to implement and adhere to the procedure."
    - Article (10/12) Paragraph (2) that states "Licensed importers and distributors shall comply with the following requirements: 2. Comply with the Manufacturer's requirements in addition to the requirements for Transportation and Storage of Medical Devices published on the SFDA's website."

- Article (10/14) Paragraph (1) that states “Requirements for Medical Devices Warehouses: 1. Compliance with the Manufacturer’s requirements and the requirements for Transportation and Storage of Medical Devices published on the SFDA's website.”
- Article (17/1) that states “Establishments subject to the provisions of the Medical Devices Law shall abide by labelling requirements provided by the Manufacturer in all their procedures related to transportation, storage, installation, maintenance, and destruction..”

Requirement

General Requirements	1	– Required licenses from the competent authorities shall be obtained. – Any establishment practice storage activities for medical devices shall obtain a warehouse license or a third-party storage license in accordance to the "Requirements for Licensing of Medical Devices Establishments" (MDS-REQ9), while for retailers (establishments that only have retail outlets), a storage zone inside the establishment's building is sufficient, provided that the storage zone is proportional to the quantity of stored medical devices. – Warehouse or third-party storage license shall be renewed before it expires. – A full-time Technical Manager shall be appointed for the warehouse who shall be a biomedical engineer, a medical device technician, or qualified in a medical devices related speciality. – The Medical devices that will be stored or transported shall have obtained a valid medical device marketing authorization (MDMA) certificate or importation permission. – Documents related to storage and transportation mentioned in Annex (1) shall be retained for a minimum of three (3 years). – Circulars, conditions or requirements related to transportation and storage issued by the SFDA or competent authorities shall be adhered with.
Storage Area	2	The storage zone shall be: • Designed or adjusted for the purpose of medical devices storage. • Clean and has enough space to allow for cleaning and inspection. • Equipped with sufficient lighting to enable clear vision of the medical device labeling and warehouse instructional panels. • Equipped with sufficient ventilation, and supported by filters to protect from dust and contaminants. • Equipped with all personal protection equipment (PPE). • Equipped with transport and handling equipment. • Equipped with the necessary safety tools and means (such as fire extinguishers and hoses for firefighting).

		• Consist of surfaces and shelves that are raised above floor level and below ceiling level, and which made of or covered with an impermeable material to enable proper and safe cleaning, pallets may be used. • Containing a place for isolating medical devices that have not been fully clearedor those seized by the SFDA, returned, recalled, damaged, or expired. provided that this zone is marked with a clear sign and monitored until these isolated medical devices are subjected to certain action. • Equipped with high-quality electronic temperature and humidity measuring instruments to monitor changes and adjust values according to the manufacturer's instructions (retailers are excluded), these instruments shall be: o Configurable to specialized electronic systems. o Installed at different places and heights according to effective temperature mapping. o Subject to periodic continuous calibration and monitoring. Note: The list of Eligible establishments that provide temperature and humidity management and tracking service can be browsed on the SFDA website; Noting that this service is not limited to these establishments. – In case there are medical devices requiring cooling or air conditioning - according to manufacturer instructions - an emergency plan shall be arranged, or a backup electrical generator, that is automatically operated in case of a power outage, shall be provided. – The SFDA shall be informed in case of a modification in the design or size of the storage zone. – Necessary security measures shall be taken to prevent unauthorized access to the warehouse.
Traceability and Inventory in the Storage Zone	3	– The establishment shall be able to trace medical devices that have not been fully cleared or those seized by the SFDA, stored, dispensed, returned, recalled, expired, or damaged. This tracing shall be done using their lot/batch or serial number, and the

		establishment shall be able to specify the remaining quantity 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 the quantity and expiry dates of stored medical devices through a periodic inventory.
Means of Transportation	4	The medical devices transportation vehicle shall be: • Clean and suitable for transport purposes. • Designed and adjsuted in a way that ensure the protection of medical devices from surrounding environmental and climatic conditions. Uncovered vehicles shall never be used. • Equipped with the necessary safety tools and means (such as fire extinguishers and hoses for firefighting). • Equipped with electronic temperature means to measure temperature and humidity to monitor changes and adjust values according to the manufacturer's instructions, these instruments shall be: o Configurable to specialized electronic systems. o Installed at different places and heights according to effective temperature mapping. o Subject to periodic continuous calibration and monitoring. o Activated from shipments are delivered. Note: The list of Eligible establishments that provide temperature and humidity management and tracking service can be browsed on the SFDA website; Noting that this service is not limited to these establishments. – The SFDA shall be informed upon any modification to the type or size of transportation vehicle. Note: If contracting with third-party courier, the transportation requirements outlined above shall be referenced in the signed contract.
Adherence to the Manufacturer's Instructions	5	Nedical devices shall be transported and stored according to the manufacturer's instructions specified in the labeling to prevent their damage or safety degredation, efficiency, quality, or effectiveness.

		Moreover, those instructions shall be documented and accompanied to the medical device continuously. Examples of those instructions are those related to: • Temperature • Humidity and wetness • Exposure to light • Exposure to direct sunlight. • Vibrations. • Correct positioning of the package/container. • The maximum number of packages stacked above each other. Notes: • If the label does not include information about the required transportation and storage conditions of a medical device, establishments shall obtain this information by submitting a request to the manufacturer or its authorized representative in the KSA. • If contracting with third-party courier, the manufacturer's transportation instructions shall be referenced in the signed contract. • If the manufacturer does not explain transportation and storage conditions statements within the medical device labeling, refer to Annex (3).
Handling of Sterile Medical Devices	6	In addition to the manufacturer's instructions for sterile medical devices, transportation and storage of these devices shall be in a manner that protects their packaging from: - Wetness. - Direct sunlight. - Dirt and a non-clean environment. Note: Sterilized medical devices shall be considered unsterile if the packaging loses its integrity.
Qualification and training of Staff	7	Staff involved in the transportation and storage of medical devices shall acquire:

		• Appropriate information, experience and training to perform tasks related to transportation and storage. • Appropriate clothing and equipment to perform tasks related to transportation and storage. • The ability to handle medical devices that require special transportation and storage conditions.
Written Procedures	8	Establishments shall have documented procedures for the transportation and storage of medical devices according to the manufacturer's instructions. Note: For more details about written procedures, see Annex (4).
Adverse events/ Incident Reporting	9	National Centre for Medical Device Reporting (NCMDR) shall be reported about any incidents or complaints related to transported or stored medical devices, or in existance of any non-compliant medical devices in accordance with "Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11)".
Third party Storage	10	– **The Lessor (Warehouse) shall:** o Obtain a medical devices warehouse license issued by the SFDA. o Sign an authenticated contract with the lessee (the beneficiary establishment, such as the manufacturer, authorized representative, importer or distributor) that includes information and obligations of both parties in accordance with the SFDA's requirements, including details of the zones and spaces allocated for storage. The contract shall also specify the party responsible for unloading, stacking, loading, transportation, and delivery of the stored medical devices to the customer. o Document and maintain records of all procedures or transactions related to lessees. o Not to cancel the warehouse license while valid third-party storage licenses held by lessees remain in effect. – **The Lessee (Manufacturer, Authorized Representative, Importer or Distributor) shall:** o Obtain a third-party storage license issued by the SFDA.

		○ Sign an authenticated contract with the lessor (warehouse) which includes both parties' information and obligations according to the SFDA requirements, including details of the zones and spaces allocated for storage. The contract shall also specify the party responsible for unloading, stacking, loading, transportation, and delivery of the stored medical devices to the customer. ○ Provide the lessor (warehouse) with a copy of the documented procedure for transportation and storage of medical devices. ○ Update the third-party storage license upon any change (increase or decrease) in the rented storage space inside the warehouse. ○ Not to use the third-party storage license for storing medical devices in any warehouse other than the warehouse stated on the license that issued by the SFDA. ○ Obtain a separate third-party storage license if leasing additional zones or spaces in other warehouses at a later stage. ○ Obtain a separate Third-Party Storage License when leasing additional zones or spaces in other warehouses. ○ Provide the lessor (warehouse) with a copy of the receiving and releasing records whenever withdrawing and transporting (delivering) a medical device from the warehouse to the customer. ○ Refrain under any circumstances from subleasing the allocated storage zones or spaces to any other party. ○ Refrain from taking action on any medical device if the SFDA issues a decision to close the warehouse where the devices are stored, until receiving official notification from the SFDA permitting such action. ○ In the event of lease contract cancellation, termination, or expiration, and if neither party intends to renew, the lessee shall, within no more than ten (10 days): ▪ Submit a request to the SFDA to cancel the third-party storage license. ▪ Remove all medical devices from the warehouse.

		▪ Sign a contract with an alternative licensed warehouse. ▪ Submit a request to the SFDA to obtain a new third-party storage license.

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" published on the SFDA's website.
- The SFDA shall not bear any responsibility for any disputes, conflicts, or financial claims arising between the lessor (warehouse) and the lessee (manufacturer, authorized representative, importer or distributor). Such disputes, conflicts, or claims shall be resolved in accordance with the relevant applicable laws in the KSA.

Annexes

Annex (1): Required Document

#	Required Documents	Notice
1	A warehouse license or storage license with third parties issued by the SFDA	-Retail outlets, it is possible to suffice with a storage area within the establishment
2	The necessary licenses from competent authorities	
3	Medical Device Marketing Authorization (MDMA) for stored medical devices	
4	Shipment Clearance Letters (Issued by SFDA)	
5	IFU Accompany Medical Device	
6	Quality Management System (QMS) Certificate.	
7	Written Procedure on Transportation and Storage of Medical Device	
8	Traceability Documentation and records.	- It may be in electronic format.
9	Documents and records for Storage Conditions (e.g. Temperature and Humidity) included "Temperature Mapping" documents.	These documents shall be kept for a minimum (one year).
10	Employees Qualifications.	Includes educational qualifications, training and experience certificates.
11	Purchase Invoices for Local importers, distributors and Clients.	

Annex (2): Example of Traceability Record

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

Annex (3): Deffinitions 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 wetness
It should be kept in light proof containers	Protect from light

Annex (4): Written Procedure on Transportation and Storage of Medical Device

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

- A part of the quality management system, and includes the documents and records required by the regulatory standard for quality management systems (SFDA/MD/GSO ISO 13485:2017) or its equivalent.
- Include procedures to verify that the manufacturer's instructions for the transportation and storage of medical devices are identified and properly implemented; and that all personnel involved in such activities possess the appropriate experience and training to undertake the duties assigned to them.
- Identify the different transportation and storage conditions for each medical device according to the manufacturer's instructions, particularly when the etablishment imports, distributes, stores, or transports various medical devices, whether manufactured by a single manufacturer or multiple manufacturers.
- Clearly state that medical devices and supplies with differing transportation and storage requirements particularly those related to temperature, humidity, and light exposure, are stored and transported separately from one another.
- Specify the actions to be taken in the event of any deviation from the manufacturer specified transportation and storage conditions.
- Describe the unloading, storage, offloading, and loading areas.
- Ensure that the unloading, storage, offloading, and loading equipment prevent any damage or adverse impact on the safety, performance, quality, or effectiveness of medical devices, and do not cause any damage to receiving docks.
- Include procedures for segregating the following:
    - Medical devices with special handling requirements.
    - Medical devices containing hazardous materials.
    - Medical devices that are released with a “Do Not Dispose” restriction, seized by the SFDA, returned, recalled, damaged, or expired.
- Include an inventory control mechanism that ensures the appropriate and orderly withdrawal and movement of stored medical devices (e.g., First In, First Out or based on product expiry date).
- Include a reference to the use of suitable transport means, taking into account the manufacturer’s instructions regarding temperature, humidity, and vibration -if applicable-.

- Specify the carrier and the mode of transport used from the customs port to the warehouse/storage area, and from the warehouse/storage area to the customer -if applicable-.

Annex (5): Definition & 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, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or 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, in return it may be assisted in its intended function by such means.
Medical Supply	Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.
Manufacturer	Any national or foreign establishment whose purposes include designing or manufacturing medical devices to offer them for use in its own name, whether inside or outside the Kingdom. Manufacturing includes: • refurbishing; • assembling; • packaging; • wrapping; 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.
Importer	An establishment in the supply chain that imports a medical device to the Kingdom.
Distributor	An establishment in the supply chain which provides a medical device to another distributor or its end user.
Warehouse	A building or part thereof, licensed by the SFDA and designated for storing the medical device.
Retail Outlet	A location belonging to an import and distribution establishment for medical devices, where medical devices are sold. This includes showrooms, markets, and kiosks.

Marketing Authorization	A document issued by the SFDA for any medical device it allows to be traded in the markets.
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.
Identifying Information	Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.
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
License	A document issued by the SFDA to engage in any of the activities subject to this Law.

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

Number & Date of the Previous Version	Changes Description
3.0 28/03/2023	• Revisions to section “Basic Information.” • Revision to section “General Requirements.” • Revisions to section “Storage Area.” • Editorial revisions to section “Traceability in the Storage Area.” • Revisions to section “Transport Means.” • Revisions to section “Compliance with Manufacturer’s Instructions.” • Editorial revisions to section “Personnel Qualification and Training.” • Editorial revisions to section “Written Procedures.” • Editorial revisions to section “Incident Reporting.” • Addition of a new section: “Third-Party Storage.” • Editorial revisions to section “Final Provisions.” • Editorial revisions to “Annex (1): Required Documents.” • Editorial revisions to “Annex (3): Terms and Definitions for Transport and/or Storage Conditions of Medical Devices.” • Revisions to “Annex (4): Written Procedure for Transport and Storage of Medical Devices.”