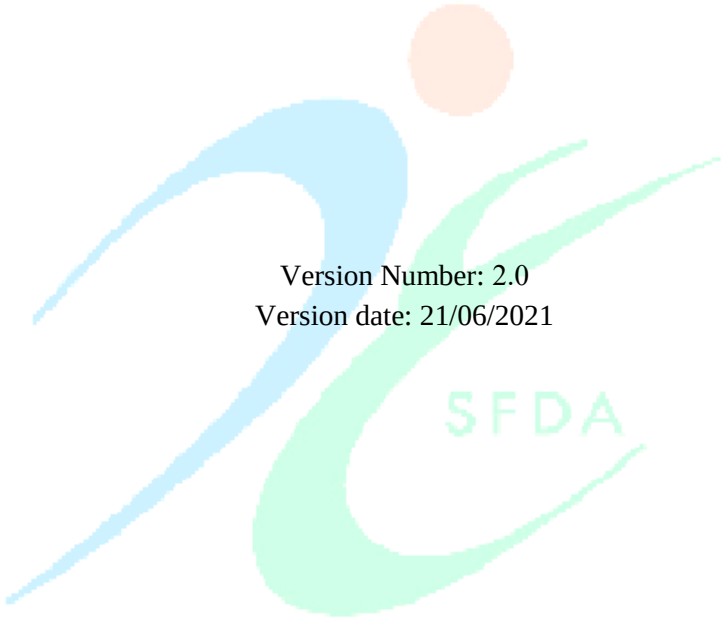
# MDS-G25

# Guidance on Requirements for Storage, Handling and Transportation of Medical Devices

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# Introduction

## Purpose

The purpose of this guidance is to clarify requirements of the storage, handling and/or transportation of medical devices.

## Scope

This guidance applies to establishments (importers, distributors, local manufacturers involved in distribution activities, or ARs involved in importation and/or distribution activities) involved in the storage, handling and/or transportation of medical devices within the KSA.

This guidance does not apply to healthcare providers. However, "Guidance for Healthcare Providers for Storage, Handling and Transportation of Medical Devices (MDS-G17)" provides recommendations to healthcare providers to ensure medical devices are properly stored, transported and handled to guarantee their safety and effectiveness.

## Background

SFDA/MDS has issued this guidance document in reference to the following:

- Article fifteen of the "Medical Devices Interim Regulation" that requires that importers, distributors, local manufacturers involved in distribution activities, or ARs involved in importation and/or distribution activities of medical devices within the KSA shall have an MDEL.
- Article Sixteen (B and C) of the "Medical Devices Interim Regulation" that requires from establishments involved in the importation and/or distribution of medical devices to ensure that medical devices are stored and/or transported under conditions specified by the manufacturer; and ensure traceability of supplied devices in the market.
- Articles five and ten of "Implementing Rule on Establishment Licensing (MDS-IR4)" that indicates that the purpose of MDEL is to ensure that establishments are able and committed to undertake the procedures specified by the manufacturer for storage, transportation, handling and tracking of medical devices they import and/or distribute.

## Requirements

| | | |
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| Storage Area | 1 | Establishments shall have a storage area that:<br>a) is designed and suitable for the purpose of medical devices storage.<br>b) is provided with electronic temperature and humidity measuring instruments to monitor changes and adjust values according to instructions provided by the medical device manufacturer, these instruments shall be capable to be connected to the SFDA electronic systems, they shall be installed at different places and heights according to the effective and accredited temperature mapping, and shall be calibrated and monitored periodically according to the risk assessment. SFDA shall be notified in case of modification in storage area that could affect the efficiency of the measuring instruments.<br>(Eligible facilities that provide temperature and humidity management and tracking service can be browsed on the SFDA website).<br>c) ensure placing warning signs to prohibit smoking<br>d) is clean and dry<br>e) is adequately lit to ensure clear visualization of product information and guiding signs<br>f) is adequately ventilated<br>g) has surfaces and shelves, if available, made of or covered by an impermeable material to enable proper and safe cleaning<br>h) has enough space to allow loading, cleaning and inspection<br>i) includes a separate area for keeping damaged, expired or recalled medical devices. This area shall be clearly labeled and monitored until a final decision is made regarding these medical devices.<br>j) if there are medical devices that require cooling in fridge or freezer, according to manufacturer instructions, shall be equipped with a backup electrical generator to be automatically operated in case of an electricity shutdown<br>k) is licensed by the Ministry of Municipal Rural Affairs and housing |
| Traceability in the Storage Area | 2 | In case of a recall by the manufacturer or the SFDA, the establishment shall be able to trace a medical device in the storage area by its lot/batch/serial number and be able to specify the quantity still available in the storage area of a given lot/batch/serial number. For an example on traceability record, see Annex (1). |

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| | 3 | Establishments shall monitor the expiry dates of medical devices in the storage area through periodic inventories to avoid unintended dispatch of expired devices, if applicable. |
| Transportation Vehicles | 4 | A. Establishments shall ensure that the vehicles used to transport medical devices are properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates. And shall use the vehicles indicated in Annex (2). Uncovered vehicle shall not be used at all.<br>B. is provided with electronic temperature and humidity measuring instruments to monitor changes and adjust values according to instructions provided by the medical device manufacturer, these instruments shall be capable to be connected to the SFDA electronic systems, they shall be installed at different places and heights according to the effective and accredited temperature mapping , and shall be calibrated and monitored periodically according to the risk assessment. These instruments shall be activated from the beginning until the shipment has been delivered. (Eligible facilities that provide temperature and humidity management and tracking service can be browsed on the SFDA website). |
| Manufacturer's Instructions | 5 | Establishments shall store, handle 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:<br>- temperature (all the medical devices shall be kept during storage and/or transportation at temperature ranges specified by the manufacturer).<br>- moister and humidity.<br>- exposure to light.<br>- the direction the package should face.<br>- the maximum number of packages stacked above each other.<br><br>Notes:<br>- If the label does not include information about the required storage, handling and transportation conditions of a medical device, establishments are responsible for obtaining such information. |

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| | | - If the manufacturer does not specify the temperature range, Annex (2) specifies the temperature ranges of temperature instructions on labels. |
| Sterile Medical Devices | 6 | In addition to manufacturer-specific instructions and if the medical device is dispatched in a sterile state, establishments shall store, handle and transport it in a manner that protects its packaging from:<br>- exposure to moisture.<br>- direct sun-light.<br>- damage.<br>- dirt and non-clean environment.<br>to ensure they are still sterile when received by the customer. Sterile 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:<br>- have appropriate knowledge about these activities.<br>- be able to deal with medical devices that have different storage and transportation requirements, if applicable. |
| Written Procedures | 8 | Establishments shall have a written procedure that describes the practices taken to ensure that the medical devices are stored, handled, and transported based on the manufacturer's instructions. For more details about writing procedures, see Annex (3). |
| Adverse events Reporting | 9 | 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 "Guidance on Requirements for Reporting and investigation of Incident and Adverse Event of Medical Devices MDS-G39" https://www.sfda.gov.sa/sites/default/files/2020-09/MDS-G39e.pdf |

# Annexes

## Annex (1): Example of Traceability Record

| # | Medical Devices Name | Manufacturer Name | Lot#/ Batch#/ Serial Number# Catalogue# | Customer Information | Expiry Date | Quantity | Remaining Quantity | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Quantity | Location |
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |
| 4 | | | | | | | | |
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## Annex (2): Interpretations of Temperature Ranges and Storage Conditions

| Instructions on Label | Temperature Range | Transportation (Vehicle) |
|---|---|---|
| Stored in Freezer | means kept in temperatures between -20 and -10 °c | Refrigerated |
| Stored in Refrigerator | means kept in temperatures between 2 and 8 °c | Refrigerated |
| Stored in Cold place | means kept in temperatures does not exceed 8 °c | Refrigerated |
| Stored in Cool place | means kept in temperatures between 8 and 15 °c | Air-conditioned |
| Stored in Room temperature | means kept in temperatures between 15 and 30 °c | Air-conditioned |
| Stored in Warm place | means kept in temperatures between 30 and 40 °c | Covered |
| Avoid Excessive heat | means temperature should not exceed 40 °c | Covered |
| Do not store over 30 °c | means to store within the range from +2 to +30 °c | Air-conditioned |
| Do not store over 25 °c | means to store within the range from +2 to +25 °c | Air-conditioned |
| Do not store over 15 °c | means to store within the range from +2 to +15 °c | Air-conditioned |
| Do not store over 8 °c | means to store within the range from +2 to +8 °c | Refrigerated |
| Do not store below 8 °c | means to store within the range from +8 to +25 °c | Air-conditioned |
| Protect from humidity/ moisture | means to protect it from conditions where humidity exceeds 60%, and should be kept in a humidity resistant container | As per manufacture instruction |
| Protect from light | means that should be stored in places not exposed to light. It should be kept in light proof containers | As per manufactrure instruction |

## Annex (3): Written Procedure on storage, transportation and handling of medical devices

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

- ideally be part of the quality management system and include the records and controls this system requires;
- 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 requirements;
- ensure that storage and transport conditions, including those in the receiving bay, will prevent damage, deterioration or other adverse effects of the medical devices pending their distribution; Such conditions shall be controlled using instruments equipment installed in different heights level and connected to SFDA systems, in order to measure temperature and humidity levels;
- 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, handled 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 (4): Required Documents

| | Required Documents | Notes |
|---|---|---|
| 1 | MDEL | |
| 2 | License from the Ministry of Municipal Rural Affairs and Housing | |
| 3 | Medical devices AR License | • If applicable |
| 4 | MDMA or Medical Device Listing National Registry Number Issued | • Applicable for all medical devices in the storage area |
| 5 | Shipment Clearance Letters (Issued at SFDA's Port of Entries) | |
| 6 | IFU Accompany Medical Device | • Applicable for all medical devices in the storage area<br>• 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 | |
| 9 | Traceability Documentation | • It may be in electronic format |
| 10 | Records for Storage Conditions (e.g. Temperature and Humidity) included “Temperature Mapping” documents are kept for a minimum one year | • If applicable |
| 11 | Record for Recalled and/or Damaged Medical Devices | • If applicable |
| 12 | Employees Qualifications | |
| 13 | Purchase Invoices for Local Agents and Clients | |

# Annex (5): Violations list

(including violation of requirements of storage, handling and transportation of medical devices)

| # | Violation |
|---|---|
| 1 | No MDEL Available |
| 2 | The MDEL is not valid or renewed |
| 3 | The establishment did not update the their information in GHAD system incase of critical changes (e.g. establishment relocated, contact information changed,etc.) |
| 4 | The establishment did not list all their medical devices in GHAD system |
| 5 | Presence of non-license or listed medical devices |
| 6 | Establishment used unapproved advertisement material |
| 7 | Establishment is unable to provide copy of sales or services employees' qualification. |
| 8 | Applied traceability methods are ineffective or insufficient |
| 9 | Absence of a written procedures for transportation, installation or maintenance |
| 10 | Written procedures for transportation, installation or maintenance is not implemented by establishment. |
| 11 | Current practice of transportation , installation or maintenance does not meet the manufacturer’s instructions |
| 12 | Absence of a written procedure for storage and handling of medical devices |
| 13 | Storage area is not licensed by Ministry of Municipal Rural Affair and housing |
| 14 | Absence of emergency plan for the storage of medical devices in case of an electricity shutdown |
| 15 | Procedure for storage and handling of medical devices is not implemented |
| 16 | Storage area is not clean |
| 17 | Storage area is not suitably spaced to allow cleaning and inspection |
| 18 | Absence of storage shelves (medical devices are placed on floor) |
| 19 | Surfaces/Shelves are made of permeable material which prevents appropriate cleaning |
| 20 | Storage area is not adequately illuminated |
| 21 | Storage area is not adequately ventilated |
| 22 | Storage conditions (e.g. temperature, humidity) are not effectively monitored |
| 23 | Storage, transportation and handling requirements are not appropriately communicated to the staff performing these tasks |
| 24 | Storage, transportation and handling practices are not appropriate for sterile medical devices |

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| 25 | Absence of separate storage area for damaged, expired and recalled medical devices |
| 26 | Establishment does not monitor expiry dates of medical devices including IVDs in the warehouse |
| 27 | Establishment does not keep records of the disposal of medical devices |
| 28 | Current conditions for storage, transportation and handling of medical devices don't follow manufacturer's instructions |
| 29 | Information of the medical device's label are not clear |
| 30 | Establishment has expired, damaged or used medical devices |
| 31 | Establishment has counterfeit medical devices. |
| 32 | Corrective actions are not taken on previous noncompliance reports |
| 33 | Absence of a written procedure for reporting medical devices adverse events |
| 34 | Procedure for reporting medical devices adverse events is not effective |
| 35 | Absence of a written procedure for implementing corrective action required for field safety notices |
| 36 | No registration in the NCMDR |
| 37 | No storage temperature mapping (for devices that require specific temperature levels) |
| 38 | Temperature mapping is ineffective |
| 39 | Not placing warning signs to prohibit smoking |
| 40 | Failure to link digital devices used to measure temperature humidity to SFDA systems/not functioning properly |

## Annex (6): Common Mistakes

- Staff involved in the storage, handling and transporting of medical devices are unaware of appropriate procedures for these activities, not informed of the existence of written procedures or the written procedures are not accessible for them.
- The stored medical devices are not well organized or aligned to facilitate inspection and cleaning process.
- The absence of writte procedures for storing, transporting and handling of medical devices.
- The written procedures of storing, transporting and handling of medical devices are not being applied.
- The absence of an emergency plan to be used in case of an electricity shutdown (power outage) in the storage area, if applicable.
- The absence of a separate area for keeping damaged, expired or recalled medical devices.

## Annex (7): Definitions & Abbreviations

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| KSA | Kingdom of Saudi Arabia |
| SFDA | Saudi Food and Drug Authority |
| MDS | Medical Devices Sector |
| 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 |
| Establishment | any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer. |
| Manufacturer | means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person. |
| Authorized Representative (AR) | means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA. |
| Importer | means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA. |
| Distributor | means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user. |
| MDEL | Medical Devices Establishment License |
| MDMA | Medical Devices Marketing Authorization |

## Annex (8): List of Modifications on previous version

| Number and date of previous version | Description of adjustment |
|---|---|
| 1.0<br><br>10/04/2018 | • A requirement is added regarding the temperature mapping, referred to in section (1b) and (4b) in “requirements”<br>• Modification in section (1j) regarding the backup generator<br>• A requirement is added regarding reporting medical devices incidents, referred to in section (9) in “requirements”<br>• Modification in required documents in annex (4)<br>• Update in Violations list in annex (5) |