MEDICAL DEVICES SECTOR

Requirements for the Storage, handling and transport of Medical Devices
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Scope: The requirements described in this document applies to all establishments* involved in the importation and/or distribution of medical devices* in the Kingdom of Saudi Arabia and involved in the storage and transport of such devices.

Storage of medical devices

1. Storage area:

Storage areas designated for the storage of medical devices shall be designed or adapted as to meet the following conditions:

- the area should be clean and dry.
- the area should be suitably spaced to allow cleaning and inspection.
- all surfaces and shelves should be made of/covered by an impermeable material to enable proper and safe cleaning.
- areas should be adequately lit and ventilated in order for tasks to be performed in a correct and safe manner.

Storage area must have the appropriate license from the Ministry of Municipal and Rural Affairs and the General Directorate of Civil Defense.

2. Traceability in the storage area:

In case of a recall by the manufacturer or the SFDA, the establishment shall be able to trace a product 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.

The establishment shall also monitor the expiry dates of products in the storage area through periodic inventories to avoid unintended dispatch of expired products.

3. Damaged, expired or recalled products:

There shall be a physically separate area for keeping damaged, expired or recalled products. This area shall be clearly labeled and controlled to prevent the use of these products until a final decision is taken on their fate. Other means of segregation shall be considered if proven to effectively prevent mix-up.

* As Defined by the Saudi Food and Drug Authority in the Medical Devices Interim Regulation
Transportation of medical devices

Vehicles used to transport medical devices should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates.

The use of vehicles with defects that could affect the quality of the medical devices should be avoided.

**Manufacturer requirements:**
All medical devices shall be stored, handled and transported under conditions specified by the manufacturer 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

If the manufacturer require products to be stored or transported at certain conditions (e.g. temperature and humidity), these conditions shall be monitored and periodically recorded. Such records shall be available for review.

If the packaging labels does not include information about the required storage and transportation conditions of a medical device, it is the establishment’s responsibility to obtain such information from the manufacturer.

**Temperature:**
all the products should be kept during storage and transportation at temperature ranges specified by the manufacturer. These temperature ranges should also be maintained in the receiving/preparation areas if the products are to be kept there for more than one hour.

If the manufacturer require products to be stored or transported at certain temperature ranges, these ranges shall be monitored and periodically recorded. Temperature monitors are to be placed where temperatures are most likely to fluctuate or rise.

If the manufacturer does not specify the temperature range, the following definitions for the instructions on labels shall apply when storing and transporting medical devices:

- stored in freezer: means kept in temperatures between -20 and -10 Degrees Celsius.
- **Stored in refrigerator**: means kept in temperatures between 2 and 8 Degrees Celsius.
- **Stored in a cool place**: means kept in temperatures between 8 and 15 Degrees Celsius.
- **Stored in room temperature**: means kept in temperatures between 15 and 30 Degrees Celsius.
- **Stored in a warm place**: means kept in temperatures between 30 and 40 Degrees Celsius.
- **Avoid excessive heat**: means temperature should not exceed 40 Celsius.
- **Not to exceed 30 Degree Celsius**: means to store within the range from +2 to +30 Degrees Celsius.
- **Not to exceed 25 Degree Celsius**: means to store within the range from +2 to +25 Degrees Celsius.
- **Not to exceed 15 Degree Celsius**: means to store within the range from +2 to +15 Degrees Celsius.
- **Not to exceed 8 Degree Celsius**: means to store within the range from +2 to +8 Degrees Celsius.
- **Do not store below 8 Degree Celsius**: means to store within the range from +8 to +25 Degrees Celsius.
- **The product should be protected from humidity**: means to protect it from conditions where humidity exceeds 60%, and should be kept in a humidity resistant container.
- **Keep away from light**: means that should be stored in places not exposed to light. It should be kept in light proof containers.

**Sterile products:**

In addition to manufacturer-specific requirements, products that are dispatched in a sterile state should generally be stored, handled and transported in a manner that protects its packaging from exposure to moisture, direct sun-light and damage to ensure they are still sterile when received by the customer. Sterile products shall be considered unsterile if packaging loses its integrity.

**Staff:**

Staff involved in the storage, handling and transport of medical devices shall have appropriate knowledge about the storage, handling and transport requirements of all the products with which they deal. If products with different requirements are to be stored or transported under different conditions, the involved staff shall be able to sort such products based on their storage and transport requirements.
Written procedures:
Establishments involved in the storage, handling and transport of medical devices shall have a written procedure that describes the practices taken to ensure these devices are stored, handled and transported based on their manufacturer requirements.

The procedure should:

- ideally be part of a quality management system and include the records and controls such a system requires;
- identify a member of staff responsible for ensuring the manufacturer’s requirements for the storage, handling and transport 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;
- where the organization imports or distributes medical devices from more than one manufacturer, identify the range of different requirements and accommodate them all within the procedure;
- ensure that medical devices are stored apart from other goods and under conditions complying with the instructions of the manufacturer, in particular, concerning ambient humidity, temperature and light requirements;
- ensure that storage and transport conditions will prevent damage, deterioration or other adverse effects of the medical devices pending their distribution; and are properly monitored and, where appropriate, recorded;
- 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:
  1. any quarantined medical devices or, where necessary
  2. 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 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 suitably 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.