MDS – G17

GUIDANCE FOR HEALTHCARE PROVIDERS FOR STORAGE, HANDLING AND TRANSPORTATION OF MEDICAL DEVICES

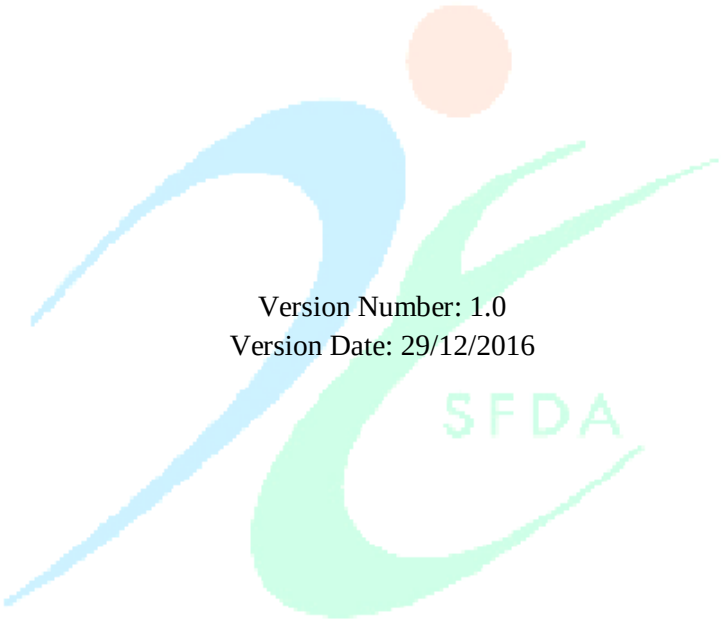

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TABLE OF CONTENT

DEFINITIONS & ABBREVIATIONS **3**
Definitions 3
Abbreviations 4

INTRODUCTION **5**
Purpose 5
Scope 5
Background 5

RECOMMENDATIONS **6**

ANNEXES **9**
Storage Temperature Values and Storage Condition Definitions 10

DEFINITIONS & ABBREVIATIONS

Definitions

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.
Labelling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.
Field Safety Corrective Action	an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.
Recall/Field Safety Notice	a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.

Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector

INTRODUCTION

Purpose

This guidance provides ***recommendations*** to healthcare providers to ensure medical devices are properly stored, transported and handled to guarantee their safety and effectiveness.

Scope

This guidance is applicable to ***healthcare providers involved in the storage, transportation and/or handling of medical devices***.

Background

SFDA/MDS aims to ensure a high level of safety and health protection of patients, users and third parties with regard to the use of medical devices as it relates to their manufacture, supply and use, including storage, handling and transportation activities. The safety, effectiveness and quality of medical devices can be adversely affected by absence or inadequate control over these activities. Therefore, SFDA take the initiative by developing this guidance for the healthcare providers in order to control these activities.

RECOMMENDATIONS

Storage Area	1	○ It should be ***designed or adapted for the storage*** of medical devices. ○ It should be ***clean***. ○ It should be equipped with ***thermometers/hygrometers***. The thermometers/hygrometers should be placed to allow effective monitoring where temperatures/humidity are most likely to fluctuate or rise. ○ All ***surfaces and shelves***, if applicable, should be made of or covered by an impermeable material to enable proper and safe cleaning. ○ It should be suitably ***spaced*** to allow cleaning and inspection. ○ It should include a ***physically separate area*** for keeping ***damaged, defect, expired, counterfeit or recalled medical devices***. This area should be clearly ***labeled and controlled*** to prevent the use of these devices until a final decision is taken on their fate. ○ It should be adequately ***lit.*** ○ It should be adequately ***ventilated.*** ○ Emergency plan should be set up and used in case of an electricity shutdown (***power outage***), if applicable.
Traceability in the Storage Area	2	In the case of a ***recall/field safety notice*** by the SFDA or the manufacturer, the healthcare providers should be able to ***trace*** a product in the storage area by its lot/batch/serial number.
	3	The ***expiry dates*** of medical devices in the storage area should be monitored through periodic inventories to avoid unintended dispatch of expired medical devices.
Transportation	4	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.
	5	Medical devices should be transported in such a manner that does ***NOT allow exceeding of appropriate temperature and relative humidity conditions*** which could negatively affect the integrity and quality.
	6	Medical devices should be transported and ***carried carefully*** in a manner that corresponds to the special transport precautions for each medical device's nature.
	7	Any case of spoilage or breakage should be ***reported***.

	8	The transporting vehicle or containers should be adequately ***suitable for the intended purpose and cleaned***.
Manufacturer's Instructions/ Requirements	9	Medical devices should be stored, handled and transported under conditions specified by the manufacturer's instructions/requirements to prevent deterioration. These conditions might be related to one or more of the following: o temperature (all the medical devices should be kept during storage and/or transportation at temperature ranges specified by the manufacturer) o moister and humidity o exposure to light o the direction the package should face o the maximum number of packages stacked above each other o other specific instructions/requirements Note 1: If the packaging labelling do not include information about the required storage and transportation conditions of a medical device, ***healthcare providers should obtain such information from the manufacturer and/or its authorized representative located within the KSA.*** Note 2: If the manufacturer does not specify the temperature values or not define the storage conditions on the packaging labelling, see ***Annex 1*** to determine these values and the set of storage definitions. Note 3: If the ***manufacturer requires medical devices to be stored or transported under certain conditions*** (e.g. temperature and humidity), healthcare providers should monitor and periodically record these conditions.
Sterile Medical Devices	10	In addition to manufacturer-specific instructions, medical devices that are dispatched in a ***sterile state***, should be stored, handled and transported in a manner that ***protect their packaging from***: o exposure to moisture o direct sunlight o damage o dirt and unclean environment Note:

		Sterile medical devices should be ***considered unsterile if packaging loses its integrity***.
Staff	11	Staff involved in the storage, handling and/or transport of medical devices should: o have proper knowledge about these activities, and o be able to deal with those devices that have different storage and transportation requirements, if applicable.
Written Procedures	12	Healthcare providers should have a written procedure that describes the practices taken to ensure those medical devices are ***stored, handled and/or transported*** based on the manufacturer's instructions/requirements. The written procedure ideally should be part of a quality management system.

ANNEXES

Annex 1

Medical Devices Storage Temperature Values and Storage Condition Definitions

ON THE LABELLING	GUIDANCE VALUES
Freezer	The temperatures are between -20 °C and -10 °C
Refrigerator	The temperatures are between 2 °C and 8 °C
Cold Place	The temperatures do NOT exceed 8 °C
Cool place	The temperatures are between 8 °C and 15 °C
Room temperature	The temperatures are between 15 °C and 30 °C
Warm place	The temperatures are between 30 °C and 40 °C
Excessive heat	The temperature are above 40 °C
Do not store over 30 °C	The temperatures are between +2 °C to +30 °C
Do not store over 25 °C	The temperatures are between +2 °C to +25 °C
Do not store over 15 °C	The temperatures are between +2 °C to +15 °C
Do not store over 8 °C	The temperatures are between +2 °C to +8 °C
Do not store below 8 °C	The temperatures are between +8 °C to +25 °C
Protect from moisture	No more than 60% relative humidity in normal store conditions; to be provided to the user in a moisture-resistant container
Protect from light	To be made available to the user in a light-resistant container