MDS-REQ 3

Requirements for Safe Use of Medical Devices Inside Healthcare Facilities

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Content

Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for safe use of medical devices and radioactive medical materials inside healthcare facilities in order to ensure safety, efficiency and quality of them, and reduce potential risks corresponding to use and handle them inside healthcare facilities.

Scope

This document applies to healthcare providers in KSA.

Background

SFDA has issued this document in reference to the following:

- Article (26) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H stipulated that “The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices in diagnosis and treatment”.
- Item (2) within the “Monitoring duties” in (Article 5) of the Law of the Saudi Food and Drug Authority, issued by Royal Decree No. (M/6) dated 25/1/1428 H stipulated that “Monitoring compliance of health establishments with international standards of safety related to the safe performance of medical devices”.
- Item (5) in (Article 3) of the Law of the Saudi Food and Drug Authority, issued by the issued by the Royal Decree No. (M/6) dated 25/1/1428 H stipulated that “Ensure that medical devices and in vitro diagnostic medical devices are accurate, safe and not affect human health”

Requirements

A. General

Healthcare providers shall:

1. Not deal with any Establishment engages in any of the activities subject to the Medical Devices Law, unless it is registered and licensed by the SFDA in the same scope of the dealing.
2. Adhere to the requirements of Safe Use of Medical Devices contained in this document to ensure their safety, efficacy and quality.
3. Ensure that all medical devices located in their facilities have a Marketing Authorization (MDMA) or Import Permission issued by the SFDA.
4. If the Marketing Authorization (MDMA) certificate expires and cannot be renewed, or in case of medical devices that didn't obtain a Marketing Authorization (MDMA) certificate and have been purchased or supplied before the mandatory enforcement of marketing authorization (before 2015), the following shall be provided:
    a) Letter from the manufacturer guaranteeing that original spare parts will be available as well as the technical support for medical software.
    b) Recent reports about periodic preventive maintenance of the device and quality assurance tests.
    c) Any other requirements requested by the SFDA.

    If these requirements, which ensure the safety, efficacy and quality of the medical device, not provided, then the device will be suspended.
5. Appoint a liaison officer with the National Center for Medical Devices Reporting. He/she has to be scientifically qualified in biomedical engineering or any medical devices related specialty, to carry out the tasks and responsibilities contained in the Requirements of medical device post-market surveillance published on the SFDA's website.
6. Issue a documented procedure for reporting medical devices incidents in accordance with the requirements of medical device post-market surveillance published on the SFDA's website.
7. Adhere to the requirements of the SFDA for radiology departments for safe use, which published on the SFDA's website.

B. Healthcare providers responsibilities

Health care providers shall:

1. Use the medical device according to the intended purpose of use approved by the SFDA, and not use it for other purposes contrary to the permitted purpose.
2. Ensure that Radioactive Medical Materials have been approved by the SFDA in relation to technical and clinical specifications.
3. Comply with the safe use requirements of radiology and medical imaging devices (ionizing and non-ionizing) referred to in section (D).
4. Comply with the safe use requirements for radioactive medical materials referred to in Section (E).
5. Medical devices classified as high risk in accordance with the Classification System shall not be dispensed for use outside the facility of the healthcare provider without prescription.
6. Ensure that the implant card is provided by the manufacturer and given to the patient after including the following additional information:
    a) The name of the patient and the physician.
    b) Address of the health care facility.
    c) Date of Implantation.
7. Ensure that the medical device supplied with the accessories provided by the manufacturer, in addition to all the necessary information and documents including instructions for use and maintenance.
8. Inform the SFDA about medical devices that violate the provisions and requirements of the law and its regulation, including fraudulent, unregistered and medical devices that do not have marketing authorization (MDMA).
9. Provide all information about the violated medical devices.
10. Adhere to report to NCMDR immediately about all medical devices related incidents in accordance with the requirements of post-market surveillance published on the SFDA website, and to provide the NCMDR with all necessary information and documents including the available and dispensed quantities of related devices.
11. In case there is a safety alert, the medical device shall be dealt in accordance with the recommendations included in the field safety corrective action.
12. Suspend the use of the medical device if the corrective action states that, pending a notification by the NCMDR indicating that the Field Safety Corrective Action has been completed.
13. Notify the SFDA through the NCMDR about any incidents resulting from the use of radiology and medical imaging devices (ionizing and non-ionizing) within radiology departments, in addition to any incidents or radiological contamination related to the use of radioactive medical materials or in the event of loss of any of them, and provide the SFDA

with the results of the investigation, taken action, and new developed policies and procedures to ensure that such incidents do not recur.

14. Ensure that the clinical trials conducted in their facilities is approved by the SFDA, and that there is a documented policy for clinical trials within the facility in accordance with the requirements for clinical trials of medical devices published on the SFDA website.
15. Ensure that the advertising materials displayed in their facility are approved by the SFDA in accordance with requirements for the approval of advertising and conducting awareness or charitable campaigns of medical devices published on the SFDA website.
16. Providing maintenance services for medical devices in accordance with the responsibilities referred to in Section (C), through the following:
    a) Establishing and developing a specialized department in medical devices.
    b) Supervising the parties who have been contracted to manage and provide maintenance services for medical devices after ensuring that they are licensed by the SFDA.
17. The staff of the specialized department in medical devices should hold academic or technical qualifications in biomedical technology/ engineering or any related specialty.
18. Appoint a Radiation Protection Officer in radiology departments as well as qualified and trained medical physicists, to conduct quality assurance tests and radiation measurements, provided that they should not be administratively associated with radiology departments. A quality assurance and radiometric service providers licensed by the SFDA may be contracted.
19. Provide a dedicated and equipped place for the maintenance of medical devices, in case that the health care provider is maintaining medical devices.
20. Adhere with manufacturer instructions, in addition to the requirements for storage and transportation of medical devices described in Annex (2).
21. Single-use medical devices shall not be reprocessed.
22. Comply with the requirement of destruction of medical devices in accordance with article (20/1) in the regulation.
23. Comply with the requirement of donation or loan of medical devices in accordance with article (20/5) in the regulation.
24. Issue documented policies covering responsibilities and procedures for all stages of dealing with the medical device.
25. Any other requirements published on the SFDA website.

C. Responsibilities of the specialized department in medical devices

In addition to the responsibilities of the healthcare provider contained in this document, the specialized department in medical devices shall undertake the following responsibilities:

1. Have documented policies for:
    a) Maintenance of medical device, including periodic preventive maintenance (PPM), corrective maintenance, calibration and quality assurance tests.
    b) Reprocessing medical devices in accordance with the reprocessing requirements contained in article (20/2) in the regulation.
    c) Follow up with safety alerts and field safety corrective actions.
2. Provide pre-installation requirements for the medical device, and all other requirements associated with the medical device (e.g. chemical requirements, medical gas requirements, central supply requirements, sterilization or cleaning requirements) as per the manufacturer recommendations.
3. Conduct pre-installation acceptance tests to ensure receiving the device in a good condition.
4. Supervising the configuration and installation of the medical device at the designated site in accordance with the manufacturer recommendations and with the documented policy, and ensuring that it is fully functional.
5. Obtain an installation report shows that the device has been installed in a good condition, it is fully functional, and has passed all acceptance tests, in addition to that the end user has been trained to operate it. Both the biomedical technician\engineer and the end user shall approve such report.
6. Receiving of all documents related to device configurations, implemented schematics and IT specifications.
7. Assign a control number and affix it on the medical device, along with any other appropriate tags (e.g., the warranty expiry date).
8. Identify appropriate training needs for operation and maintenance.
9. Ensure that the manufacturer or a trained person by the manufacturer provides appropriate training on the device for the user and the biomedical engineer/technician and retain the training records and certificates.
10. Conduct the necessary tests to ensure the safety, efficacy and quality of the medical device during use in accordance with the manufacturer instructions, and notify the NCMDR In case of any failure of the tested device.
11. Ensure that maintenance is provided by the manufacturer or by a maintenance services provider licensed from SFDA, or by qualified technical staff who received specialized training from the manufacturer or from a trained person by the manufacturer.
12. Determine the requirements for periodic preventive maintenance in accordance with the manufacturer instructions.

13. The obligation to conduct electrical safety tests, as well as periodic preventive maintenance (PPM) as follows:

    a) The medical device should be clean, disinfected (if needed) and functioning properly.
    b) It should be conducted by trained people from the manufacturer, and its procedures and frequency consistent with the manufacturer requirements.
    c) Scheduling periodic preventive maintenance (PPM).
    d) Documenting the details of periodic preventive maintenance (PPM) (records, tool kits, etc.) within the medical device log in the maintenance management system, and retain these information for at least five years.
    e) Affixing a tag on the medical device after conducting the periodic preventive maintenance (PPM), indicating at least the date of the previous PPM, the date of the next PPM and who perform it.
    f) Approval of periodic preventive maintenance (PPM) report by the end user and the biomedical engineer/technician or the maintenance service provider.

14. Monitor all processes of periodic preventive and corrective maintenance.

15. Provide appropriate testing equipment to examine the function, calibration, performance and safety of the medical device in accordance with the Law of Calibration and Measurements.

16. Ensure that the test equipment has been calibrated by the manufacturer or an accredited entity, in accordance with the Law of Calibration and Measurements issued by Royal Decree No. (M/51), date 13/11/1434 H, its regulation and related instructions, and retain the calibration certificates.

17. Conduct functional tests of the medical device using test equipment in accordance with the manufacturer instructions, and notify the NCMDR In case of any failure of the tested device.

18. Provide a maintenance management system and inventory management system to collect, store, organize, analyze and record medical device information, in addition to the necessary spare parts and a list of all assigned spare parts suppliers by the manufacturer.

19. Apply the manufacturer's instructions of corrective maintenance and calibration. In the absence of instructions, refer to the standards and guidance approved by the SFDA.

20. Review reports issued by the NCMDR or the manufacturer concerning safety alerts and corrective actions.

21. Establish a record within the maintenance management system for each medical device includes at least the following information:

    a) General information about the medical device.
    b) Periodic preventive maintenance (PPM): frequency of PPM, updated procedures, calibration requirements, used spare parts, date of each PPM, used test equipment and tools, who perform the maintenance and consumed time.
    c) Corrective maintenance: problem date and description, used spare parts and consumed time.

d) Field Safety Corrective Action: date of safety alert, description of the problem and the required corrective action, date of implementation of the field safety corrective action.

22. Provide appropriate tags in accordance to the device condition, for example (Out of Service and PPM).
23. Any other requirements published on the SFDA website.

D. Requirements for the safe use of radiology and medical imaging devices (ionizing and non-ionizing)

Along with abovementioned requirements and responsibilities, all departments operating radiology and medical imaging devices (ionizing and non-ionizing) shall comply the following:

1. Provide documented policies and procedures related to radiation protection and safety, and Quality Assurance programs for radiology departments and review them regularly.
2. The documented policies and procedures related to radiation protection and safety in dealing with radiology and medical imaging devices.
3. Apply National Diagnostic Reference Level (NDRL) published on the SFDA website and keep all relevant records.
4. Periodically conduct quality assurance tests for radiology and medical imaging devices through qualified and trained specialists in the healthcare facilities or third party that is licensed from the SFDA to provide this service, and retain the tests reports.
5. Notify SFDA through the NCMDR in case of any failure of the tested device and attach a corrective action plan to fix such failure within (3) working days from the date of receiving the test report. The continuity of using the device is restricted by the recommendation found in the report.
6. Periodically conduct the necessary tests to ensure the efficiency and quality of shielding of the radiology rooms (which are required to be shielded and retain the tests reports).
7. Immediately stop using radiology and medical imaging devices that fail in the efficiency and quality of shielding tests and notify SFDA through the NCMDR and attach a corrective action plan to fix such failure within (3) working days from the date of receiving the test report.
8. Provide personal protective equipment (PPE) for staff and patients to protect them from the risk of ionizing and non-ionizing radiation, while obligate to the following:
    a) Provide adequate number of different sizes (for adult and children) and for various uses (e.g. full body apron, pelvic apron, thyroid collar, gloves, and glasses), and/or any other protective equipment in every room containing a medical device emitting ionizing and non-ionizing radiation.
    b) Use PPE if not interfering with the imaging procedure.
    c) Store PPE properly to keep its efficiency.
    d) Test PPE periodically to ensure their efficiency and retain test reports.
    e) Provide adequate number of laser safety glasses corresponding to the device wavelength, and store them properly to protect from any fractures or scratches that may affect its efficiency while excluding the damaged ones.
    f) Provide adequate number of laser safety glasses for patients that are completely impermeable to laser.
9. Commit to monitor the ionizing radiation doses exposed by worker during their work period according to the following:

a) Provide each classified worker with two personal dosimeter badges (A&B) that used alternately when one of them sent off for reading.
b) Keep personal dosimeter records during entire work period.
c) Provide additional personal dosimeter for extremities when exposure to high radiation dose is expected.
d) Perform a risk assessment to determine the expected annual dose for the classified worker in the dental radiology departments, and determine the need to provide personal dosimeter badge accordingly.
e) Provide additional personal dosimeter for pregnant worker in radiology departments to be wear at the level of pelvic area regardless of the expected dose level.

10. Equip the radiology rooms' doors with radiation warning signs (ionizing and non-ionizing radiation) in Arabic and English in radiology departments, including pregnancy warning signs for ionizing radiation rooms.
11. Equip the ionizing radiation rooms' entrances with warning lights that automatically illuminate when the radiation dose is released.
12. When mobile ionizing radiation devices is permanently used in a particular room, a risk assessment shall be performed for the operators as well as for who frequently pass through that room and the surroundings to determine the need for shielding while retain the risk assessment report.
13. Provide mobile radiation barriers to be used with ionizing radiation devices to protect patients and staff from unjustified radiation exposure.
14. Equip radiation rooms (ionizing and non-ionizing) with means that allow the operator to continuously monitor the patient during procedure.
15. Configure dedicated area for operators of ionizing radiation devices to ensure their safety from radiation hazards.
16. Any other requirements published on the SFDA website.

E. Requirements for the safe use of medical radioactive materials

Along with abovementioned requirements and responsibilities, all departments deal with radioactive medical materials shall comply the following:

1. Provide documented policies and procedures for the safe use of radioactive medical materials. This should include, but not limited to, adverse events related to radioactive contamination or the loss of radioactive material, and retain the adverse events reports and investigation reports.
2. Configure dedicated and secure place to store radioactive medical materials (active or decayed) to restrict unauthorized access.
3. Install surveillance cameras inside the hot lab.
4. All accesses within nuclear medicine and radiotherapy departments shall be secured from unauthorized access.
5. Install a communication device inside the hot lab to use in case of emergency.
6. Install area monitor inside the hot lab, regularly calibrate it and provide alternative backup devices.
7. Provide survey meters, regularly calibrate it and provide alternative backup devices.
8. Provide radiation safety equipment to use in case of emergency, this include:
    a) Sink and eye washer/shower.
    b) Radiation contamination monitoring kit.
    c) Radiation Decontamination kit.
9. Assign a designated path for the transfer of radioactive medical material from the collection area to the hot lab.
10. The RSO shall escort the radioactive material from collection area to the assigned storage area.
11. The RSO shall keep track of all radioactive materials with their serial numbers and retain all documentations.

Annexes

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Regulation	Executive Regulation of the Law.
NCMDR	The National Center for Medical Devices Reporting
RSO	Radiation Safety Officer
Medical Device	Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, 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, 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 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 substances and products used in diagnosis, treatment, prosthetics, orthotics, or in disability cases or other medical uses for humans, including medical gases.
Medical Radioactive Material	A material that emits ionizing radiation either by itself or when used with other medical devices for the purpose of diagnosis and treatment.
Reprocessing	Procedures implemented on a used medical device for safe reuse, such as cleaning, disinfection, sterilization, testing and restoration of its technical functions and safety.
User	A person, whether a professional, lay person, or a patient, who uses a medical device.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices for use under its name within the Kingdom or abroad. Manufacturing includes: refurbishing, assembling, packaging, and labelling.
Healthcare Provider	Any government or private establishment that provides healthcare services.
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 in the market.
Quality Assurance	A set of technical tests, measurements, and calibrations approved by the SFDA to verify the safety and effectiveness of radiological medical device and the accuracy, and quality of images
Technical Regulation	Mandatory documents issued by the SFDA for medical devices which specify the principles of safety, performance, and manufacturing, and provide relevant instructions, including terms and symbols as well as packaging and labelling requirements.
Technical and Clinical Specification	A set of criteria that determine the quality, effectiveness, and safe use of a radioactive material in medical applications.
Safety Alert	A notification issued by the NCMDR indicating the risk associated with a medical device and the corrective actions to be taken to mitigate the associated risk Field Safety
Field Safety Corrective Action (FSCA)	An action taken by the manufacturer to eliminate or reduce the risks affecting the safety of a medical device.
Medical Devices Incidents	Any defect, malfunction or change in the characteristics or performance of a medical device that may directly or indirectly cause or contribute to the death or serious injury of a user.
Medical Imaging Materials	Materials used to enhance the contrast of medical imaging equipment.
Advertising	Any written, audible or visible or other displays intended to promote medical device or its technology, or to direct or indirect sale.
Corrective Action	An action taken to solve nonconformity reasons for the establishment, manufacture or medical device.
Implantable Medical Device	A medical device intended to be totally surgically introduced into the human body or to replace superficial/epithelial surface or the surface of the eye. Including those partially or wholly absorbed and remain in place after the medical surgical intervention and include those devices that partially surgically introduced for a purpose of 30 days or more.
Medical Gases	Gases that are used to operate or sterilize medical devices, or that are used for treatment or diagnosis while do not interact by pharmacological, immunological or metabolic means to achieve its intended purpose.
Radiological Departments	Any department inside healthcare facilities that use radiology and medical imaging devices (ionizing and non-ionizing) included, but not limited to, radiology department, nuclear medicine, radiotherapy, dental radiology, laser therapy and dermatology.
Classified worker	Any worker inside health care facility that may exposed to an expected annual dose of more than (1) mSv.
Calibration	The required corrective adjustments to medical devices and testing equipment to maintain its performance accuracy according to a standard.

Testing equipment	The Equipment or tools used to perform functional tests or calibration for medical devices.
Maintenance Management Systems	A Computer-based software system that is used to automate processes related to technical support of medical devices, the inventory management system, corrective maintenance, periodic preventive maintenance (PPM) and contracts management; and provides a wide range of data reports (such as downtime, life cycle cost and inventory reports related to device type, location or selected manufacturers related to the medical device lifecycle.
Corrective Maintenance (CM)/ Repair	An unscheduled process or procedure to correct or repair malfunctions of medical device or its components, including repair, restore or replace used components or systems to restore safety and performance of a medical device
the specialized department in medical devices	The department concerned with all issues related to the medical device lifecycle from purchase to disposal. This includes planning, setting technical specifications, evaluation, maintenance and inventory management, follow-up of supply chains and suppliers, training and other related tasks.
Periodic Preventive Maintenance (PPM)	A scheduled process or procedure at specific intervals includes specific maintenance processes such as lubrication, cleaning or replacing parts that are expected to wear or which have a finite life. The procedures and intervals are usually specified by the manufacturer
Liaison Officer	A designated person by health care provider who works as a liaison with the National Center for Medical Devices Reporting (NCMDR)
Control Number	A set of letters, numbers and symbols, placed on the medical device for monitoring and tracking, It is included in the maintenance management system database inside the health care facility.

Annex (2): Storage and Transportation of Medical Devices for Healthcare Provider

Storage Area	1	The storage area for medical devices should be: o Designed or adapted for the storage of medical devices. o Clean and enough space to allow cleaning and inspection o Equipped with thermometers/hygrometers to monitor changes in temperature and/or humidity. o All surfaces and shelves, if applicable, should be made of or covered by an impermeable material to enable proper and safe cleaning. o Include/contain 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. o Adequately lit and ventilated. o Emergency plan set up and used in case of an electricity shutdown (power outage).
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	A copy of the transfer form should be sent to the department responsible for medical devices to update the medical device record in order to track for the purpose of maintaining, use, or future evaluation needs.
	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	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.
	7	When the medical device needs to be disassembled and reassembled in different locations, it should be done by a qualified person and under conditions specified by the manufacturer's recommendations.
	8	Medical devices should be transported and carried carefully in a manner that corresponds to the special transport precautions for each medical device's nature.

	9	Any case of spoilage or breakage should be reported.
	10	The transporting vehicle or containers should be adequately suitable for the intended purpose and cleaned.
Manufacturer's Instructions/ Requirements	11	Medical devices should be stored 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: ○ Temperature (all the medical devices should be kept during storage and/or transportation at temperature ranges specified by the manufacturer) ○ Moister and humidity ○ Exposure to light ○ The direction the package should face ○ The maximum number of packages stacked above each other ○ 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 3) to determine these values and the set of storage definitions. Note 3: Healthcare providers should monitor and periodically record these conditions (such as temperature and humidity).
Sterile Medical Devices	12	In addition to manufacturer-specific instructions, medical devices that are dispatched in a sterile state, should be stored and transported in a manner that protect their packaging from: ○ Exposure to moisture ○ Direct sunlight ○ Damage ○ Dirt and unclean environment Note: Sterile medical devices should be considered unsterile if packaging loses its integrity.
Staff	13	Staff involved in the storage and transport of medical devices should: ○ Have proper knowledge about these activities, and

		○ Be able to deal with those devices that have different storage and transportation requirements.
Written Procedures	14	Healthcare providers should have a written procedure that describes the practices taken to ensure those medical devices are stored and transported based on the manufacturer's instructions/requirements. The written procedure ideally should be part of a quality management system.

Annex (3): Temperature Rates Related to Medical Devices Storage Conditions

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

SFDA

Annex (4): List of Changes on the Previous Version

Description
• The following documents have been replaced and the requirements are included in this document: - Guidance for Healthcare Providers for Storage and Transportation of Medical Devices (MDS-G17). - Requirements for Quality, Safety and Effectiveness of Medical Devices at Healthcare Facilities.