MDS-REQ 11

Requirements for Post-Market Surveillance of Medical Devices

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"Translated Copy"

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for post-market surveillance of medical devices including the procedures and activities listed in the “Scope” below.

Scope

This document applies to the following procedures and activities:

1. Reporting and investigation of adverse events and complaints of medical devices
2. Reporting violating medical devices
3. Safety alerts and field safety corrective action (FSCA) for medical devices
4. Appointing a contact officer with the NCMDR
5. Reprocessing of medical devices
6. Resale, loaning or donating used medical devices
7. After-sale and maintenance services for medical devices
8. Destruction of used medical devices

Background

SFDA has issued this document in reference to the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH through articles (14), (16), (20), (28), (30) and (31), and in accordance to the "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 AH through articles (10/29), (10/30), (14/1), (16/1), (16/2), (20/2), (20/5), (28/1), (28/2), (30/1), (30/2) and (31/1).

1) Reporting and investigating adverse events and complaints of medical devices

Requirements

General Requirements	- Manufacturers, authorized representatives, and healthcare providers shall report to the NCMDR about any adverse events and complaints related to their medical devices, and follow up investigation and provide the NCMDR with all documents and information. - They shall comply with the Requirements for Clinical Trials of Medical Devices (MDS-REQ 2) with regard to reporting and investigating serious adverse events or device deficiencies related to clinical trials. - Manufacturers, authorized representatives, importers and distributers shall, if requested by the SFDA, track medical devices. - Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to the supply and distribution of medical devices. - Manufacturers, authorized representatives, importers and distributors shall document and implement written work procedures to follow up incidents and adverse events of medical devices. - Healthcare providers shall appoint a contact officer with the NCMDR. - Manufacturers, authorized representatives, importers and Distributors shall appoint an authorized person to communicate with the SFDA.
Reporting Timeframe	○ Within (2 days) from the date of occurrence or awareness of adverse events or complaint, in case it represents a serious public health threat. ○ Within (10 days) from the date of occurrence or awareness of adverse events or complaint, in case it represents a threat that may cause or contribute, directly or indirectly, in death or serious injury. ○ Within (30 days) from the date of occurrence or awareness of adverse events or complaint, in case it represents any effect other than what mentioned in the aforementioned items. - When the NCMDR contacts manufacturers, authorized representatives and healthcare providers for following up the investigation of incident, adverse event or complaint, they shall response within (5 days).
Required information and Documents	- Manufacturers, authorized representatives and healthcare providers shall provide the NCMDR with investigation reports, and technical documents and test reports related to the medical device associated with the adverse event based on the stage of investigation and the availability of information. Initial report shall include the information mentioned in the "MD Reporting From". - Manufacturers and authorized representatives shall submit to the NCMDR complaints. The "MD Complaints and Malfunctions Form" shows the data and information required to be available. Additional information, documents or procedures shall be

	provided when needed based on the progress of investigation and evaluation of the complaint. - Investigation reports include: ○ Initial Report: It contains the initial information about the medical device and the adverse event or complain. It includes the information mentioned in the "MD Reporting From" and shall be submitted to the NCMDR according to the aforementioned time frame. ○ Follow-up Report: • Contains additional information, investigation progress and actions taken. • It shall be submitted if the investigation takes more than (30 days) with providing justification. SFDA shall assess the provided information and justification. ○ Final Report • The last submitted report related to the adverse event or complaint. It contains all information and details, and the actions taken and final recommendations. • It shall determine the type of corrective or preventive action taken by the manufacturer or the authorized representative, which subject to an evaluation by the SFDA.
Investigation conclusion and Final Report Submission	- Investigation procedures shall be concluded and the final report shall be submitted to the NCMDR within: ○ (15 days) from the date of occurrence or awareness of adverse events or complaint that does not require testing or technical evaluation. ○ (30 days) from the date of occurrence or awareness of adverse events or complaint that require testing the device inside KSA. ○ (60 days) from the date of occurrence or awareness of adverse events or complaint that require testing the device outside KSA.
Reporting Channels	- Submitting adverse event or complaint related information and documents through: ○ National Centre for Medical Device Reporting (NCMDR) ○ Saudi Vigilance ○ Call Center (19999)

2) Reporting violating medical devices

Requirements

General Requirements	- Manufacturers, authorized representatives, importers, distributors and healthcare providers shall report to the SFDA about medical devices in violation of the provision of the Law and Regulation; including medical devices that are fraudulent, unregistered, or unauthorized for marketing. - Manufacturers, authorized representatives, importers, distributors and healthcare providers shall provide information and documents related to the violating medical devices including data of supply and sale, quantities, and contact information of person to whom the medical devices are dispensed or sold. - Manufacturers, authorized representatives, importers, distributors and healthcare providers shall provide the SFDA with the corrective plan within (5 days) from the date of reporting the SFDA about the violating medical devices or the date of respond to SFDA enquiry indicating the presence of fraudulent or violating medical devices. - SFDA approval shall be obtained for the corrective plan. - In case the SFDA issue a decision to destruct the violating medical devices, the destruction shall be carried out by a committee or more formed for such purpose. The violator shall incur destruction costs.
Reporting Channels	- Notifying the SFDA and submitting information and documents related to the violating medical devices through: ○ National Centre for Medical Device Reporting (NCMDR) ○ Saudi Vigilance ○ Call Center (19999)

3) Safety alerts and field safety corrective action (FSCA) for medical devices

Requirements

General Requirements	- Manufacturers and authorized representatives shall report the NCMDR any field safety corrective action (FSCA) or warnings affecting KSA and issued by the manufacturer or similar regulatory authorities outside the Kingdom. - Manufacturers and authorized representatives shall inform the NCMDR of the corrective actions resulting from post-market follow-up investigations conducted by the manufacturer for medical devices circulated in KSA, with explaining of the causes and providing information on the corrective actions that the manufacturer has taken or intends to take. The technical file of the medical device shall be updated according to the corrective action and in accordance with the Guidance on MDMA Significant and Non-Significant Changes (MDS- G 12). - Manufacturers and authorized representatives shall identify the risks associated to the safety alerts affecting KSA, without underestimating the risks, and providing supply and distribution information. - Manufacturers, authorized representatives and healthcare providers shall provide the information and reports required for the safety alert. - Manufacturers and authorized representatives shall submit a plan of implementing FSCA, including specifying the date of completing the implementation. - Manufacturers and authorized representatives shall provide evidence of completing the implementation of FSCA according to the approved plan by the NCMDR. - Healthcare providers shall use the medical device as per the recommendations mentioned in the safety alert. - Importers and distributors shall not import or distribute any medical device that has been withdrawn or discontinued. - Importers, distributors and health care providers shall stop circulating the medical device if the FSCA stipulates that. - Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to medical devices imported and distributed within KSA, and provide the NCMDR with the information upon request according to the following: o Contact information of medical devices manufacturers o Information of supply, distribution and points of sale o Quantity supplied and information of their transfer and storage o Lists of users' name and contact information.

	○ Information of the circulated medical device, including its name, brand name, identification number, serial numbers, batches supplied, and other information necessary to identify and track it ○ Any other information requested by the SFDA as published on its website.
Stages of Field Safety Corrective Action (FSCA)	
Stage One: Reporting FSCA to NCMDR or Receiving an Inquiry from SFDA	- The manufacturer or authorized representative shall report to the NCMDR about FSCA affecting KSA within (2 days) from the issuing date of FSCA letter, and attach the FSCA letter including information required in Annex 1. - In case the SFDA issue a safety alert or receiving inquiries from the NCMDR about FSCA, the manufacturer or authorized representative shall respond within (5 days) through NCMDR email (ncmdr.md@sfda.gov.sa). In case KSA affected by the safety alert, the required information for safety alert shall be sent (see Annex 1), while in case KSA not affected, jump to "Stage Five: Closure".
Stage Two: Notifying the Affected Users	- The manufacturer or authorized representative shall notify importers, distributors, healthcare providers and users about the safety alert within (5 days) from the date of reporting to the NCMDR, or from the date of responding to NCMDR inquiry indicating that KSA affected by the safety alert. - The manufacturer or authorized representative shall notify importers, distributors, healthcare providers and users about the safety alerts via the following methods: ○ Email ○ National address Phone call ○ Visiting affected customers (in case no-response to the other methods) - The manufacturer and authorized representative shall have a documented proof of notifying importers, distributors, healthcare providers and users about the safety alerts through one of the following methods: ○ Signing the acknowledgment letter attached with the field safety FSCA letter (see Annex 2). ○ Sign on the FSCA letter directly in case the acknowledgment letter not attached with the FSCA letter. - The manufacture or authorized representative shall keep records of communication with the importers, distributors, healthcare providers and users which proves that they took all possible means to notify them about the safety alert, including communicating them at least (3 times) via two different methods. - Communication records shall include the following: ○ Dates of communication ○ Method of communication

	○ Data of authorized persons/healthcare contact officers ○ Acknowledgments letters
Stage Three: FSCA Implementation Plan	- The manufacturer or authorized representative shall submit FSCA implementation plan within (5 days) from the date of reporting to the NCMDR, or from the date of responding to NCMDR inquiry indicating that KSA affected by the safety alert, through NCMDR email (ncmdr.md@sfda.gov.sa). - " FSCA Implementation Plan form" shall be filled. - The FSCA implementation plan shall include the following: ○ Description and number of affected products. ○ Description of any other corrective actions other than notifying importers, distributors, healthcare providers and users. ○ Specifying any corrective actions not mentioned in the safety alert and cannot be implemented in the meantime. ○ Specifying the expected date to complete implementation of FSCA with a justification for specifying that date. ○ Risk Assessment form ○ Specifying the time for providing the NCMDR with periodic reports if FSCA implementation is expected to take more than (90 days). - The NCMDR approval for the FSCA implementation plan shall be obtained.
Stage Four: Implementing FSCA	- The manufacturer or authorized representative shall document the following information: ○ Safety alert reference number ○ Model/Batch (LOT) Number/Serial Number of the affected medical devices ○ Data of importers, distributors, healthcare providers and users for whom FSCA implemented on their affected medical devices, with authorized person/contact officers' signature, their job titles, contact information and date of signature ○ A detailed description of the action taken as required in FSCA letter - The manufacturer or authorized representative shall record and document proof for implementing any action (e.g., withdrawal, software update, updating IFU, replacement, destruction). - In case the manufacturer or authorized representative unable to comply with the expected date to complete implementation of FSCA, a request to extend the expected date shall be submitted to the NCMDR through email (ncmdr.md@sfda.gov.sa) with a justification and explanation of the remaining actions and their expected completion date. - In case there was an agreement to submit periodic progress reports of FSCA implementation and the manufacturer or authorized representative unable to submit

	such reports on the due dates, then the NCMDR shall be notified through email (ncmdr.md@sfda.gov.sa) with a justification and specifying alternative dates to submit the reports.
Stage Five: Closure	- In case the KSA market affected by the safety alert, and after confirming the implementation of FSCA for all affected medical devices in KSA, the manufacturer or authorized representative shall submit "Confirmation Statement for Completing the Corrective Action in the Safety Alert)" and the "FSCA Closure Report form"to NCMDR email (ncmdr.md@sfda.gov.sa). - In case the KSA market not affected by the safety alert, the manufacturer or authorized representative shall submit "Statement Confirming Saudi Arabia is Not Affected by Safety Alert" to NCMDR email (ncmdr.md@sfda.gov.sa). -The closure is not considered completed unless receiving a confirmation from the NCMDR. -The NCMDR has the right to request any document that supports the implementation of FSCA, for example: FSCA periodic progress reports, medical devices destruction proof).

4) Appointing a contact officer with the NCMDR

Requirements

Qualifications	-The NCMDR contact officer shall be scientifically qualified in biomedical engineering/biomedical technology or any medical/health specialty. - The NCMDR contact officer shall be fluent in English.
Contact Officer Tasks and Responsibilities	-Acting as a liaison between the healthcare provider and the NCMDR for all matters of medical devices that either located inside the healthcare facility or dispensed for use outside the healthcare facility. -Reporting incidents or submitting complaints to the NCMDR related to the medical devices that located inside the healthcare facility, and submitting information and documents related the incident, adverse event or complaint through: ○ The National Center for Medical devices reporting (NCMDR) ○ Saudi Vigilance -Follow-up and cooperating with the NCMDR during incidents, adverse events and complaints investigation procedures, and provide the NCMDR with all information and documents. -Responding to the weekly report of safety alerts, whether or not medical devices that located inside the healthcare facility affected by any safety alert, through replying to the email received from the NCMDR. -Communicating with the manufacturer or authorized representative in case the medical devices that located inside the healthcare facility affected by any FSCA. -Submitting information and reports required for the safety alert, such as updates of the FSCA implementation by the manufacturer or authorized representative, and submitting maintenance or destruction reports related to the affected devices. -Ensuring completion of FSCA implementation on the affected medical device according to the FSCA implementation plan approved by the NCMDR. -Cooperating with the SFDA in monitoring the compliance healthcare providers' compliance with the Requirements of Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3). -Responding to the SFDA surveys and questionnaires related to the medical devices.

5) Reprocessing of medical devices

Requirements

- The medical device shall not be intended for single use.
- Healthcare providers and providers of maintenance services for medical devices shall adhere to the following when reprocess a medical device:
  - Existence of competency and capabilities for the person who performs reprocessing of medical devices.
  - Reprocessing the medical device according to the manufacturer instructions, related standards and establishment approved policies, in a way that does not affect its safety and performance efficiency.
  - Keeping all records of medical device reprocessing throughout the period of use inside the healthcare facility.

6) Resale, loaning or donating used medical devices

Requirements

Manufacturers, authorized representatives, importers, distributors and healthcare providers shall adhere to the following:

- The medical device shall have medical device marketing authorization (MDMA).
- The medical device shall not exceed the expected service life as specified by the manufacturer.
- Notifying the SFDA and the manufacturer or authorized representative when carrying out the resale, loaning or donating procedure.
- The intended use of using the medical device [professional use/home use (intended for lay person)] shall be appropriate to the nature of the recipient.
- The medical device shall not be capable of transmitting infection or causing injuries.
- The medical device shall be free of any medical contamination, biological residue, radioactive waste, stains or any dangerous medical residue.
- The medical device shall not been previously destroyed.
- Delete all patients' data and medical records from the medical device memory.
- The medical device has successfully passed mechanical tests, calibration and electrical safety tests, including but not limited to leakage current testing.
- Sterilizing or disinfecting and cleaning, packaging and storing the medical device according to the manufacturer's instructions, and satisfying the related SFDA requirements.
- Providing the medical device recipient with all technical documents proving that the medical device satisfied the SFDA requirements, including instructions for use (IFU), maintenance manual, periodic preventive maintenance (PPM) and performance reports. In addition to providing complete information about missing spare parts and accessories – if applicable-.
- Documenting procedures and records of resale, loaning or donation and submitting them to the SFDA upon request.
- The recipient is responsible for the availability of necessary technical staff and tools for the use and maintenance of the medical device.

7) After-sale and maintenance services for medical devices

Requirements

General Requirements	-The manufacturer or authorized representative shall renew the medical device marketing authorization (MDMA) before its expiration. -The manufacturer shall provide after-sales services for its medical devices including spare parts approved and compatible with the standards and technical specifications of the medical device, and provide a technical support to ensure the continuity of the medical device according to the intended use throughout the expected service life of the medical device. -In case of a permanent discontinuance of a medical device, the manufacturer or authorized representative shall notify the SFDA and update the medical device marketing authorization (MDMA) related information, in addition to obligate toward providing after-sales services throughout the expected service life of the medical device. -The providers of maintenance services for medical devices, and importers and distributors wishing to provide maintenance services for medical devices not belong to them shall obtain the SFDA license for providers of maintenance services for medical devices in accordance with the Requirements for Medical Devices Establishments Licensing (MDS-REQ 9). -Applying the manufacturer instructions for the periodic preventive maintenance (PPM), corrective maintenance (CM) and Calibration. In case such instructions was not exist, the SFDA related standards should be followed. -Reporting the NCMDR about incidents and adverse events of the medical devices under maintenance.
Technical Staff for Maintenance Services	-The manufacturer shall ensure hiring, qualifying and direct training specialized technical staff in maintenance and operation of medical devices. This may be done by another party licensed from the SFDA to provide maintenance services for medical devices in accordance with the Requirements for Medical Devices Establishments Licensing (MDS-REQ9). -The providers of maintenance services for medical devices, importers, and distributors wishing to provide maintenance services for their medical devices shall hire technical staff consist of biomedical engineers and technicians according to the following conditions: o Holding academic or technical qualifications in biomedical engineering/biomedical technology or any related specialty. o Receiving specialized training on their medical devices by the manufacturer or a certified body by the manufacturer-. -The providers of maintenance services for medical devices shall provide the SFDA with the organizational structure, a list of technical and administrative staff, and a certified copy of their qualifications, training certificates and job description.

Spare Parts, Facilities and Equipment for Maintenance Services	-Providing immediately spare parts approved and compatible with the standards and technical specifications of the medical device to the department/person requesting a maintenance service in the healthcare facility. Delaying is not acceptable unless in case of corrective maintenance (CM) with providing a justification. -Allocating a designated equipped place for maintenance of medical devices. -Allocating appropriate storage spaces for medical devices and spare parts as recommended by the manufacturer and in accordance with the Requirements for Storage and Transportation of Medical Devices (MDS-REQ 12). -Providing appropriate testing equipment to calibrate the medical device and test its safety, function and performance efficiency. Such equipment shall comply with the "Law of Measurement and Calibration" issued by the Royal Decree No. (M/51) dated 13/11/1434 AH and its implementing regulation, and related instructions. This equipment shall be inspected to ensure its calibration and safety before reuse. -Using Kilovolts (kV) and milliamperes-seconds (mAs) meters frequently for X-ray devices to ensure that the dose delivered from the X-ray tube is compatible with the device settings. -Providing testing equipment for all patient applied parts to check leakage current, insulation resistance and ground resistance. - Providing testing equipment to monitor the quality of image, laser and UV radiation.
Documentation of Maintenance Services	-Providing a maintenance management system and inventory management system to record, store, organize and analyze medical device information, in addition to the necessary spare parts information and a list of all spare parts suppliers authorized by the manufacturer. -Maintenance records and data shall not be altered. -Documented procedures shall be set to ensure the following: o Completing all maintenance service orders after getting the approval of the department/person requesting a maintenance service in the healthcare facility. o Getting feedback from the department/person requesting a maintenance service in the healthcare facility regarding the level of satisfaction about the quality of provided service and the response time through specific KPIs. -Creating written work procedures and forms for every maintenance service of a medical device. -Affixing appropriate tags according to the device condition, (e.g., "PPM" tag including information of the providers of maintenance services for medical devices, "Out of Service" tag and others).
Particular Requirements for After-sales Services	-The manufacturer shall specify the warranty period that shall be a minimum of (2 years). -Clarifying after-sales services to the customers before conclusion of a contract or issuance of a sale invoice.

	-Clarifying check/inspection fees, labor costs and spare parts prices before providing the after-sales service. -Providing means of communication with customers and keep a list of customer data. -Keeping sufficient quantities of consumable (in-demand) spare parts to ensure immediate supplying to customers. -Supplying rare demand spare parts within (14 days) from the order date.

8) Destruction of used medical devices

Requirements

In case the establishment or healthcare provider wishing to destruct any used medical device, The following requirements shall be complied with:

-Obtaining approvals from competent agencies in the Kingdom - if necessary -.

-Performing the destruction by a specialized body in the presence of the establishment official or somebody in his behalf, or in cooperation with the relevant authorities.

-Applying the manufacturer instructions related to destruction procedures.

-Complying with the GCC Uniform Law for Medical Waste Management.

-The destructed medical device shall become unusable by any way.

-Documenting all data related to the destruction including data of destructed medical device, causes of destruction and related risks, and keep destruction records for a period of at least (3 years).

-Providing the SFDA with the destruction records upon request.

-Creating documented procedures for destruction process, including compliance with the conditions described above.

-Disposing the destructed medical devices shall be in accordance to the “Waste Management Law” and its Implementing Regulation.

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".

Annexes

Annex (1) Required information for field safety corrective action (FSCA) Letter

- The subject in bold (**URGENT FIELD SAFETY CORRECTIVE ACTION OR FIELD SAFETY NOTICE**) mentioning the name of the affected medical device.
- **Safety alert reference number.**
- **Attention to the user**: (establishment/user/healthcare provider's information).
- **Purpose of safety alert:**
  - Purpose of field safety corrective action (FSCA).
  - If any deaths or serious injuries has been occurred or could occur, they shall be mentioned along with the probability of its occurrence.
- **Affected medical devices:**
  - Mentioning all affected medical devices.
  - How to identify the affected medical devices.
- **Cause of the field safety corrective action (FSCA):**
  - Simplified overview of the medical device and how it works.
  - Description of the problem, which was the cause to issue the safety alert.
  - Frequency of malfunction and complaints.
  - If the device malfunction could result injuries or treatment delay, or may require surgical intervention, such effect shall be clarified.
  - How the user can identify that the medical device malfunctioned or subject to malfunction – if possible-.
- **Actions to be taken by the user:**
  - Description of the action required to be taken (e.g. isolating the affected medical devices, returning, following instructions, etc.).
  - The time limit for implementing the required actions.
  - Notifying the users about the safety alert or advising to review the patients' previous results - if recommended -.
  - In case that Acknowledgment letter has been attached with the field safety corrective action (FSCA) letter, the time limit to respond with acknowledgment.
- **Field safety corrective action (FSCA):**
  - Description of the actions going to be taken by the manufacturer (e.g. withdrawing, modifying, providing instructions for use, updating software).
  - Specifying the time period to complete implementation of field safety corrective action (FSCA).
- **Contact information of the manufacturer/authorized representative:**
  - Name of authorized person.
  - Email.
  - Phone number.
  - National address.

Annex (2) Required information for acknowledgment letter

- **Safety alert information:**
  - Safety alert reference number.
  - Issuing date.
  - Name of affected medical device.
  - Labeling information of affected medical device.
- **User information:**
  - Name of (establishment/healthcare provider/user).
  - National address.
  - Name and job title (for healthcare providers).
  - Email.
  - Phone number.
- **Actions to be taken by the user:**
  - The Statement "*I acknowledged that I have received the safety alert and read and understood its content*".
  - The Statement "*I took all actions mentioned in the safety alert*".
  - The Statement "*I (disposed/isolated/returned) the mentioned devices (quantity and identifier)*".

    Or
  - The Statement "*The mentioned devices are not available (out of service or missing) (quantity and identifier)*".
- **Contact information of the authorized person:**
  - Name.
  - Email.
  - Phone number.
  - Date.
  - Signature.
- **Contact information of the manufacturer/authorized representative:**
  - Name of authorized person.
  - Email.
  - Phone number.
  - National address.

- **The time limit to respond with acknowledgment.**

Annex (3) Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
NCMDR	The National Center for Medical Devices Reporting
Medical Device	Any instrument, apparatus, implement, implant device, 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 and supplies; providing information for medical or personal 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 or products used in diagnosis, treatment, prosthetics, orthotics, or in disability cases or other medical uses for humans, including medical gases.
Accessories of Medical Devices and Supplies	Any substance or product intended specifically to be used with a medical device or supply to enable it to achieve its purpose.
Single-use Medical Device or Supply	A disposable article intended for use on a patient in a single medical procedure.
Home-Use Medical Device	A medical device or supply intended for use in any environment outside a healthcare facility.
Establishment	A legal entity engaged in an activity related to medical devices and supplies.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, 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 supplies a medical device to the Kingdom.
Distributor	An establishment in the supply chain that supplies a medical device to another distributor or its end user.
Healthcare Provider	Any government or private establishment that provides health care services.
User	A person, whether a professional, non-professional, or a patient, who uses a medical device or supply.
Lay Person	A person who does not have formal education or training in a relevant field of healthcare or medical discipline.

License	A document issued by the SFDA to engage in any of the activities subject to this Law.
Registration	A procedure for listing in the MDNR any medical device or supply and any establishment that engages in any activity governed by this Law.
Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Surveillance	A group of procedures to control safety, efficiency, quality and effectiveness of medical devices while circulated in the Kingdom.
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
Adverse Event	Any defect 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.
Complaint	Any kind of communication whether written or oral about insufficiency related to the medical device or its quality, efficiency, efficacy, usability, safety or performance, in addition to insufficiency related to the service that impacts the performance of the medical device. *Note: Complaint include reporting medical devices incidents result from any defect or change in the characteristics or performance of a medical device that may not directly or indirectly cause or contribute to the death or serious injury of a user.
Malfunction	Failure of a medical device to fulfill its safety or performance specifications
Serious public health threat	Event which could result in imminent risk of death, serious deterioration in a person's state of health or serious illness that may require prompt remedial action and that may cause significant morbidity or mortality. Such event may be unusual or unexpected for the given place and time;
Tracking	Procedures and measures that enable the tracing of medical devices, at any stage of the supply chain.
Fraudulent Medical Device or Supply	A device or supply the identity or source of which is deliberately altered with the intent to defraud. A medical device or supply shall be deemed fraudulent if its components have been altered in a manner that compromises its safety and efficacy, or if it is packed in counterfeit containers.
Safety Alert	A notice issued by the NCMDR indicating the risk associated with a medical device or supply and the corrective actions required to avoid such risk.
Field Safety Corrective Action (FSCA)	An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.
Corrective Action	An action taken to resolve causes of nonconformities detected on the establishment, manufacture or medical device.
Acknowledgment Letter	A document proves the user has viewed the information and the corrective actions mentioned in the safety alerts letter.
Contact Officer	A designated person by health care provider who works as a liaison with the National Center for Medical Devices Reporting (NCMDR)

Providers of Maintenance Services for Medical Devices	Any party that maintains or repairs a medical device after distribution, in order to restore the level of safety, efficiency and performance set by the manufacturer.
Biomedical Engineer/Biomedical Technician (BME/BMT)	A professional person who supports patient care by applying engineering and management skills in healthcare technology. Note: The biomedical engineer/biomedical technician must have an academic background in Medical/Biomedical Engineering or Biomedical Tech - Instruments.
Testing equipment	The equipment or tools used to perform functional tests or calibration for medical devices.
Calibration	The required corrective adjustments to medical devices or testing equipment to maintain its performance accuracy according to a reference standard.
Maintenance Management Systems	A Computer-based software system that is used to automate processes related to technical support of medical devices, corrective maintenance, periodic preventive maintenance (PPM) and contracts management; and provides a wide range of data reports related to the medical device lifecycle.
Periodic Preventive Maintenance (PPM)	A scheduled procedure at specific intervals includes specific maintenance processes such as lubrication or 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.
Corrective Maintenance (CM)/ Repair	An unscheduled 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
Reprocessing	Procedures implemented on a used medical device or supply for safe reuse, such as cleaning, disinfection, sterilization, and testing and restoration of its technical functions and safety.
Destruction	Permanent disposal of the medical device that ensures that it will not be reused.
Labeling	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.

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

Number & Date of the Previous Version	Changes Description
1.0 27/10/2022	• Editorial modification on the following sections: ○ Reporting and investigating adverse events and complaints of medical devices. ○ Reporting violating medical devices. ○ Safety alerts and field safety corrective action (FSCA) for medical devices. ○ Destruction of used medical devices. • Editorial modification on the following annexes: ○ Annex (1) Required information for field safety corrective action (FSCA) Letter. ○ Annex (3) Definitions & Abbreviations.