MDS – G29

Guidance on Risk Communication of Medical Devices

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Introduction

Purpose

The purpose of this document is to enhance and improve effective communication in the exchange of information related to the risks associated with medical devices among concerned parties, including users of medical devices, such as patients and the general public, in order to enable them to identify potential risks and make appropriate decisions that contribute to enhancing user safety.

Scope

This document applies to parties involved with medical devices throughout the medical device lifecycle, including the stages of design, manufacturing, importation, distribution, use, and post-market follow-up, whether acting as sources or recipients of risk communication information, including:

- Manufacturers, authorized representatives, importers, distributors, and warehouses.
- Healthcare facilities.
- Sponsors and Contract Research Organizations (CROs).
- Organizations that serve, educate, or communicate with medical device users.
- Patients and the general public.

Background

SFDA has issued this document:

- in reference to:
  - to Articles (14), (15), (26), (27), (28), (29), (30), (32) and (34) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH and their corresponding articles of 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.
  - Requirements for Safe Use of Medical Devices Inside Healthcare Facilities (MDS–REQ3).
  - Requirements for Post-Market Surveillance of Medical Devices (MDS–REQ11).
- In support of the SFDA's Fourth Strategic Plan objectives of developing the regulatory framework and enhancing communication and awareness.

General Principles

- Risk communication plays a vital role in ensuring the safety and performance of medical devices; therefore, effective communication among stakeholders is essential to support the safety and performance of medical devices.
- Appropriate communication of benefits, risks, and uncertainty is essential at every stage of the medical device life cycle.
- The related regulatory requirements are:
  - MDS–REQ2 Requirements for Clinical Trials of Medical Devices.
  - MDS–REQ3 Requirements for Safe Use of Medical Devices Inside Healthcare Facilities.
  - MDS–REQ9 Requirements for Licensing of Medical Devices Establishments.
  - MDS–REQ11 Requirements for Post-Market Surveillance of Medical Devices.
  - MDS–REQ12 Requirements for Transporting and Storage of Medical Devices.

- Risk communication should be designed to support the identification and control of risks through the implementation of appropriate risk control measures.
- Effective risk communication contributes to:
  - Increase trust and transparency in SFDA safety decisions and assessments.
  - Promote patient safety.
  - Support Informed Decision-Making.
  - Provide general recommendations and best practices of medical devices for stakeholders to ensure effective communication of the benefits and risks of medical devices.
  - Empower healthcare professionals by ensuring access to the information they need across different communication channels, and raise awareness to support safety and effectiveness.
  - Strengthen patient engagement and health literacy, highlighting the importance of involving patients in decision-making during treatment and throughout the medical technology product life cycle.
  - Ensure inclusivity by supporting communication with groups who are less digitally enabled through appropriate tools tailored to their needs.

- Effective risk communication addresses the challenges associated with medical devices, such as technical complexity, diverse audiences, balancing risk and benefit, cultural and linguistic differences, evolving regulations, as well as misinformation and misunderstanding.
- Effective risk communication promotes active stakeholder participation in sharing information related to medical devices to foster collaboration and improve the communication of incidents and complaints that may affect the safety, performance, integrity, and security of medical devices and the connected healthcare infrastructure.

Key Principles of Risk Communication

Regulatory Compliance

- Risk communication strategies should be developed in comply with SFDA applicable regulations to ensure transparent communication of risks associated with medical devices.
- Post-market activities are part of the SFDA's regulatory requirements for the continued circulation of medical devices in the market.
- All strategies and documentation should be promptly updated in response to any updated in SFDA applicable regulations .
- Records and documentation demonstrating regulatory compliance should be maintained.

Support Informed Decision Making

- Comprehensive risk information on medical devices should be collected and analyzed to support informed decision-making.
- Accurate and detailed information regarding risks and benefits should be provided to healthcare providers to assist in appropriate device selection and safe handling and usage.
- Healthcare providers should be educated and supported to ensure they are able to balance potential benefits against risks for individual patient scenarios, thereby enhancing patient safety and treatment outcomes.

Public Trust

- Transparency in risk communication should be maintained to foster trust among all stakeholders such as manufacturers, authorized representatives, importers, warehouses, distributors, healthcare providers, and patients.
- A strong commitment to patient safety and ethical practices should be demonstrated through clear, consistent communication and open dissemination of risk information.

Legal Liability

- Risks should be communicated clearly and comprehensively to mitigate potential legal liabilities for manufacturers and other stakeholders.
- Complete records of all risk communications should be maintained to provide traceability, accountability and mitigate legal liabilities.

Cultural Sensitivity

- The diverse cultural and linguistic backgrounds of patients and healthcare providers should be taken into consideration when developing risk communication materials.
- Risks should be communicated in a culturally sensitive manner to improve understanding, compliance, and inclusivity.

Consistency

- The content of all risk communication materials should be standardized to ensure clarity and reliability.
- Consistent messaging across all communication platforms should be maintained.
- Stakeholders should receive the same information to avoid ambiguity or confusion.

Accountability

- Stakeholders should be accountable for the accuracy, transparency, and timeliness of risk communication.
- Responsibilities for reporting, documenting, and disseminating risk information should be clearly defined and upheld.
- Comprehensive records of all communications should be maintained to ensure traceability and accountability across the medical device life cycle.

Clarity, Accessibility & Language

- Risk communication materials should be:
  - written in clear, simple, and unambiguous language to ensure understanding.
  - structured and presented in easily understandable formats, avoiding use of jargon when addressing non-specialist audiences.
  - translated into Arabic and English, with additional languages or accessible formats (e.g., Braille, subtitles, voiceovers or icons) provided when necessary to reach diverse and vulnerable populations.
  - designed to reach all users, including vulnerable populations, ensuring inclusivity and equitable access to safety information.
  - supported by engaging and accessible formats such as infographics, short videos, and concise posts.
- See Annex (1) for detailed guidance.

International Coordination

- Risk communication strategies should align, where possible, with international best practices and guidance from developed regulatory authorities.
- Collaboration and information exchange with international regulators should be promoted to ensure consistency of safety messages and strengthen credibility.
- Global safety alerts, recalls, or corrective actions should be reviewed and, when relevant, communicated to stakeholders in the KSA to maintain harmonization with international post-market surveillance actions.

Post-Market Surveillance

- Risk communication should cover ongoing monitoring and reporting of device performance and safety, including the emerging risks or complaints /adverse events.
- A structured system for reporting and communicating complaints/incidents or adverse events should be established and maintained.
- Healthcare providers and patients should be given timely updates regarding emerging risks and safety concerns.
- Any advertising content should comply with SFDA regulations to ensure accuracy and ethical practices, and to avoid misleading claims.

Communication Channels

- Communication Channels should be used to provide real-time updates, particularly during emergencies or when emerging risks are identified.
- All disseminated content should comply with applicable regulatory requirements and SFDA communication policies.
- In social media channels, interaction with users should be maintained through prompt responses to inquiries and concerns.
- Social media channels should be monitored for rumours, which should be promptly denied.
- Digital analytics should be applied to track the accessability and impact of risk prediction communication messages.
- Risk communication is managed through the following official channels:
  - SFDA website, including the "Consumer Corner" and "Media Center" web pages for publishing warnings, awareness materials, news, rumours and official updates.
  - Official Platforms: including the NCMDR.systemand GHAD system.
  - Official Emails for communication made by manufacturers, ARs, healthcare facilities, and other stakeholders.
  - SFDA Call Center (19999) for inquiries, complaints, and reports made by public and healthcare providers.
  - Social Media Channels – SFDA: X, Instagram, Facebook and LinkedIn.
  - Annex (2) provides an overview of SFDA Communication Channels for Medical Devices.

Crisis Communication (Emergencies)

- A dedicated emergency communication plan should be established for any crisis related to medical devices.
- Risk information should be disseminated rapidly to stakeholders, including healthcare providers and the public.
- Coordination with relevant stakeholders should be ensured to achieve a prompt and effective response.
- Continuous updates should be communicated in a routine basis to reassure stakeholders and deliver any new information.
- A post-crisis review should be conducted to evaluate the impact of the response and identify areas for improvement.

Feedback and Updates

- Risk communication practices should be regularly reviewed to strengthen communication channels and improve stakeholder outreach.
- Channels for receiving and addressing feedback from stakeholders should be established and maintained.
- The effectiveness of risk communication efforts should be continuously monitored and evaluated.
- This document should be reviewed and updated periodically to reflect regulatory changes and stakeholder inputs feedback.

Risk Communication Activities

A variety of tools are used by the SFDA to effectively carry out risk communication and surveillance activities for medical devices. These tools enable the SFDA to strengthen its communication and surveillance efforts, ensuring that manufacturers, authorized representatives, importers, warehouses, distributors, healthcare providers, users, and other stakeholders are well-informed and that medical devices are handled used safely and effectively.

Risk communication is further improved through strategic initiatives implemented by the SFDA to promote collaboration with medical device manufacturers, authorized representatives, importers, warehouses, distributors, healthcare facilities, and users.

The key risk communication activities are outlined in the sub-sections below:

Risk Assessment

This activity involves evaluating potential or confirmed risks associated with medical devices and communicating with stakeholders to collect datarelated to the nature and circumstances surrounding the operation, handling and utilization of the device.

- As part of the risk analysis process, the SFDA communicates with the manufacturer or the authorized representative mostly through official email to request and obtain relevant technical information.
- Manufacturers and Authorized Representatives shall submit the necessary technical documentation related to risks, including, but not limited to, Post-Market Surveillance Reports (PMSR), Periodic Safety Update Reports (PSUR), Clinical Evaluation Reports (CER), and the Risk Management File through GHAD Platform.
- When a potential safety signal is identified, the SFDA conducts targeted surveys among specialists, healthcare providers, relevant Saudi health societies and experts to collect informed feedback and accurately assess the signal. “Guidance on Saudi Food and Drug Authority Policy for Engagement with Healthcare Practitioners (MDS – G017)” supports structured communication across all review areas. Real-World Data (RWD) collected during the post-market phase are collected through several engagement channels that rely on surveys as a primary tool, such as the Saudi HCP Expert Network, Special Interest Working Groups, and Healthcare Officer Nominations. These mechanisms collectively support robust evaluation of safety signals.
- Depending on the nature of the identified risk, the SFDA may prepare and disseminate awareness materials in forms of News or Warnings through SFDA website (Media Center), or even launch awareness campaign to enhance understanding of risks among healthcare providers and the public.

Education and Awareness

Initiatives carried out by the SFDA to stakeholders regarding the safe use of medical devices. These activities aim to ensure that stakeholders are informed about device risks, safe handling and usage, and regulatory updates.

- The SFDA issues and disseminates materials including circulars, guidelines, workshop invitations, and other risk communication related content through SFDA website (Media Center).
- Audio-visual awareness materials (e.g., videos, voice messages, and infographics) produced and shared across the media channels, SFDA's social media platforms (e.g., LinkedIn, X, Facebook) and via official emails sent directly to healthcare facilities' Contact Officers, healthcare providers, and other relevant stakeholders.
- Healthcare professionals and expert groups will be encouraged to participate in surveys related to medical device via official emails.
- Awareness workshops are conducted for Contact Officers in healthcare facilities both remotely via platforms like Zoom and Webex and /or and on-site, with invitations published in the SFDA website and sent through emails and SFDA communication channels, to guide officers on their responsibilities.
- Conducting awareness sessions for Manufacturers and ARs on the requirements and procedures of adverse event and complaints, and their responsibilities in following up Safety Alerts with affected stakeholders, ensuring corrective actions are effectively implemented.
- Providing education and awareness materials in multiple languages to ensure that patients are informed about medical device risks and proper handling and usage.
- Providing awareness materials tailored to specific community groups, (e.g., Braille, subtitles, voiceovers or icons), to ensure inclusive access to safety information about medical devices.
- Collecting feedback from participants through forms, surveys, or other tools at the end of workshops and awareness activities to capture opinions, assess impact, and gather suggestions for improvement.
- All relevant stakeholders will be informed about any changes in handling and usage guidelines or risk mitigation strategies based on post-market surveillance findings through official emails and the SFDA's channels.

Safety Alerts Management/ Field Safety Corrective Actions (FSCAs)

This activity involves receiving, reviewing, and assessing the risk level of Field Safety Corrective Actions (FSCAs) implemented by the manufacturer to inform of potential safety issues involving a medical device, verifying their impact on Saudi Arabia, and disseminating Safety Alerts related to the affected devices to the relevant parties, to ensure risk mitigation, maintain patient safety.

Refer to the section "Safety alerts and field safety corrective action (FSCA) for medical devices" within the regulatory document "Requirements for Post-Market Surveillance of Medical Devices" (MDS–REQ11)

Adverse Events and Complaints

This activity involves receiving, handling, and investigating any adverse event or complaint reported to the SFDA through various sources by ARs, healthcare providers, or the public to determine the root cause of the issue by assessing it according to its level of risk, with the aim of preventing its recurrence, mitigating its impact, and enhancing the protection of patients, users, and the public.

Refer to the section "Reporting and investigating adverse events and complaints of medical devices" within the regulatory document "Requirements for Post-Market Surveillance of Medical Devices" (MDS – REQ11)

Safety Communication

A communication provides an important information and recommendations about safety of medical devices, issued by SFDA and addressed to public, healthcare providers and/ or health professional.

- Safety Communications are directly sent to Healthcare Providers or healthcare facilities' Contact Officers via official email: NCMDR.md@sfda.gov.sa, particularly in urgent or high-risk situations.
- In cases where the safety concern poses a risk to public health, the SFDA disseminates Safety Communications to the general public through its SFDA website (Warnings) or SFDA social media accounts.
- All Safety Communications are published and archived on the SFDA website to ensure transparency and accessibility.

Safe Use of Medical Devices within Healthcare Facilities

Safe use of medical devices within healthcare facilities refers to the responsibilities of healthcare providers indicated in "Requirements for Safe Use of Medical Devices Inside Healthcare Facilities (MDS–REQ3)" to ensure compliance with SFDA requirements, including reviewing safety alerts, reporting incidents, and preventing the circulation of unauthorized or fraudulent devices to safeguard patient safety.

- Healthcare providers shall assign a qualified Contact Officer to act as the designated liaison with the SFDA.
- Healthcare providers/Contact Officer shall regularly review safety alerts and corrective actions issued by the NCMDR or the manufacturer to ensure timely and appropriate action.
- Healthcare providers shall notify the SFDA regarding any medical devices that violate applicable laws and regulations, including unregistered, fraudulent, or unauthorized devices through the SFDA's channels.
- Healthcare providers shall report all medical device-related adverse events to the NCMDR along with all relevant documentation and information through the SFDA's channels.
- Official Emails are used as a primary channel for communication between healthcare providers/ Contact Officers and the SFDA to ensure compliance with the Safe Use of Medical Devices requirements, report violations, and respond to regulatory inquiries.
- Healthcare providers shall comply with any additional requirements requested by the SFDA to ensure the continued safety, performance, and quality of medical devices.

Corrective Actions

An action taken to resolve the causes of nonconformities detected in an establishment, manufacturer, or medical device. Within the SFDA's post-market surveillance framework, this activity involves coordinating with stakeholders to ensure that appropriate measures are implemented, documented, and monitored to restore compliance, improve device safety and performance.

Refer to the section "Safety alerts and field safety corrective action (FSCA) for medical devices" within the regulatory document "Requirements for Post-Market Surveillance of Medical Devices" (MDS – REQ11)

Annexes

Annex (1): Message Components and Format in Risk Communication

A. General:

When preparing risk communication messages, the following considerations should be taken into account to ensure clarity and effectiveness:

- Ensure the message is structured and clear, providing sufficient information to support decision-making while respecting medical ethics.
- Use plain language for non-expert audiences; avoid jargon, fractions, or complex numerical formats that may confuse readers.
- Include all relevant aspects of risk, such as side effects, complications, contraindications, and instructions for safe use.
- Adapt messages to be culturally appropriate and understandable for diverse groups of patients and healthcare providers.
- Whenever possible, present benefits and risks using absolute values rather than relative terms.
- Use multiple formats (written, visual, audio, or digital) and pretest them with target audiences to ensure understanding.
- Provide additional support resources (such as FAQs, helplines, dedicated webpages) to enhance understanding.
- Consider training materials as part of the communication process, enabling healthcare professionals to effectively counsel patients.
- Evaluate the effectiveness of communication formats regularly through participant feedback and adjust accordingly.

B. Example (1) ─ Survey Invitation (For Guidance Only)

Subject: Invitation to Participate in a Survey on the Safety and Performance of Medical Devices

Dear [Recipient / such as: Contact Officer/Healthcare Professional],

As part of our commitment to ensuring the safety, performance, and efficacy of medical devices, [The sender] is conducting a survey concerning [The medical device name] across healthcare facilities. The aim is to evaluate the safe use of these devices and to identify any potential safety signals.

Concerned Device Information:

- Manufacturer: [All / specify if applicable]
- Medical Device: [Device category/Name]
- Brand Name/Model: [All / specify if applicable]

The survey will take approximately 5 minutes to complete. To begin, please access the survey through the link below:
[Insert Survey Link Here]

All information provided will remain confidential and will only be used for regulatory and safety monitoring purposes.

We highly appreciate your participation and encourage you to share this survey with other professionals who are specialized in, or have experience with, the specified device.

For any inquiries, please contact us via [official email address].

Kind regards,
[Name/Department]

C. Example (2) ─ Safety Communication Message (For Guidance Only)

Subject: Safety Communication for [Device Name / Model / Brand]

Dear [Recipient / such as: Authorized Representative / Healthcare Provider / Public],

The [The Sender Name] is issuing this safety communication regarding the following medical device(s):

- Device Name/Model: [Insert details]
- Manufacturer: [Insert details]
- Authorized Representative: [Insert details]
- Affected Batch/Lot Number(s): [Insert details]
- Marketing Authorization Number (if applicable): [Insert details]

Reason for Communication:
[Briefly describe the safety issue such as: defect, malfunction or risk identified, then the circumstances under which it occurs]

Risk Description: [Summarize the potential impact on patients/users, including severity of the risk and possible consequences]

Corrective Actions Required:

- [Action 1, such as stop using affected batches immediately]
- [Action 2, such as Report to the NCMDR]

Next Steps:

- Healthcare providers/users are requested to [follow instructions].
- Authorized Representatives/Manufacturers are required to [submit corrective action plan].

For questions or additional information, please contact:

- SFDA Call Center: 19999
- NCMDR reporting system: [Insert link]
- Email: [Insert official email]

Sincerely,
[Name/Department]

D. Example (3) ― Multilingual Patient Safety Information Leaflet (For Guidance Only)

Subject: Important Safety Information for Patients Using [Device Name]

Dear Patient,

This leaflet provides important information to help you use [Device Name] safely and effectively. Please read it carefully and follow the instructions of your healthcare provider.

What You Need to Know:

- Potential Risks: [Description of potential side effects and adverse events]
- Signs to Watch For: [Symptoms that may indicate a problem with the device]
- What to Do:
  - Follow the instructions provided by your healthcare provider.
  - If you experience any of the symptoms listed, contact your healthcare provider immediately.
  - Do not stop using the device without consulting your healthcare provider.

We are committed to your safety and well-being. If you have any questions or concerns, please contact our patient support team at [contact information].

Thank you for your attention to this important information.

Sincerely,
[Name]
[Contact Information]

E. Example [4]: Field Visit Invitation Email (for Guidance Only)

Subject: Field Visit to [Healthcare Facility Name] for the Evaluation of Safe Use of Medical Devices

Dear [Recipient],

As part of the evaluation program for safe use of medical devices within healthcare facilities, your institution has been selected to participate in a field assessment. Below are the visit details:

- Facility: [Insert facility name]
- Assessment Team: [Insert names/roles of team members]
- Date: [Insert day and date]

Attached you will find the evaluation form. Kindly review it prior to the visit.

For reference, please ensure compliance with the requirements of *Safe Use of Medical Devices Inside Healthcare Facilities (MDS-REQ3)* [provide link or reference as appropriate].

For any questions, please contact us at [contact number/email].

We kindly request you to confirm receipt of this email.

Best regards,
[Name]

Annex (2): SFDA Communication Channels for Medical Devices

	Risk Assessment	Post Market Clinical Evaluation	Education and Awareness	Safety Alerts Management/ Field Safety Corrective Actions (FSCAs)	Adverse Events And Complaints	Safety Communication	Safe use of Medical Devices	Corrective Action
Media Center of SFDA website	Yes	Yes	Yes	Yes		Yes		Yes
Saudi Vigilance Platform.(NCMDR Platform)				Yes	Yes		Yes	Yes
GHAD Platform	Yes	Yes						
Official Email	Risk.MD@sfda.gov.sa	CIA.MD@sfda.gov.sa		NCMDR.MD@sfda.gov.sa	NCMDR.MD@sfda.gov.sa	NCMDR.MD@sfda.gov.sa	SafeUse.MD@sfda.gov.sa	NCMDR.MD@sfda.gov.sa
Call Center (19999)					Yes		Yes	
Social Media: X, Instagram, Facebook and LinkedIn.			Yes			Yes		Yes
Surveys and feedback tools	Yes	Yes	Yes				Yes	
Consultations and expert meetings	Yes	Yes				Yes		
Workshops and webinars delivered on-site or remotely through platforms such as Zoom and Webex, with invitations published in the SFDA website and sent through emails and the above channels.			Yes				Yes	Yes
On-site visits and meetings					Yes		Yes	

Annex (3): Definitions & Abbreviations

Kingdom/KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Law of Medical Devices
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; 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.
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 shall include refurbishing, assembling, packaging, and labeling.
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 Regulations.
Importer	An establishment in the supply chain that supplies a medical device to the Kingdom.
Distributor	An establishment in the supply chain that supplies the medical device to another distributor or end user.
Marketing Authorization (MDMA)	A document issued by the SFDA permitting the circulation of a medical device in the market.
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 includes 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	An 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	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)

Advertising	Any written, audible or visible or other displays intended to promote medical device or its technology, or to direct or indirect sale
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 and Date of the Previous Version	Changes Description
0.0	- New document