Implementation timetable

Context of Submission	Applied on which classes	The Requirement	Proposed effective date: for MAH that applies for the procedure on the below dates
registration	**Medical devices** • I & IIa devices with regulatory action • IIb devices • III devices **Invitro diagnostic** • (class (A) or general) and (class (B) or self-testing) IVDs with regulatory action • Class (C) or Annex II list B • Class (D) or Annex II list A	PSUR and National appendix	- Medical Devices: July/2025 - IVDs: January 2026
		Post market surveillance plan	January/2027
re-registration procedures for products that were registered before August 2022:	**Medical devices** • I & IIa devices with regulatory action • IIb devices • III devices	PSUR and National appendix	July/2025
		Post market surveillance plan	January/2027
re-registration procedures for products that were registered after August 2022:	For all classes MD/ IVDs	PSUR with its National appendix	July/2025*[1]
		Post market surveillance plan	
Variation	For all classes MD/ IVDs upon transfer letter	PSUR with its National appendix	July/2025.

[1] *the first file to fulfil these criteria is expected to have re-registration due date in 2027*

Post market (After registration)	**Medical devices:** Class I	Post-market surveillance report (PMSR)	on demand- Already implemented
Post market (After registration)	**Invitro diagnostic :** (class (A) or general) IVDs	Post-market surveillance report (PMSR)	On demand- July/2025.
Post market (After registration)	**Medical devices** • IIa devices • IIb devices • III devices	Periodic safety update report (PSUR)	Already implemented
Post market (After registration)	**Invitro diagnostic** • (class (B) or self-testing) • Class (C) or Annex II list B • Class (D) or Annex II list A	Periodic safety update report (PSUR)	January/2026.
IMDRF Adverse Event coding	For all classes MD/ IVDs	Incidents reporting using Manufacturer incident report (MIR) form	Acceptable from 01/06/2025 Obligatory starting from January/2027.
Nomination	For all MD/ IVDs Companies	Sending official nomination with supporting documentations as proof	July/2025.
SOPs for all vigilance activities	For all MD/ IVDs Companies	SOPs Documents	January/2026.

Central Administration Pharmaceutical Care
General Administration For Pharmceutical Vigilance

The Egyptian Guideline for Medical Device Vigilance System

2025

Table of content

Definitions

Abnormal Use:

Act or omission of an act by the operator or user of a medical device that is counter to or violates normal use, which is beyond any means of risk control by the manufacturer.

Authorized Representative/ Marketing Authorization Holder (MAH):

Any natural or legal person established in the community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the community instead of the manufacturer with regard to the latter's obligations by law.

Complaints:

any written, electronic, or oral communication that declares insufficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.

Correction:

Action to eliminate a detected nonconformity

Note 1: A correction can be made in advance of, in conjunction with, or after a corrective action.

Note 2: A correction can be, for example, rework or regrade.

Corrective Action:

Action to eliminate the cause of a potential or actual nonconformity or other undesirable situation

Note 1: There can be more than one cause for non-conformity.

Note 2: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Note 3: There is a distinction between correction and corrective action.

Custom-made device:

It is any device that:

− is specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications; which gives

− specific design characteristics provided under that person's responsibility; and

− is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

Distributor:

Any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end user.

Note 1: More than one distributor may be involved in the supply chain of a medical device.

Note 2: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

Economic operator:

A manufacturer, an authorized representative, an importer, a distributor or the person combining

different medical devices into one pack or sterilizing a system or procedure pack with the intent to place them on the market

Field Safety Corrective Action (FSCA):

A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a field safety notice.

Field Safety Notice (FSN):

A communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action (FSCA).

Note: An FSN can also be non-safety related, e.g., quality-related, customer product information.

Generic device group:

A set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

Harm:

Injury or damage to the health of people, or damage to property or the environment.

Immediately:

means without any delay that could not be justified.

Importer:

Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

Incident:

Any malfunction or deterioration in the safety, quality or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Note: The term adverse event (in its post-market meaning) and incident can typically be used interchangeably.

Indirect Harm:

In the majority of cases, diagnostic devices IVDs (In vitro diagnostic medical devices) and IVF/ART (In vitro fertilization & Assisted Reproduction Technology) medical devices will, due to their intended use, not directly lead to physical injury or damage to health of people. These devices are more likely to lead to indirect harm rather than to direct harm. Harm may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device or as a consequence of the treatment of cells (e.g. gametes and embryos in the case of IVF/ART devices) or organs outside of the human body that will later be transferred to a patient.

Examples of indirect harm include

- misdiagnosis
- delayed diagnosis

- delayed treatment
- inappropriate treatment
- absence of treatment
- transfusion of inappropriate materials

Indirect harm may be caused by

- imprecise results
- inadequate quality controls
- inadequate calibration
- false positive result.
- false negative result.

For self-testing devices, a medical decision may be made by the user of the device who is also the patient.

In vitro diagnostic medical device (IVD):

A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Intended purpose:

The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

Instructions for use:

The information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

Label:

The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Lot:

Defined amount of material that is uniform in its properties and has been produced in one process or series of processes

Manufacturer:

A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Market surveillance:

The activities carried out and measures taken by competent authorities (regulatory authorities) to check and ensure that devices comply with the requirements set out in harmonization legislation and do not endanger health, safety or any other aspect of public interest protection.

Medical device:

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilization of devices.

Manufacturer Incident Report (MIR):

Form used by the manufacturer/ any economic operator to report serious incident i.e., reportable event.

National Appendix:

A supplementary document required by national regulatory authorities that extracts, organizes, and summarizes information from the Periodic Safety Update Report (PSUR) concerning the safety and performance of a medical device. This appendix ensures that all relevant data complies with specific national regulations, presenting key safety information such as but not limited to: number of adverse event / incidents, literature review, any regulatory actions, and other critical details in a format that meets the local regulatory agency's expectations.

(National) regulatory authority (NRA):

A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Nonconformity:

Non-fulfilment of a requirement.

Notified body (NB):

An organization designated by an EU Member State (or other countries under specific agreements) to assess the conformity of certain products before being placed on the market.

Periodic Summary Reporting (PSR):

Periodic summary reporting is an alternative reporting regime that is agreed between the

manufacturer and the national competent authority for reporting similar incidents with the same device or device type in a consolidated way where the root cause is known or a FSCA has been implemented.

Post-market surveillance (PMS):
All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

Preventive action:
Action to eliminate the cause of a potential nonconformity or another undesirable situation.
Note 1: There can be more than one cause for nonconformity.
Note 2: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Procedure pack:
A combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

Periodic Safety Update Report (PSUR):
is a stand-alone document that allows a periodic but comprehensive assessment of the worldwide safety data of a marketed medical device. It is prepared by manufacturers of certain classes of medical devices that summarizes the results and conclusions drawn from the analysis of PMS data collected as part of the manufacturer's PMS plan.

Registry (medical device):
Organized system with a primary aim to increase the knowledge on medical devices contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g., international, national, regional and health system).

Risk:
is the combination of the probability of occurrence of harm and the severity of that harm.

Serious incident:
Any incident that directly or indirectly led, might have led or might lead to any of the following:
(a) the death of a patient, user or other person,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health such as:

- life-threatening illness or injury
- permanent impairment of a body structure or a body function
- hospitalization or prolongation of patient hospitalizations
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- chronic disease
- fetal distress, fetal death or a congenital physical or mental impairment or birth defect

(c) a serious public health threat

Serious Public Health Threat:

Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time

This would include:

- Events that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the National Competent Authority or the manufacturer.
- The possibility of multiple deaths occurring at short intervals.

System:

A combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose.

Trend Reporting (TR):

A reporting type used by the manufacturer when a significant increase in events not normally considered being incidents occurred and for which pre-defined trigger levels are used to determine the threshold for reporting.

Unanticipated:

A deterioration in state of health is considered unanticipated if the condition leading to the event was not considered in a risk analysis.

Note: documented evidence in the design file is needed that such analysis was used to reduce the risk to an acceptable level, or that this risk is well known by the intended user.

Unique Device Identifier (UDI):

A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Use Error:

Act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

Note: use error includes slips, lapses, mistakes and reasonably foreseeable misuse.

User:

The health care institution, professional, career or patient using or maintaining medical devices.

Vigilance:

One of the post-market activities undertaken by the manufacturer to protect the health and safety of patients, which relates to monitoring of adverse events, investigation of adverse events to determine root causes and the consequent corrective and preventive action.

Abbreviations

CAPA Corrective and Preventive Action

FSCA Field Safety Corrective Action

FSN Field Safety Notice

IFU Instructions for Use

IMDRF International Medical Device Regulators Forum

IVDs In Vitro Diagnostic Medical Devices

MDSU Medical Devices safety Unit

MDV Medical Device Vigilance

MIRs Manufacturer Incident Reports

NB Notified Body

NRA National Regulatory Authority

PMCF Post-Market Clinical Follow-Up

PMPF Post-Market Performance Follow-Up

PMS Post-Market Survillance

PMSR Post-Market Survillance Report

PSRs Periodic Summary Reports

PSUR Periodic safety Update Report

QMS Quality Management System

TR Trend report

UDI Unique Device Identification

UDI-DI Unique Device Identification Device Identifier

UDI-PI Unique Device Identification Production Identifier

UIRs User incident Reports

Introduction

This document pertains to the objectives and processes for vigilance system for medical devices conducted by manufacturers with the assistance of their economic operators, as well as market surveillance conducted by regulators, and the role of other stakeholders in these processes. It describes the measures taken to ensure the ongoing compliance of medical devices with the requirements for safety, quality and performance after they are placed on the market.

Vigilance system:
is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. It is a crucial tool to ensure that medical devices continue to be safe and well performing, and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the medical device.
Thus, the terms post-market surveillance, vigilance and market surveillance are closely linked.

Purpose:

- To improve the protection of health and safety of patients, users and others by reducing the repetition of the same type of adverse incident. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.
- To enable the Regulatory Authorities to monitor the effectiveness of the manufacturers' follow-up on reported incidents. The Regulatory Authority should take any further action that may be necessary to supplement the actions of the manufacturer.
- To facilitate a direct and early implementation of field safety corrective action, by allowing the data to be correlated between regulatory authorities and manufacturers.
- To enable the health-care professionals and user representatives who are responsible for the maintenance and the safety of medical devices to take the necessary steps once the corrective (or other) action is identified. Such steps should, where practicable, be taken in cooperation with the manufacturer.
- Regulatory Authorities may also monitor experience with devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification.

Egyptian Medical Device vigilance system:
The Medical device safety Unit (MDSU) has been established in the Central Administration for Pharmaceutical care, Egyptian Drug Authority to be responsible for the **collection** and **evaluation** of information on medical devices marketed in Egypt with particular reference to adverse events/ incidents. Concerning medical devices MDSU is taking all appropriate measures to:

a) Encourage the healthcare institution, professionals, or patients using or maintaining medical devices to voluntarily report all the adverse incidents to MDSU as well as the manufacturer.

b) Oblige medical devices manufacturers to systematically collect information on risks related to their products and to transmit them to MDSU.

c) Provide information to end-users through adverse incident news bulletins, alerts, and seminars.

MDSU is handling these medical device vigilance data in a way, which is compatible with Global Harmonization Task Force and the European Commission guidelines for medical devices.

Scope:

Specific and structured data collections are required of the manufacturer in one of two situations:

(1) As a condition of product approval (Pre market phase), or

(2) To re-affirm product safety when post-market adverse incident reports suggest that pre-market safety claims are inconsistent with actual use and result in unacceptable risk.

All medical devices, including IVDs, are covered by this guidance.

This guideline describes the Egyptian system for the pre-market and post market requirements and **focus on the responsibilities of**

- The manufacturer.
- The user.
- Medical Device Safety Unit (MDSU).

Stakeholders' roles and responsibilities

1. Responsibilities of the Users:

Feedback from users and patients/clients on the safety, quality and performance of medical devices is of crucial importance. Although users **have no official responsibility** for medical devices vigilance, most of the information on the experience with the actual use of medical devices will come from users. Therefore, the role of users to provide feedback on the use of medical devices is essential for manufacturers' medical devices vigilance obligations. As safe and effective medical devices are important for users, they should be encouraged to provide feedback and thereby take their role in the medical devices' vigilance process.

a) Healthcare institutions shall appoint a contact officer with the MDSU.

b) Appropriate use of medical devices

Users should ensure they fully understand the intended purpose, handling and use of the medical device, according to manufacturer's Instructions for use (IFU), to maintain its quality, safety and performance. The principles for the use of the medical device should be laid out in the manufacturer's IFU. The IFU is considered part of the medical device, as without it, the user is unable to use the medical device safely and correctly. The IFU describes how to correctly use and dispose of medical devices, as well as warnings, precautions and contra-indications. Every user must ensure proper storage of medical devices according to the manufacturer's IFU. This may include climate-control of the storage area, and to ensure that the storage areas are protected from sunlight, water, and excessive dust and dirt, as applicable.

Detect/observe:

How and what to detect:

Upon delivery, users should, for example:

- Verify if the correct product was delivered and the presentation (configuration) of the product is what was ordered.
- Verify if labelling matches the labelling for the product on the manufacturer's website, if possible .
- Ensure manufacturer's contact details are present.
- Check for any evidence of tampering of labels and/or packaging such as cracks, abrasion, erosion, breaks, seal integrity.
- Check for problems with labelling (including IFU); and/or need for training, including inadequate instructions to the user; unclear, missing, worn out, incorrect or inaccurate labels; if intended users are required to be adequately trained according to the labelling and IFU.
- Check for manufacturing, packaging or shipping problems, including defective components, defective medical devices, medical devices damaged prior to use, damage to the materials used to construct the cover or outer packaging (which can lead to compromised microbiological state, e.g., sterility of the medical device), missing listed components.
- Check for storage conditions (see label and/or IFU) and store medical device or IVD accordingly. Users may request a certificate of analysis for the lot or serial number, if applicable, and use this as a reference for the physical inspection of the product name, product code, lot number, expiry date, etc .

General Notes:

- During routine use of medical devices, users should be aware of product problems related to patient device incompatibility, manufacturing, packaging or shipping, chemical composition,

material integrity, mechanical or optical or electrical/electronic properties, calibration, output (such as false negative or false positive result for an IVD), temperature, computer software, connection, communication or transmission, infusion or flow, activation, positioning or separation, protective measures, compatibility, contamination/ decontamination, environmental compatibility, installation-related, label, IFU or training, human-device interface, and use of device. Incidents of a more serious nature, such as death or serious deterioration in health of the patient, user or other person, should always be considered part of feedback.

Registries:

- Registries are being increasingly used, especially for implantable medical devices, that can be used to collect data on clinical use and to assess use in the medical device's target population. Registries are generally maintained by health care facilities, health care authorities including regional databases, and relevant professional associations. Manufacturers might request access to certain data from a given registry at the discretion of the registry owner. Signal detection may be conducted using data collected in registries whereby associations or unexpected occurrences can be detected that might impact patient management and/or change the established benefit-risk profile of a device.

c) Providing feedback:

- User feedback can be either positive or negative. Positive feedback may include, for example, experiences and suggestions for improvement. Negative feedback can include incidents, complaints, use errors or abnormal use, etc.
- Complaints are defined as any written, electronic, or oral communication that declares insufficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.
- Users can provide feedback by reporting relevant information to the manufacturer using a user feedback form (Annex 1). No information that could allow the patient to be personally identified should be reported. Feedback should be sent to the manufacturer's address as indicated in the contact details on the labelling or otherwise to the place where the medical device was bought/purchased, where staff will ensure the feedback is communicated to the manufacturer. Users may also inform the MDSU directly by submitting User Incident Report (UIR) (Annex 2) via mail (pv.md@edaegypt.gov.eg), as applicable.
- Initial incident reports should contain as much relevant detail (e.g., equipment type, make and model) as is immediately available and reporting should not be delayed for the sake of gathering additional information.
- Reporters are encouraged to cooperate with the manufacturer and MDSU by providing further information:
  - Concerning incidents which should become available e.g., relevant outcomes of internal investigations.
  - Concerning the device or patient outcomes e.g. subsequent death.

d) Document feedback:

- Users should document any feedback related to the use of medical devices at any facility or user site including product name and product code of the affected medical device, affected lot or serial numbers (and expiry dates), affected patients/clients (age, concomitant diseases, current treatments, etc.), procedure/treatment the device was used for and any measures taken, as applicable. Users are not required to perform their own investigation unless described by their site's QMS. Moreover, they may assist the manufacturer's investigation.

- Photographs of the affected medical device and labelling and/or injuries should be taken to illustrate the feedback, if possible. Please be mindful of ethical/privacy considerations when sharing information.
- With regard to software-driven medical devices, when possible and relevant, record the log files, or avoid resetting the medical device until the manufacturer has had the opportunity to check it.

e) What to do with the medical device:

- Users should appropriately store one or more of the affected medical devices (All items, together with relevant packaging materials) as a retention sample for later inspection and testing, if possible; they should **NOT** be repaired, or discarded. With regard to software-driven medical devices, when possible and relevant, record the log files, or avoid resetting the medical device until the manufacturer has had the opportunity to check it.
- The device should be returned to the manufacturer in accordance with their instructions unless otherwise required by MDSU or other legal requirements.
- Users should contact the manufacturer to obtain information relating to the procedure for returning the suspect device. The device should be appropriately decontaminated, securely packaged, and clearly labeled, including manufacturer reference number if needed.
- Medical devices should NOT be sent to MDSU unless it has been specifically requested.

f) Follow manufacturer's instructions:

- Users will be informed of important information on the use of the medical device via a Field safety notice (FSN) and they should take the actions advised in the FSN. These actions ought to be taken in co-operation with the manufacturer where required. They may also include associated actions recommended by MDSU and/or inspection department in connection with the Field safety corrective action (FSCA), including providing any requested feedback.
- Patients/clients should be made aware of FSNs usually via targeted mailings when users are known or by press release when not (e.g., over-the-counter medical device) – in any case they should contact their health care facility.
- It is therefore important that users are encouraged to develop effective closed loop systems that ensure the dissemination of the Field Safety notices and reaches all in the organization that needs to be aware and/or take the recommended action and the timely completion of the actions outlined.

2. Responsibilities of manufacturers:

I. Pre-market requirements/Regulatory Procedure:

Premarket approval requires evaluation of the safety and effectiveness of medical devices before they allowed to be marketed. As level of risk associated with class of medical device increase, the documents required to be submitted to assess the safety of the medical device increase.

A. For registration/(re-registration procedures of medical devices that were previously registered before August 2022):

a) For class (I) and class (IIa) medical devices/ (class (A) or general) and (class (B) or self-testing) IVDs that have no recalls/ regulatory actions issued for them during the previous three-year period from the date of applying for registration/ re-registration:

Declaration 1 (Annex 3) signed, stamped and dated from the legal manufacturer shall be submitted stating that no recalls/ regulatory actions have been taken during the previous three-year period from the date of applying for registration in Egypt. This declaration shall be sent directly by the legal manufacturer to the Central Administration of Medical Devices.

b) For the following Classes:

Medical devices	Invitro diagnostic
• **I & IIa devices with regulatory action** • **IIb devices** • **III devices**	• **(class (A) or general) and (class (B) or self-testing) IVDs with regulatory action** • **Class (C) or Annex II list B** • **Class (D) or or Annex II list A**

1. The Marketing authorization holder shall submit the latest Periodic Safety update Report (PSUR)[1] prepared by the legal manufacturer (Annex 4) + ***a National appendix template fulfilled by Marketing authorization holder company (Annex 5)*** for these devices for an **interval of (three years** before date of applying for registration / re-registration of devices previously registered before August 2022). This PSUR shall be submitted to the Medical Devices Safety Unit (MDSU), based on a transfer letter issued by the Central Administration of Medical Devices.

2. Declaration 2, signed, stamped and dated by the legal manufacturer (Annex 6) shall be submitted by the marketing authorization holder to the Medical Devices Safety Unit (MDSU) as well as the Central Administration of Medical Devices.

3. The Marketing authorization holder shall submit Medical Device's post market surveillance plan[2] prepared by legal manufacturer.

* ***In case of PSUR not available, the legal manufacturer shall prepare and submit the PSUR using the template of the National appendix.***

N.B: In case the information provided in the report is insufficient to evaluate the device safety, other procedures/requirements can be requested to evaluate the product safety,

1 For further details refer to 2.II.A.3 Periodic safety update report (PSUR)
2 For further details refer to 2.II.A.1 Post-market surveillance plan

such as conducting a study, proactive surveillance, questionnaires or other measures to ensure the product safety in Egypt.

B. Re-registration procedures of any medical device registered after August 2022:

For all classes MD/ IVDs:

1. The Marketing authorization holder shall submit latest Periodic Safety update Report (PSUR) (Annex 4) prepared by the legal manufacturer + ***a National appendix template fulfilled by Marketing authorization holder company (Annex 5)*** for these devices covering the period of the registration license (5 or10 years according to registration license). This PSUR shall be submitted to the Medical Devices Safety Unit (MDSU), based on a transfer letter issued by the Central Administration of Medical Devices.

2. Declaration 1 or 2 (Annex 3,6) -according to the medical device's classification- should be signed, stamped and dated by the legal manufacturer and shall be submitted by the marketing authorization holder to MDSU as well as the Central Administration of Medical Devices.

3. The Marketing authorization holder shall submit Medical Device's post market surveillance plan prepared by legal manufacturer.

C. For medical device variation (all classes MD/ IVDs):

1. The Marketing authorization holder shall submit the latest Periodic Safety update Report (PSUR) prepared by the legal manufacturer (Annex 4) + a National appendix template fulfilled by Marketing authorization holder company (Annex 5) covering the interval of the three years before applying for variation. This PSUR shall be submitted to the Medical Devices Safety Unit (MDSU), based on a transfer letter issued by the Central Administration of Medical Devices.

2. Declaration 1 or 2 (Annex 3,6) -according to the medical device's classification- should be signed, stamped and dated by the legal manufacturer and shall be submitted by the marketing authorization holder to MDSU as well as the Central Administration of Medical Devices.

II. Post-market requirements:

This section describes manufacturers' post-market surveillance obligations and focuses on the evaluation of feedback. Other economic operators (authorized representatives, distributors, importers) may be required to act on behalf of the manufacturer. Therefore, an agreement should be in place between manufacturers and their respective economic operators to receive feedback from users and to forward this feedback to the manufacturer in a timely manner. This may include translation of feedback into the language used by the manufacturer. Economic operators may conduct investigation on feedback, at the request of and/or in agreement with manufacturer.

A. post-market surveillance System:

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate

for the type of device. That system shall be an integral part of the manufacturer's quality management system.

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:
(a) to update the benefit-risk determination and to improve the risk management
(b) to update the design and manufacturing information, the instructions for use and the labelling;
(c) to update the clinical evaluation;
(d) to update the summary of safety and clinical performance
(e) for the identification of needs for preventive, corrective or field safety corrective action;
(f) for the identification of options to improve the usability, performance and safety of the device;
(g) when relevant, to contribute to the post-market surveillance of other devices; and
(h) to detect and report trends
The technical documentation shall be updated accordingly.

4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported.

1) Post-market surveillance plan:

a) The manufacturer (and their economic operators, as applicable) shall have/ submit a post-market surveillance plan in place, which will cover a specific medical device, medical device type or family, and at minimum, should include the following 7 steps:

1. **Scope of the post-market surveillance plan:** the manufacturer shall indicate for which specific medical device, medical device type or family the plan is applicable. As for different medical devices, different approaches might be needed. This can be due not only to differences in medical devices and risks associated with them, but also to differences in time spent on the market and experiences gained.

2. **Objective of the post-market surveillance plan:** the manufacturer shall indicate what is to be achieved by the post-market surveillance for that device. At a minimum, for every post-market surveillance plan, the manufacturer shall include the following objectives:

- Has any new hazard or hazardous situation been identified for the medical device or similar medical devices or has the risk acceptability changed?
- Has any misuse of the medical device occurred?
- Are there any unforeseen side-effects for the medical device or similar medical devices?
- Is there a medical device malfunction that impacts the benefit-risk analysis?

The above-mentioned questions relate mainly to the observation of incidents that users will report to the manufacturer.

Other objectives can be addressed as part of post-market surveillance. These objectives will provide the manufacturer with more information on the performance of the medical device(s). Examples of other objectives are:

- Do users experience any usability issues?
- Are recurring malfunctions due to service/maintenance deficiencies?
- How does treatment affect the quality of life of the patient?
- Can user/patient training reduce the likelihood of malfunction?
- Are there any improvements that can be made to the medical device?
- Has state-of-the-art changed since design and development of the medical device?
- Are indications or contra-indications appropriate to ensure safety and effectiveness for the intended use of the medical device?

3. **Responsibilities:** Responsibilities and capabilities for post-market surveillance activities shall be defined by the manufacturer. The manufacturer shall ensure the availability of resources for post-market surveillance activities. Preferably, a team of people with the necessary independence and competence should be involved in post-market surveillance, covering all expertise required.

4. **Data collection**: a proactive and systematic method for data collection shall be described. The manufacturer shall choose the appropriate data sources to allow the fulfilment the objectives of the post-market surveillance plan. For example, to ensure that the medical device remains state-of the-art, actively collecting data on similar medical devices and procedures from literature, congresses and trade shows is required. The data sources selected should provide reliable data, which need to be verified. After the appropriate data sources have been selected, methods to collect the data need to be in place, including the time span for which the data need to be collected. When establishing the data collection method, it is necessary to ensure the data collected can be examined in a meaningful way.

5. **Data analysis**: effective and appropriate methods and processes for data analysis shall be described. To be able to obtain useful information from the data collected through post-market surveillance, the data need to be analyzed. Data analysis should be considered when setting up the data collection. The data analysis can vary from simple qualitative analysis to advanced statistical analysis. Qualitative analysis will often be required as an initial step for the analysis of an incident. The data obtained from the qualitative analysis of incidents can also be used for quantitative analysis. A frequently used method for quantitative analysis is trend analysis. Trend analysis can only be performed if enough data for a sufficiently long period are available.

6. **Using data analysis in risk management and other processes**: a system shall be in place to input the data obtained from post-market surveillance into other processes, such as risk management, improvement, clinical evaluation. By using the post-market surveillance data in other processes, conclusions can be drawn on the changes in risk, the need to make changes to a medical device or to obtain more clinical data.

7. **Considering and implementing required actions**: Based on the outcome of further analysis of post-market surveillance data in other processes, actions might be required to correct problems or defects related to a medical device (correction), to remove cause of nonconformity to avoid recurrence (corrective action) or to prevent occurrence of additional issues (preventive action). The manufacturer shall consider the options to remedy the unwanted situation and decide on the appropriate action and implement that action.

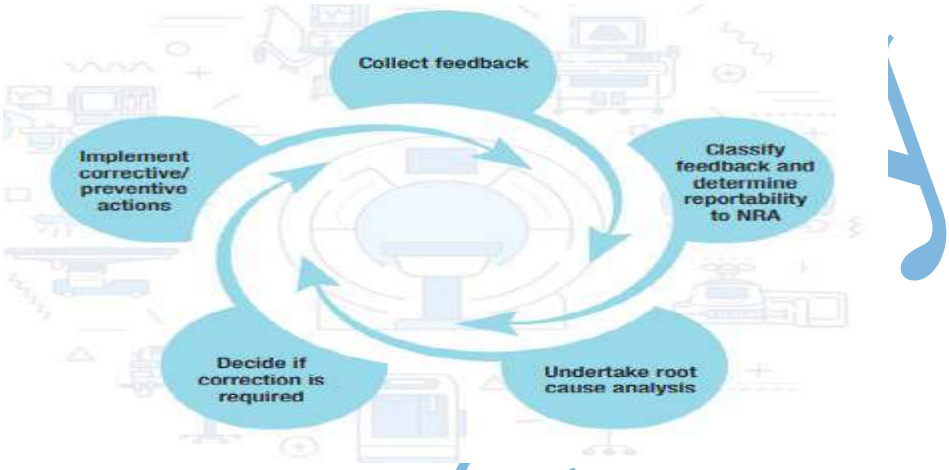

Fig. 1 for details on actions taken by manufacturers

b) As a plan will cover a specific medical device, medical device type or family, a number of plans can be required to cover the manufacturer's portfolio

c) Manufacturers shall keep an updated post-market surveillance plan which address the collection and utilization of available information, in particular:

- information concerning serious incidents, including information from PSURs, and field safety corrective actions;
- records referring to non-serious incidents and data on any undesirable side-effects;
- information from trend reporting;
- relevant specialist or technical literature, databases and/or registers;
- information, including feedbacks and complaints, provided by users, distributors and importers; and
- publicly available information about similar medical devices.

2) **Post-market surveillance report (PMSR):**

Manufacturers of class I MD/ (class (A) or general) IVDs shall prepare a post-market surveillance report summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

3) **Periodic safety update report (PSUR):**

1.Manufacturers of class IIa, class IIb and class III medical devices/ (class (B) or self-testing), (class (C) or Annex II list B) and (class (D) or Annex II list A) IVDs shall prepare/ submit a periodic safety update report (PSUR) **along with national appendix** for each device and

where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) the conclusions of the benefit-risk determination;

(b) the main findings of the PMCF; and

(c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

2. PSUR reporting should be linked to the post market surveillance plan, the risk management plan, the PMCF plan and the clinical evaluation plan as appropriate.

3. Manufacturers of class IIb and class III devices / (class (C) or Annex II list B) and (class (D) or Annex II list A) IVDs shall update/ submit the PSUR at least annually.

4. Manufacturers of class IIa devices/ (class (B) or self-testing) IVDs shall update/ submit the PSUR when necessary and at least every two years.

5. For custom-made devices, the PSUR shall be updated / submit annually or every 2 years according to their class.

6. For devices other than those referred above, manufacturers shall make PSURs available to MDSU upon request.

7. The PSUR objectives are double:

A. Identification and evaluation of changes of the benefit-risk profile:

- The main objective of a PSUR is to present a summary of the results and conclusions of the analyses of both reactive and proactive post-market surveillance data relating to a device or a device group, thus allowing the reporting of any possible changes to the benefit-risk profile of the medical device(s), considering new or emerging information in the context of cumulative information on benefits and risks.
- When concerns have been identified, this gathered information should be used to re-evaluate the benefit-risk profile and the state of the art of the medical device(s).
- When there is evidence of an adverse change to the benefit-risk profile of the medical device(s), this information should be evaluated and considered in line with the clinical evaluation and Risk Management. In the event of such circumstances, there should be clear consideration and evaluation as to whether the medical device remains safe and effective.

B. Provide Information on Preventive or Corrective Actions (CAPA)

8. The evaluation that was done by the notified body on PSUR/ PMSR shall be made available to MDSU when submission.

9. The PSUR should be presented in a clear, organized, readily searchable and unambiguous manner.

10. The PSUR should be generated as a stand-alone document that can be assessed independently from the supporting documentation. The PSUR should provide a general overview of all post-market surveillance activities and the data collected and analyzed based on the PMS plan for the device. Therefore, the aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but to summarize all results and conclusions.

11. The manufacturer should specify the relevant information and sections of the different reports and provide a summary of the data collected, their assessment and conclusion as well as the actions taken when appropriate. If a manufacturer decides that specific datasets are not used or deemed not to be required, the manufacturer should duly justify why these datasets are not included in the PSUR.
12. It is recommended to add an executive summary in particular as regards the main relevant information related to benefits and risks and to the changes in the acceptability of the benefit-risk profile.
13. To the extent possible, a similar presentation of the PSUR should be followed regardless of the device class. A recommended template for the PSUR is provided in (Annex 4) of this guidance.
14. In case of a group of devices covered by the same PSUR, the manufacturer should assign a "leading device" which drives the schedule of that PSUR. The "leading device" needs to be the highest risk class or one of the highest risk classes. The "leading device" determines the schedule applicable to the whole group of devices (data collection period covered, PSUR frequency, issuance timeline). Therefore, for the other devices, these requirements should be aligned on the "leading device", irrespective of their device class or certification date.
15. When a device grouping has been established, it could be amended for the PSUR update(s) by removing or adding devices except for the "leading device" which cannot be changed.
16. In case a PSUR includes several Basic UDI-DIs, the data should be presented in a clear, organized manner so that it is easy to determine how each device performs independently.
17. In case of a change related to the "leading device" (new device model /change of the Basic UDI DI), a new PSUR should then be issued and PSUR updates for the group of devices which includes the former "leading device" should continue in parallel independently it continues or not to be placed on the market.

4) Unique device identification:

Implementation of IMDRF's UDI systems for medical devices is intended to "facilitate unambiguous identification of the medical device through distribution and use by providing a single global identifier that can be used to link and integrate existing government, clinical, hospital, and industry databases". Unique device identification will allow manufacturers and their economic operators, as well as MDSU to more rapidly identify medical devices implicated by user feedback. The UDI may be added to manufacturer reports, and to registries.

The UDI shall contain two parts: the UDI-DI and the UDI-PI(s).

a. The UDI-DI is unique to a specific manufacturer's device and shall be globally unique at all levels.

b. If a lot number, serial number, software identification, expiration date (use by), or manufacturing date, is on the label or package, it shall be included in the UDI-PI.

The UDI device identifier (UDI-DI) and UDI production identifier (UDI-PI) allow for traceability of the medical device throughout distribution and use.

B. Incidents reporting, Investigation and Outcome guidance:

Manufacturers of devices made available on the market shall report to the MDSU any serious incident involving devices made available on the market, except expected side-effects which are

clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting.

so, Manufacturers shall have a system for recording and reporting of incidents.

1) Reporting adverse events and complaints of medical devices:

General Requirements:

1. The manufacturer shall make it possible for users and patients/clients to provide feedback as easily as possible. This means that the methods to submit feedback shall be readily available and provide as few barriers as possible to users and patients/ clients to provide the feedback. The contact details of the manufacturer / authorized representative should be included on the labelling in a way that is evident to the user and patients/clients.
2. Manufacturers, authorized representatives, importers and distributors shall report serious incidents occurred in Egypt to the MDSU about any adverse events and complaints related to their medical devices, and follow up investigation and provide MDSU with all documents and information.
3. Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to the supply and distribution of medical devices.
4. Manufacturers, authorized representatives, importers and distributors shall document and implement written work procedures to follow up incidents and adverse events of medical devices.
5. Manufacturers, authorized representatives, importers and Distributors shall appoint an authorized person to communicate with the MDSU (Safety officer).
6. Where MDSU obtains such reports on suspected serious incidents from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.
    - Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide an initial report on that serious incident to MDSU and shall take the appropriate follow-up action (Follow up/ Final Report)
    - Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting/ PSR or complaint file, it shall provide an explanatory statement. If the MDSU does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report and require it to ensure that appropriate follow-up action is taken.
7. Where an incident occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different manufacturers, each manufacturer should submit a report to MDSU.
8. It is possible that the reporter will not have enough information to decide on the reportability of an incident. In such a case, the reporter should make reasonable efforts to obtain additional information to aid in the decision. Where applicable, the reporter should consult with the medical practitioner or the health professional involved, and make all reasonable efforts to retrieve the device for evaluation.
9. If the manufacturer, upon its initial evaluation, determines that an incident is not a serious incident, it must still investigate whether it directly or indirectly might lead to/might have led to harm to user,

if the circumstances were less favorable (for instance, without the performance of an intervention by a third party or if there was exposure of more vulnerable patients to the same situation, etc.).

10. If the manufacturer cannot exclude that the incident could potentially have led to serious outcomes, the incident must be considered serious and reported to MDSU.
11. As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the report ability of an incident.

What to be reported:

1. Any incident occurred in Egypt which meets all of the three basic reporting criteria (listed below), is considered a reportable incident and must be reported to MDSU.

Note: When a manufacturer, or importer, receives a complaint about a device which meets the three basic criteria, it must be reported even if the device no longer holds a market authorization in Egypt.

The three basic reporting criteria A – C is:

A. An event has occurred:

A problem has occurred with a device. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction, or design. The events include, but are not limited to:

a) A malfunction or deterioration in the characteristics or performance: a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.
b) Unanticipated adverse reaction or unanticipated side effect.
c) Interactions with other substances or products.
d) Degradation/destruction of the device (e.g. fire).
e) Inappropriate therapy.
f) An inaccuracy in the labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.
g) For IVDs where there is a risk that an erroneous result would either (1) lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual's offspring, or (2) cause death or severe disability to the individual or fetus being tested, or to the individual's offspring, all false positive or false negative test results shall be considered as events.
For all other IVDs, false positive or false negative results falling outside the declared performance of the test shall be considered as events.

Notice:

- Reporting for IVDs may be more difficult since IVDs do not generally come into contact with patients. Therefore, it can be difficult to demonstrate direct harm to patients, unless the device itself causes deterioration in state of health. Harm to patients is more likely to be indirect (a result of action taken or not taken on the basis of an incorrect result obtained with an IVD). Whether as a result of direct or indirect harm, incidents should be reported.

- It may be difficult to determine if a serious deterioration in the state of a patient's health was or could be the consequence of an erroneous result obtained with an IVD, or if the harm was the consequence of an error by the user or third party. There should be a predisposition to report under such circumstances.
- In the case of potential errors by users or third parties, labelling and instructions for use should be carefully reviewed for any possible inadequacy. This is particularly true for devices used for self-testing where a medical decision may be made by the patient. Inadequacies in the information supplied by the manufacturer that led or could have led to harm to users, patients or third parties should be reported.
- In particular, it can be extremely difficult to judge events in which no harm was caused, but where harm could result if the event was to occur again elsewhere.

B. The device is suspected to be a contributory cause of the incident

The manufacturer must investigate whether there is a causal relationship between the serious incident and their device, or if such a relationship is reasonably possible, i.e., the device cannot reasonably be excluded as a contributory cause of the serious incident.
In assessing the link between the device and the incident the manufacturer should take account of:

- Clinical or medical plausibility.
- The opinion based on available information from healthcare professionals.
- The results of the manufacturer's own preliminary assessment of the incident.
- Known information provided in the technical documentation and evidence of previous similar serious incidents.
- Other evidence held by the manufacturer.
- Complaint trends.

This judgment may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have caused or contributed to the incident and the manufacturers should report on the side of caution.

C. Event which directly or indirectly led, or might have led, to one of the following outcomes:

1. Death of a patient, user or other person.
2. Serious deterioration in state of health of a patient, user or other person such as:
   - life-threatening illness
   - permanent impairment of a body function or permanent damage to a body structure
   - a condition necessitating medical or surgical intervention to prevent life-threatening illness or permanent impairment
     Examples: - clinically relevant increase in the duration of a surgical procedure
   - a condition that requires hospitalization or significant prolongation of existing hospitalization
   - any indirect harm (see definitions) as a consequence of an incorrect diagnostic or IVD test results when used within manufacturer´s instructions for use
   - fetal distress, fetal death or any congenital abnormality or birth defects
3. Potential for death or serious deterioration in health of a patient, user or other person:
   - Not all incidents lead to a death or to a serious deterioration in health, either owing

to fortunate circumstances or to the timely intervention of health care personnel, for example. These situations are known as **near incidents**. If the incident, in the case of recurrence, could lead to a death or to a serious deterioration in health, it must be reported to MDSU.

- This requirement also applies if the testing, examination of the device, or a deficiency noted in the information supplied with the device, or any information associated with the device, indicates some factor which could lead to an incident involving death or serious deterioration in health.

(See **annex 7** for examples of the reportable incidents)

4. A serious public health threat such as the possibility of multiple deaths occurring at short intervals or events that are of significant and unexpected nature, such that they become alarming as a potential public health hazard.

   Examples of serious public health threats linked to a device can include the following:

   - An IVD test for infectious diseases that fails to perform as intended, potentially affecting a large population group with an infectious disease. For instance, the failure of an IVD test used in a blood bank; this could lead to the widespread distribution of contaminated blood, causing potential exposure to individuals and potentially triggering an outbreak of an infectious disease.
   - High risk of disease progression due to exposure to carcinogenic, mutagenic or reprotoxic (CMR) chemicals linked to the use of a device, which affects a significant portion of the population, a specific patient population (e.g., diabetics, cardiac patients), or a vulnerable population (e.g., children, pregnant women).
   - Widespread distribution of falsified or incorrectly labelled devices, leading to multiple serious incidents (e.g. distribution of non-sterile devices labelled as sterile).
   - Cyberattack related to life supporting or life-saving devices

Note: Identifying these threats will depend on manufacturers' trending of multiple events of the same or similar nature, root causes, exposure routes etc., and may require information concerning multiple devices from multiple manufacturers.

Reporting Timeframe:

Only reports of the incidents which occur at Egypt are to be submitted to MDSU at the time of occurrence.

The period for the submitting initial report (MIR) shall take account of the severity of the serious incident as following:

Serious public health threat	Death or an unanticipated serious deterioration in a person's state of health	Any other serious incident
Immediately, not later than 2 days after the manufacturer becomes aware of that threat.	Immediately, not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.	Immediately, not later than 15 days after they become aware of the incident.

Note:

- **Serious incident also known as serious deterioration in state of health.**
- **Other incident means:** ***No death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person if the event recurs, also other incidents known as near incident.***

1. Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.
2. If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required.
3. When the MDSU contacts manufacturers, authorized representatives and healthcare providers for following up the investigation of incident, adverse event or complaint, they shall response within (5 days).
4. In addition to the above immediate reporting of incidents, all feedback should be reported to the MDSU as part of a periodic summary of post-market surveillance reports (PSUR/ PMSR).

Required information and Documents

1. The manufacturer or MAH must submit an **initial incident report** to MDSU for recording and evaluation *(for the manufacturer; reporting is mandatory)*. Initial report shall include the information mentioned in the "MIR From" (Annex 8).

**N. B:*
•The manufacturer should present the data in fulfilling MIR form utilizing the International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology when the content of the data facilitates it.
•The following IMDRF Adverse Event Terminologies, terms and codes should at least be utilized: ➢ *Annex A: Medical Device Problem* ➢ *Annex C: Cause Investigation - Investigation Findings* ➢ *Annex D: Cause Investigation - Investigation Conclusion* ➢ *Annex F: Health Effects - Health Impact* *o Level 2 terms are satisfactory to enable the grouping of cases.* *o When the Level 2 terms are not available, manufacturers can use Level 1 terms/codes.*
The following link is provided to facilitate consultation: *https://www.imdrf.org/documents/terminologies-categorized-adverse-eventreporting-aer-terms-terminology-and-codes.*

2. Each initial report must lead to a final report unless the initial and the final report are combined into one report. But not every incident report will lead to a corrective action.

Reporting and Investigation reports include:

o Initial Report (Annex 8):

- It contains the initial information about the medical device and the adverse event or complaint. It includes the information mentioned in the "MIR form" (Annex 9) and shall be submitted to the MDSU according to the aforementioned time frame.

- If the initial report is made by oral means (e.g. telephone), it should always be followed as soon as possible by a written report by the manufacturer or the authorized representative.

To whom to report:

In general, the incident reports which occurred at Egypt should be submitted (according to the previously mentioned timeframes) to the medical device safety unit (MDSU) which is part of the Egyptian Drug Authority.

How to report:

A "medical device incident reporting form" **(Annex 8)** with all the necessary data is made available on the **Egyptian Drug Authority web site** (www.Edaegypt.gov.eg) to be downloaded, filled, and then submitted to MDSU via e-mail. (Pv.md@edaegypt.gov.eg)
This reporting form can be used by the manufacturer for the purpose of initial, follow up, and final reporting.

Use Error/ Abnormal Use:

a. Use Error:

A 'use error' is when the user's action, or lack thereof, while using the device, leads to a different result or outcome than that expected by the user or intended by the manufacturer. Use errors can be caused by a user's failure to pay attention, memory lapses, mistakes during device use, or a lack of understanding or knowledge in relation to device use. Such use errors do not fall within the definition of an incident. However, use errors that are caused by the unclear/ inappropriate ergonomic features of a device e.g.: components such as measurement and monitoring features, display scales, alarms, software menus, and any other factors related to the user interface qualify as incidents (i.e. use errors caused by the design and physical configuration of the device, including the features with which the intended user interacts). When these incidents, fulfil the criteria of serious incidents, they must be reported by the manufacturer to MDSU.

All potential use error events should be evaluated by the manufacturer. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

- **Reportable use errors:**
  Use error related to medical devices, which **did result** in:
  - Death or
  - Serious deterioration in state of health or
  - Serious public health threat,
  - Use errors which did not result in death or serious deterioration in health, but which have the potential to result in death or serious deterioration in health, also need to be reported to MDSU.
- **Non- Reportable use error:**
  Use error related to medical devices, which **did not** result in death or serious deterioration in state of health or serious public health threat, need not be reported by the manufacturer to MDSU. Such events should be handled within the manufacturer's quality and risk management system. **A decision to not report must be justified and documented**.

b. Abnormal Use:

Abnormal use is the deliberate violation of the intended use of a device. It is a deliberate act

or omission of an act by the user that is counter to or violates the normal use of a device and is beyond any further reasonable means of interface-related risk control measures by the manufacturer.

An example of abnormal use may include off-label use of a device, such as a healthcare professional who, based on a medical decision, uses a device for an indication different from that specified in the manufacturer's instructions for use.

Abnormal use need not be reported by the manufacturer to the national competent authority under adverse event reporting procedures. Abnormal use should be handled by the health care facility and appropriate regulatory authorities under specific appropriate schemes.

For Examples: see (Annex 9).

Periodic summary reports (PSR) reporting: (Annex 10)

For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports (PSR) instead of individual serious incident reports, on condition that MDSU has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

When a manufacturer has received the agreement of a national competent authority of other countries to switch to periodic summary reporting, he shall inform MDSU about this agreement and of its modalities.

What to be reported periodically by PSR?

a. **Incidents described in a field safety notice:**
Incidents specified in the field safety notice that occur after the manufacturer has issued a field safety notice and conducted a field safety corrective action need **not be reported individually**. Instead, the manufacturer can agree with MDSU on the frequency and content of the periodic summary report. The periodic summary report must be sent to all affected national competent authorities.
Example:
A manufacturer issued a field safety notice and conducted a field safety corrective action of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarized in quarterly reports concerning the field safety corrective action and individual incidents did not have to be reported.

b. **Common and well-documented incidents:**
Common and well-documented incidents (identified as such in the risk analysis of the device and which have already led to incident reports assessed by the manufacturer and MDSU) may be exempted from reporting individually and changed to periodic summary reporting. However, these incidents shall be monitored and trigger levels determined. Trigger levels for interim (trend) reporting should also be agreed with the MDSU. An interim (trend) report should be made whenever trigger levels are exceeded.

If the manufacturer detects a change in the risk-benefit-ratio (e.g. An increase of frequency and/or severity) based on reports of expected and foreseeable side effects that led or might lead to death or serious deterioration of state of health, this must be considered as a deterioration in the characteristics of the performance of the device. A trend report must be submitted to MDSU.

Examples:

- A patient who is known to suffer from claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured. Potential for claustrophobia is known and documented in the device product information.
- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
- A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.
- A Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Risk assessment documents that endocarditis at this stage is clinically acceptable in view of patient benefit and the instructions for use warn of this potential side effect.

Note: If the manufacturer can't use PSR, then report these serious incidents individually, using MIR Form.

Trend reporting:

1. A trend report (Annex 11) to MDSU should be made where there is a significant increase in the rate of:
   - Already reportable incidents.
   - Incidents that are expected undesirable side effects that are usually exempt from reporting.
   - Events that are usually not reportable.

   that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks (to the health or safety of patients, users or other persons) that are unacceptable when weighed against the intended benefits.
2. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.
3. To enable this, the manufacturer should have suitable systems in place for proactive scrutiny of trends in complaints and incidents occurring with their devices.
4. The manufacturer shall specify how to manage the incidents and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan.
5. MDSU may conduct their own assessments on the trend reports and require the manufacturer to adopt appropriate measures in accordance with this regulation in order to ensure the protection of public health and patient safety.

Trending procedure and significant increase:

- Based on the diversity of the medical devices in the market it is not meaningful to define a single trending procedure valid for all devices. Depending on the type of device (e.g. IVD, implant, diagnostic and therapeutic device, surgical and dental instrument, hearing aid, compression, etc.), the devices risk classification, the number of products delivered, single or multiple use of devices, devices with traceability requirements, unavailable information on device disposals and other parameters a ***manufacturer must adopt a trending procedure which is applicable and adequate for his operations and devices***.

- Basic methods for performing trending can be found in the literature (e.g. For statistical quality control). While for many manufacturers the use of simple graphs and charts will be sufficient, the implementation of more sophisticated methods will be advisable for others. It is important that valid statistical methods are used for trend evaluation. MDSU may request the manufacturer to demonstrate that the applied method is appropriate for the particular case.

What is NOT usually required to be reported:

a. Event caused by patient conditions:

When the manufacturer has information that the root cause of the event is due to **Solely** patient condition, the event does not need to be reported.

To justify no report, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious deterioration in state of health accordingly; it is recommended that the manufacturer involves a clinician in making the decision.

Examples:

- Revision of an orthopaedic implant owing to loosening caused by the patient developing osteoporosis.
- A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
- The death of a patient that was unrelated to any implanted device or device used to treat the patient.

b. Service life or shelf-life of the medical device exceeded:

When the only cause for the event was that the device exceeded its service life or shelf-life as specified by the manufacturer.

The service life or shelf-life must be specified by the device manufacturer and included in the (technical file) and, where appropriate, the instructions for use (IFU) or labeling, respectively. Reporting assessment shall be based on the information in the technical file or in the IFU.

Examples:

- Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.
- Insufficient contact of the defibrillator pads to the patient was observed. The patient could not be defibrillated due to insufficient contact to the chest. The shelf life of the pads was labeled but exceeded.
- A patient is admitted to hospital with hypoglycemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer.

c. Protection against a fault functioned correctly:

Events which did not lead to serious deterioration in state of health or death because a design feature protected against a fault becoming a hazard do not need to be reported.

As a precondition, there must be no danger for the patient to justify not reporting.

Examples:

- An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
- Microprocessor-controlled radiant warmers malfunction and provide an audible

appropriate alarm. (e.g., in compliance with relevant standards) and there was no deterioration in state of health of the patient.

- During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.
- A laboratory analyzer stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the operator. No results were reported.

d. Handling abnormal use:

Potential abnormal use events should be evaluated by the manufacturer but needs not be reported by the manufacturer to MDSU. Abnormal use should be handled by the health care facility.

If manufacturers become aware of instances of abnormal use, they may bring this to the attention of other appropriate organizations and healthcare facility personnel.

e. Deficiency of a device found by the user prior to its use:

Deficiencies of devices that would **always** be detected by the user, and where death or serious deterioration in health has not occurred, do not need to be reported. In these situations, "always" means that even if the incidents were to recur, the user would, again, always detect the defect or malfunction prior to use.

Examples:

- Intravenous administration set tip protector has fallen off the set during distribution resulting in a nonsterile fluid pathway. The intravenous administration set was not used.
- A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.
- In an IVD testing kit a bottle labeled lyophilized is found to be fluid, this is discovered by the USER prior to use.

2) Investigating adverse events and complaints of medical devices:

1. Following the reporting of a serious incident, the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action. Timeframe(s) for follow up and/or final reports should be defined.
2. The manufacturer shall provide a final report to MDSU setting out its findings from the investigation. The report shall set out conclusions and where relevant indicate corrective actions to be taken.
3. If the manufacturer is not able to perform the investigation of an incident, then he should inform MDSU without delay.
4. MDSU may intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable.
5. If MDSU performs the investigation then the manufacturer shall be informed of the result.
6. A manufacturer may consult with the user on a particular incident before a report has been made to MDSU, or after the report had been received by the manufacturer from MDSU (in case the user sends the report to MDSU, accordingly forwarded by MDSU to the manufacture).
7. Manufacturers, authorized representatives, importers and distributors shall establish a tracking

system to record all information related to medical devices imported and distributed within Egypt and provide the MDSU with the information upon request.

a. Access to the device suspected to be involved in the incident:

1. The manufacturer may also need to have access to the device suspected to have contributed to the incident for the purpose of deciding whether the incident should be reported to MDSU. The manufacturer should in such cases make reasonable efforts to gain access to the device and may request support from MDSU to gain access to the device so that testing can be performed as soon as possible. Any delay can result in loss of evidence (e.g. Loss of short-term memory data stored in the device software; degradation of certain devices when exposed to blood) rendering future analysis of the root cause impossible.

2. If the manufacturer gains access to the device, and his initial assessment (or cleaning or decontamination process) will involve altering the device in a way which may affect subsequent analysis, then the manufacturer should inform MDSU before proceeding. MDSU may then consider whether to intervene. Due to the frequency of these requests, the following statement should be introduced in the initial vigilance report made by the manufacturer to MDSU

"The MANUFACTURER will assume destructive analysis can begin ----- days following issuance of this Initial INCIDENT Report, unless MDSD contacts the MANUFACTURER within this time frame opposing a destructive analysis of the device".

b. Investigation plan consisting of several steps. These should include:

1. Investigation:
   - Develop a plan to research the problem and cause of nonconformities, written document of problem investigation should include objectives for action, investigation strategy, assignment of responsibility and required sources.
   - The objective is a statement of the desired outcome of investigation.
   - Instruction to determine the causes of the problem, all circumstances related to the problem must be considered.
   - Responsible person needs to be assigned.
2. Analysis:
   - Perform a thorough assessment, every possible cause is identified, and appropriate data is collected.
   - List of all possible causes form the basis for collecting relevant information.
   - Results of the data collection need to be documented.
   - Primary goal: find the root cause of the problem.
   - Collected data must be organised and determines the effectiveness of the analysis.
   - Data is used to complete a root cause analysis. Finding the primary cause is essential for determining appropriate CAPA
3. Identification:
   - Clearly define the problem, should include: detailed explanation of the problem (complete and concise), documentation of the available evidence that a problem exists.
   - Identify the necessary actions.
4. Verification/Validation:
   - Corrective and preventive actions need to be verified and validated to ensure their effectiveness.
   - These actions should have no adverse effect on the finished device.
   - Actions need to be evaluated and evaluation must verify the successful completion of identified tasks.

- All results need to be verified, validated and documented.

5. Implementation:
   - If changes in methods or procedures occur, they should be implemented and recorded.
   - These corrective and preventive actions need to correct and prevent identified problems.
   - All changes must be documented.

3) Outcome of an investigation and follow-up (Action taken)

1. Outcome of Incidents investigation may be either:

a. Submission of Follow-up Report (Annex 8)

It contains additional information, investigation progress and actions taken. Manufacturer/ Authorized representative shall provide a follow-up-report to MDSU if the investigation time reaches the time line given to MDSU within the initial report with providing justification. MDSU shall assess the provided information and justification.

b. Submission of Final Report (Annex 8)

The last submitted report related to the adverse event. It contains all information, details and outcome of investigations 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 MDSU.

Examples of actions may include:

- No action;
- Additional surveillance of devices in use;
- Preventive action on future production;
- Field Safety Corrective Action (FSCA).

c. Submission of Field Safety Corrective Action (FSCA) (Annex 12)

1. If the manufacturer/ authorized representative identifies a failure of a device (that has already been placed on the market) to perform according to the characteristics specified in the IFU and this failure might lead to or might have led to death or serious deterioration in health, the manufacturer must initiate a field safety corrective action (FSCA).
2. A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.
3. The FSCA may include:
   a. The return of a medical device to the supplier.
   b. Device modification such as:
      1. Permanent or temporary changes to the labeling or instructions for use.

      For example:
      - Advice relating to a change in the way the device is used e.g. manufacturer advises revised quality control procedure such as use of third-party controls or more frequent calibration or modification of control values for the device.
      - Changes to storage conditions for sample to be used with an IVD.
      - Software upgrades including those carried out by remote access.

   c. Device exchange.
   d. Device destruction.
   e. Retrofit by purchaser of manufacturer's modification or design change.

f. Advice given by manufacturer regarding the use of the implanted devices/ IVDs
For example:
Advice given by the manufacturer may include modification to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device such as:

- For implantable devices it is often clinically unjustifiable to explants the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return, constitutes FSCA.
- For any diagnostic device (e.g. IVD, imaging equipment or devices) the recall of patients for retesting or the retest or review of previous results constitutes FSCA.

4. Manufacturers and authorized representatives shall submit a plan of implementing FSCA, including specifying the date of completing the implementation.
5. Manufacturers and authorized representatives shall provide evidence of completing the implementation of FSCA.
6. Importers and distributors shall not import or distribute any medical device that has been withdrawn or discontinued.
7. Importers, distributors and health care providers shall stop circulating the medical device if the FSCA stipulates that.
8. Removals from the market for purely commercial non-safety related reasons are not considered FSCA.
9. The manufacturer / authorized representative is required to report to MDSU any technical or medical reason leading to a systematic recall of devices of the same type by the manufacturer.
10. MDSU may take any further action it deems appropriate, consulting with the manufacturer where possible.
11. Manufacturers, authorized representatives and healthcare providers shall provide the information and reports required for the safety alert.

Investigation conclusion and Final Report Submission timeframe:

Investigation procedures shall be concluded and the final report shall be submitted to the MDSU within:

- (15 days) from the date of occurrence or awareness of adverse events that does not require testing or technical evaluation.
- (30 days) from the date of occurrence or awareness of adverse events that require testing the device inside Egypt.
- (60 days) from the date of occurrence or awareness of adverse events that require testing the device outside Egypt.

C. Notification of Field Safety Corrective action (FSCA)/Field Safety Notice (FSN) Guidance:

Manufacturers/ authorized representative shall report to the MDSU any field safety corrective action in respect of devices made available on the market, including any field safety corrective

action undertaken in a third country in relation to a device which is also legally made available on the market, if the reason for the field safety corrective action is not limited to the device made available in the third country, so Manufacturers shall have a system for recording and reporting of field safety corrective actions.

1) Notification to the MDSU:

1. The manufacturer/authorized representative should issue a notification to the competent authorities of all countries affected at the same time and the content of the field safety notice shall be consistent in all countries affected (Unless duly justified by the local situation).
2. The manufacturer /authorized representative shall, without undue delay, report the field safety corrective action in advance of the applying the field safety corrective action, except in cases of urgency, in which the manufacturer needs to undertake field safety corrective action immediately.
3. This notification should include all relevant documents necessary for MDSU to monitor the FSCA.
4. In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected should be mentioned.
5. FSCA should be notified to the customers via a field safety notice (FSN) (Annex 13). This should be done before or at the same time as FSCA is being issued.

*"Normally, the MANUFACTURER should allow a **minimum of 48 hours for receipt of comment** on the Field Safety Notification unless the nature of the FSCA dictates a shorter timescale e.g. for SERIOUS PUBLIC HEALTH THREAT."*

2) Notification to the user (field safety notice) (Annex 13)

1. A communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action.
2. Healthcare providers shall use the medical device as per the recommendations mentioned in the safety notice.
3. The manufacturer should use a distribution means ensuring the appropriate organizations have been informed, e.g. By confirmation of receipt.
4. Confirmation that MDSU have been advised of the FSCA must done.
5. Any comments and descriptions that attempt to serve to play down the level of risk in an inappropriate manner or advertise products or services, should be omitted.
6. Contact details for customers to be able to communicate in case if they need information about the FSN should be mentioned in FSN.

3) Stages of Field Safety Corrective Action (FSCA):

1. The manufacturer or authorized representative shall report MDSU about FSN within (2 days) from the issuing date of FSN letter, and attach the FSCA letter including all information required as well as distribution list where affected medical devices were distributed.
2. The manufacturer or authorized representative shall submit FSCA implementation plan. 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 FSN and cannot be implemented in the meantime.
- Specifying the expected date to complete implementation of FSCA with a justification for specifying that date.
- Specifying the time for providing the MDSU with periodic reports if FSCA implementation is expected to take more than (90 days).

3. MDSU will issue approval letter to approve content of FSN and FSCA implementation plan and permit distribution of FSN to all affected customers.
4. The manufacturer or authorized representative shall notify importers, distributors, healthcare providers and users about FSN within the timeline mentioned in MDSU approval letter.
5. 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 FSN.
   - Sign on the FSN letter directly in case the acknowledgment letter not attached
6. 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 FSN, including communicating them at least (3 times) via two different methods.
7. Communication records shall include the following:
   - Dates of communication.
   - Method of communication.
   - Data of authorized persons/healthcare contact officers.
   - Acknowledgments letters.
8. The manufacturer or authorized representative shall record and document proof for implementing any action (e.g., withdrawal, software update, updating IFU, replacement, destruction).
9. 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 MDSU through email (pv.md@edaegypt.gov.eg) with a justification and explanation of the remaining actions and their expected completion date.
10. 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 MDSU shall be notified through email (pv.md@edaegypt.gov.eg) with a justification and specifying alternative dates to submit the reports.
11. In case the Egyptian market affected by the FSN, and after confirming the implementation of FSCA for all affected medical devices in Egypt, the manufacturer or authorized representative shall submit “Confirmation Statement for Completing the Corrective Action in the Safety Alert)” to MDSU via email (pv.md@edaegypt.gov.eg).
12. The MDSU has the right to request any document that supports the implementation of FSCA, for example: FSCA periodic progress reports, medical devices destruction proof.

13. In case the Egypt market not affected by the FSN (e.g.: impacted batches/lots not marketed in Egypt, but medical device models/codes are marketed in Egypt), the manufacturer or authorized representative shall submit "Statement Confirming Egypt is Not Affected by FSN" to MDSU email.

D. Surveys and Questionnaires submission upon scientific committee recommendation:

Manufacturer/ authorized representative may be requested to submit surveys and questionnaires about safety of their medical devices / accessories from institutions where these medical devices were used recently in the Egyptian market.

N.B: In case of the information provided in the report is insufficient to evaluate the device safety, other procedures shall be taken to evaluate the product safety, such as conducting a study, proactive surveillance, questionnaires or other measures to ensure the product safety in Egypt.

III. General Requirements: Nomination and SOPs:

- It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out within the manufacturer's organization by a person who fulfils minimum conditions of qualification.

- For manufacturers who are not established in the Egypt, the authorized representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Egypt. Accordingly, the authorized representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorized representative should be defined in a written mandate. Considering the role of authorized representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

A. Appointing a safety officer with the MDSU:

1) Qualifications along with supporting documentation as proof:

- The Safety officer shall be scientifically qualified in any medical/health specialty (**National ID and Graduation Certificate**)
- The Safety officer shall be fluent in English.
- The Safety officer Shall has medical devices vigilance training certificate from well-known accredited center (**Curriculum Vitae and the Relevant certificates**)
- The Safety officer Shall provide a **signed declaration acknowledging their responsibilities**.

2) Contact Officer Tasks and Responsibilities:

- Acting as a liaison between the healthcare provider and the MDSU 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 EDA related to the medical devices that located inside the healthcare facility, and submitting information and documents related the incident, adverse event or complaint
- Follow-up and cooperating with the MDSU during incidents, adverse events and complaints investigation procedures, and provide the MDSU with all information and documents.
- 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 FSN, 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 MDSU.
- Cooperating with the MDSU in monitoring the compliance of healthcare providers.
- Responding to the MDSU surveys and questionnaires related to the medical devices.

B. Standard operating procedures (SOPs):

- Marketing authorization holder should have / submit SOPs for all vigilance activities that are required from it which are (Summary for Manufacturer / MAH responsibilities):

- The manufacturer must ensure that he establishes an effective communication system with all parties involved, the user, the distributor and MDSU.
- Submit pre-market safety report in case of Registration/ Reregistration / Variation.
- How to collect incidents occurring with their devices.
- How to handle adverse event that are reported to them.
- Notify MDSU about incidents when the reporting criteria are met.
- How to detect of trends in complaints and how to submit trend report to MDSU when the trend reporting criteria are met.
- Submit Periodic safety update reports (PSURs) after registration.
- The authorized representatives and the manufacturer should have an agreed practice outlining how the investigation or evaluation of adverse event should be conducted and how and what information should be recorded.
- Submit a periodic summary report to MDSU.
- Issue/ Notify MDSU about the field safety corrective actions of their products.
- Undertake any corrective action necessary.
- Issue a field safety notice in relation to the field safety corrective action and approve it from MDSU.
- Distribute the field safety notice to the appropriate organizations/ users.
- The manufacturer should ensure that the following parties are kept informed about these guidelines, incident reports as appropriate, so that the manufacturers' responsibilities may be fulfilled in Egypt:

- Authorized representatives in Egypt,
- Persons responsible for placing devices on the market and
- Any other agents authorized (e.g. Distributors) to act on their behalf for purposes related to medical devices vigilance.

- How to encourage and promote the involvement of the users in the incident reporting and implementation of FSCA.

3. Responsibilities of the Medical devices Safety Unit:

1. Receive incident report from manufacturer, users or other systems

- Receive initial, follow up, final incident report from manufacturer (MIR).
- A report received by the MDSU from a user, other reporting system or other source, ***shall be sent to the manufacturer without delay.*** In doing so, patient confidentiality should be maintained.
- MDSU should send an acknowledgement of receipt of the report to the sender.

2. The risk assessment of an incident or FSCA reported may include where relevant:

- Acceptability of the risk, taking into account criteria such as: causality, technical/other cause, probability of occurrence of the problem, frequency of use, detectability, probability of occurrence of harm, severity of harm, intended purpose and benefit of the product, the medical device safety principles, potential user(s), affected populations etc.
- Need for (what) corrective action.
- Adequacy of measures proposed or already undertaken by the manufacturer.

This assessment should be carried out in cooperation with the manufacturer.

3. Monitoring of manufacturers subsequent actions

MDSU in cooperation with the medical device inspection department normally monitors the investigation being carried out by the manufacturer. However, it may intervene at any time. Such intervention shall be in consultation with the manufacturer where practicable.

Aspects of the manufacturer's investigation which may be monitored include, for example:

- Course (direction the investigation is taking);
- Conduct (how the investigation is being carried out);
- Progress (how quickly the investigation is being carried out);
- Outcome (whether the results of device analysis are satisfactory).

Facts which may be needed include, for example:

- The number of devices involved;
- The length of time they have been on the market;
- Details of design changes which have been made.

Cooperation may be needed with:

- Notified bodies (involved in the attestation leading to the ce marking);
- User(s);
- Other competent authorities;
- Other independent bodies, test houses etc.

4. MDSU may also monitor experience with the use of devices of the same kind

(For instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take harmonized measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification.

5. MDSU may also monitor signals or trends:

- MDSU shall actively monitor the data available in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.
- Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, MDSU shall inform the manufacturer, or where applicable the authorized representative, which shall then take the necessary corrective actions.

6. MDSU May take subsequent actions:

MDSU May take subsequent actions as a result of a report of the manufacturer or authorized representative, which may include, for example:

- No further action;
- Gathering more information (for example by commissioning independent reports);
- Making recommendations to manufacturers (for example to improve information provided with the device);
- Consulting with the relevant notified body, or medical device registration / inspection department at EDA on matters relating to the conformity assessment;
- Consulting related EDA committees (for example if it is considered that re-classification of the device is necessary);
- Further user education;
- Further recommendations to user(s);
- Any other action to supplement manufacturer action.

7. Dissemination of information outside MDSU/ EDA (Communication)

- Careful consideration should be given to the mode of communication, the drafting (content) and the dissemination of information by the MDSU. The possible positive and negative effects of the information to be disseminated should be considered when drafting advisory notifications and when selecting the means and medium by which the message is transmitted.
- When the manufacturer has informed MDSU in advance of the start of a FSCA; this information should be held **confidential** by MDSU until the information becomes public.
- In general, preference should be given to notification communicated directly to medical practitioner or health-care facilities concerned, over communication to the public. In some cases, dissemination of information directly to the public may be needed e.g., to suggest that patients or users contact their medical practitioner for further, more specific advice.
- Where appropriate, it is recommended that the communication includes a statement indicating that medical practitioners or other health-care professionals should be consulted and that the information is intended for medical professionals only.

- MDSU should revise the press statement and the information for dissemination prepared by the manufacturer.
- Interfaces with communication media should be coordinated wherever practicable between the manufacturer and MDSU.

8. Completion of the investigation

- MDSU shall place the manufacturer's final report on file and make any other observations necessary. The files investigation may then be endorsed as "complete".
- The manufacturer's final report shall also be copied to any National Competent Authorities who were informed by MDSU of the initial report.
- The MDSU in cooperation with the inspection department should inform the manufacturer when the investigation is complete, or if no additional investigation by the manufacturer is required.
- If MDSU and/or the inspection department themselves conduct an investigation, the manufacturer (and, where appropriate, other national competent authorities) shall be informed of progress and of the results.
- Records of incident reports shall be retained to enable the investigation to be reopened if necessary, and to facilitate systems for trend analysis.

9. Encouraging reporting:

MDSU shall take appropriate measures such as organizing targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents.

Annexes

References:

1. *Regulation (EU) 2017/745:* https://eur-lex.europa.eu/eli/reg/2017/745/2024-07-09
2. *Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics:* https://iris.who.int/bitstream/handle/10665/337551/9789240015319-eng.pdf?sequence=1
3. *Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative:* https://www.imdrf.org/sites/default/files/2022-05/ghtf-sg2-fd-99-7-reporting-guidance-990629%20%281%29.pdf
4. *MDCG 2023-3 Rev. 2 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746* https://health.ec.europa.eu/document/download/af1433fd-ed64-4c53-abc7-612a7f16f976_en?filename=mdcg_2023-3_en.pdf

5. *MDS-REQ 11 Requirements for Post-Market Surveillance of Medical Devices:* *https://sfda.gov.sa/sites/default/files/2023-05/MDS_REQ%2011_V2_En.pdf*
6. *The Egyptian Guideline for Medical Device Vigilance System Year 2013:* *https://www.edaegypt.gov.eg/media/ujhhljfl/edrex-gl-cap-care-001-the-egyptian-guideline-for-medical-device-vigilance-system-2013_1.pdf*
7. *MDCG 2024-1 Guidance on the vigilance system for CE-marked Devices:* *https://health.ec.europa.eu/system/files/2024-01/mdcg_2024-1_en.pdf*
8. *Incident reporting for medical devices: Guidance document:* *https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/reports-publications/medeffect-canada/incident-reporting-medical-devices-guidance-2021/incident-reporting-medical-devices-guidance-2021-en.pdf*

Annex 1: User feedback form

Send feedback to: manufacturer and their local economic operator and as soon as you become aware.

Types of feedback:

- **Death or serious deterioration in health** of the patient/client, user or any other person *occurred.*
- **Death or serious deterioration in health** of the patient/client, user or any other person *might have occurred.*
- **Positive feedback** may include suggested improvements, positive experiences, etc

List of medical device product problems that should be considered for feedback

- Patient-device incompatibility
- Manufacturing, packaging or shipping
- Chemical
- Material integrity
- Mechanical
- Optical
- Electrical/electronic property
- Calibration
- Output, e.g. false negative or false positive result for an IVD
- Temperature
- Computer software
- Connection
- Communication or transmission
- Infusion or flow
- Activation, positioning or separation
- Protective measure
- Compatibility[PRM1]
- Contamination/decontamination
- Environmental compatibility
- Installation-related
- Label, instructions for use or training
- Human-device interface
- Use of device
- Adverse event without identified device or use

Note: this is not an exhaustive list of potential user feedback.

Contact details of the reporting user (organization/person)

Name of organization:	Street name and no.:
City and postcode:	Country:

Name of contact person (for organization):	Mobile telephone of contact person (for organization):
Position of contact person (for organization):	E-mail of contact person (for organization):
Report date:	Reporter's report identifier:

Product details

Product name/commercial name/brand name:	Product code/catalogue number(s):
Serial number(s):	Model number(s):
Lot number/batch number(s):	Expiry date(s):
Instructions for use version number:	Software version number:
Associated devices/accessories (lot numbers/expiry dates):	UDI-DI/UDI-PI:
Manufacturer name:	Authorized representative name:
Manufacturer contact details (e-mail):	Authorized representative contact details (e-mail):

Please attach a copy of the instructions for use and photographs of the device and its labelling.

Event details:

Describe the clinical/analytical procedure during which the observation was made (note: in the case of IVD, state specimen type used):

Event description (e.g. in the event of negative feedback, explain what went wrong with the medical device, and what was the health impact [death, life-threatening, indirect harm such as misdiagnosis or delayed diagnosis/treatment], and in the event of positive feedback, explain suggestions for improvement or positive experiences):	
Date of observation/event was made:	% of devices involved:
Number of devices involved:	Number of patients involved:
Operator/user at the time of the observation/event (please choose): ☐ Health care professional Patient/lay ☐ user ☐ Other (specify):	Has more than one user had the observation with the product? ☐ Yes ☐ No
Comments:	
Date of report:	Signature:

Disclaimer: The act of reporting an observation is not an admission of manufacturer, user or patient liability for the event or its consequences.

Central Administration of Pharmaceutical Care
Medical Devices Safety Department

Medical Device Incident User Report Form

I. Patient Information			
Name/Initials:	Sex: □ Male □ Female	Weight: KG	Age:

II. Medical Device Information		
Name of Medial Device:		Type of Medical Device (e.g. Pacemaker):
Manufacture Date:		Expiry Date:
Reference/Registration No.:		Code/Model No.:
Catalogue No.:	Lot/Batch No.:	Serial No.:
Manufacturer Name: Address: Phone:		Supplier Name: Address: Phone:
Quantity Defective (Number):		Current Location:
Has the manufacturer/supplier been contacted? □ Yes □ No (Keep the device till be requested by the supplier - Please Do Not Discard the device or related consumables & packaging - Do not send medical devices to MDSD/EDA unless you have been specifically requested to do so)		

III. Incident Information	
Incident Description/Nature of Device Defect (includes any action by patient, carer or healthcare professional, or by the manufacturer or supplier):	
Action Taken:	
Type of Injury: □ Death □ Serious □ Non-serious □ None	Date of Incident:

Central Administration of Pharmaceutical Care
Medical Devices Safety Department

Medical Device Incident User Report Form

IV. Reporter Information (Will Be Kept Confidential)	
Reporter's Name:	Position/Occupation:
Organization:	Address:
Phone/Mobile No.:	Email:
V. Other Comments:	

Head Quarter:
Medical Device Safety Department (MDSD)
Pharmaceutical Vigilance Administration
The Egyptian Drug Authority (EDA)

Address: 21 Abdel Aziz Al Soud Manial Al Roda, PO Box: 11451, Cairo, Egypt
Tel: +202 – 23684288 +202 - 23640368 **Ext.:** 1476
Fax: +202 - 23684194

Website: www.edaegypt.gov.eg
E-mail: pv.followup@edaegypt.gov.eg

Alexandria Regional Center:
Address: San Stefano Family Health Center, 2 El kazino St., El Awkaf building, San Stefano, Alexandria
Tel/Fax: +2 03 - 5845004
E-mail: pv.alex@edaegypt.gov.eg

Cairo Regional Center:
E-mail: pv.cairo@edaegypt.gov.eg

Sohag Regional Center:
Address: Health Affairs Directorate, the old building, 2nd floor next to the Security Directorate, Nasir City, Sohag
Email: pv.sohag@edaegypt.gov.eg

Annex (3) Declaration (1)

For MDs Class I and IIa/
Class A/B IVDs

Dear Head of Medical Devices Safety Unit,

For the following medical device applied for registration/re-registration of marketing authorization in the Arab Republic of Egypt:

- **Medical Device / IVDs Acceptance Number:**
- **Medical Device / IVDs Name:**
- **Medical Device / IVDs Models/Codes/Sizes:**

- (Company) undertakes that the medical device/ IVD applied for registration/re-registration, which will be marketed in the Arab Republic of Egypt, has not received any regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) in respect of (Models/Codes/Sizes, Lots/Batches, or Serials), in an interval of (3) three years before the date of application for registration or re-registration.

- (Company) undertakes that in case of any regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) raised after the application for registration/reregistration and before granting the marketing authorization of the medical device, those regulatory actions concerning the safety of the medical device/ IVDs in respect of (Models/Codes No., Lot/Batch No., or Serial No.) will be informed to the "Medical Devices safety Unit" by (Agent) - the company's agent in the Arab Republic of Egypt.

- (Company) undertakes that since granting the marketing authorization of the medical device/ IVD and during the marketing stage, (Company) will be obliged to communicate any incidents (MIRs), Periodic Summary Reports (PSRs), or regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) and (Company) will be obliged to follow post-market Regulation and (Company) will submit the Post market Survillance report upon request to the "Medical Device Safety Unit (MDSU)" by (Agent) - the company's agent in the Arab Republic of Egypt, this is according to the Egyptian Guidelines for Medical Device Vigilance System.

- (Company) undertakes that there is a vigilance system in place, oversights the vigilance system of the (Agent) - the company's agent in the Arab Republic of Egypt, and makes sure that (Agent) meets all vigilance requirements (in reference to the Egyptian Guideline for Medical Device Vigilance System), and communicates them with the "Medical Device Safety Unit (MDSU)".

Signature:

Title:

Date

ANNEX 4: Template for the PSUR

The PSUR should be generated as a stand-alone document that can be assessed independently from the supporting documentation. The PSUR should provide a general overview of all post-market surveillance activities and the data collected and analysed based on the PMS plan for the device. Therefore, the aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but it should summarize all results and conclusions.

The manufacturer should specify the relevant information and sections of the different reports and provide a summary of the data collected, their assessment and conclusion as well as any actions taken when appropriate. If a manufacturer decides that specific data sets are not used or deemed to be not required, the manufacturer should duly justify the absence of the data sets not included in the relevant sections of the PSUR.

It is recommended to add an executive summary in particular as regards the main relevant information related to benefits and risks and to the changes in the acceptability of the benefit-risk profile.

PSUR cover page

The PSUR cover page includes the relevant data to allow distinguishing between the various PSUR updates.

The cover page should at least include the following information:

- Manufacturer information
- Medical device(s) covered by the PSUR
- Notified body name and organization number;
- PSUR reference number assigned by the manufacturer;
- Version number of the PSUR;
- The data collection period covered by the PSUR;
- Table of contents.

Executive summary

It should include the following information:

- A brief description and status of actions taken by the manufacturer based on the previous PSUR;
- A brief description and status of actions taken by the Notified Body as part of the review of the previous PSUR;
- In case the data collection period is changed by the manufacturer, a justification should be provided, and a statement should be provided whether the change affects the comparability of the results gained;
- Once the conclusions of the PSUR have been completed, the main results of the current PSUR should include ***a clear and bold statement declaring whether the benefit-risk profile has been impacted, negatively or positively or remains unchanged,*** based on the information reported within the current PSUR. The statement could be a simple expression, for example “Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the device(s) has not been (or has been) adversely impacted / remains unchanged”.

Description of the devices covered by the PSUR and their intended uses:

This section is intended to provide an overview of the devices covered by the PSUR and the possible changes to its scope. The added and removed devices should be clearly identified. The following information should be included for the devices covered by the PSUR:

- Device Classification (risk class of device) in accordance with the applicable classification rules.
- Date from one of the following: first declaration of conformity, first EC / EU Certificate issued, first date device CE-marked, first placed on the market, first put into service, if software, date first made available.
- Status of the device(s): on the market, no longer placed on the market, recalled, field safety corrective action initiated.
- The intended purpose of the device(s) as per the Instructions for Use, any indications, contra-indications, and target populations.

The information shall be broken down by the Basic UDI-DI(s) (device group/ family of devices) and explain any device changes within each Basic UDI-DI compared to the previous PSUR to comprehend possible changes in results compared to the previous PSURs.

Provide the device trade name(s) associated to the corresponding Basic UDI- DI(s) and the European Medical Device Nomenclature (EMDN).

Grouping of the Devices

- The manufacturer should justify the grouping of the devices in one PSUR.
- The justification could be based on the benefits to report multiple devices in one PSUR or alternatively the disadvantages to report each device in separate PSURs.
- In case the group of devices is changed, a justification for the change should be provided. The manufacturer should also provide the PSUR reference number of the PSUR where the data of the removed device(s) are reported.
- The manufacturer should define the “leading device” according to which the PSUR schedule is determined.
- The PSUR reference number is attached to the “leading device” and should remain unchanged for the PSUR updates, provided the “leading device” within the grouped devices has remained the same.

Volume of Sales:

- The manufacturer should consider all the devices placed on the market. This could be volumes of sales, units shipped, or units implanted or another suitable indicator. Whichever method is used should be consistent throughout the PSUR in all areas to allow for a comparison of data. Provide accurate information the number of devices sold. The data should be presented by year to year.
- Provide further information on the volume of sales in respect to the various sizes, models and configurations of the device as deemed necessary.

- Indicate to what criteria the number of devices on the market is provided:
    - Devices placed on the market or put into service;
    - Units distributed within each time period;
    - Number of episodes of use (for reusable devices);
    - Active installed base;
    - Units distributed from the date of declaration of conformity or EC/EU mark approval to the end date of each time period;
    - Number of devices implanted;
    - Other – description/rational should be provided.

Size and other characteristics of the population using the device:

- Evaluate how many patients have been exposed to the device and the characteristics of the exposed patient group(s).
- Estimate the number of patients exposed, as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency). There are different scenarios as: Active devices may have a lifetime of several years with multiple uses each day, resulting in high number of patients exposed to the device (e.g. CTs). In case of implants, multiple devices may be used in one patient, e.g. several bone screws in one surgery. For other devices, the sales numbers directly correlate with the patient number exposed to the device.
- Describe the usage of the device in different patient populations and when available compare it to the expected usage and identify the possible over-represented or under-represented patient groups if clinically relevant and known by the manufacturer.
- When possible, consideration should be given to patient demographic aspects.
- When applicable, evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.

Post-Market Surveillance : Vigilance and CAPA information

Background information should be gathered prior to the current PSUR and may include, for example, the achieved safety and performance of the device, information related to intended benefits achieved or not and description of new risks or emerging trends reported in earlier PSURs.

Vigilance data consist of information concerning serious incidents, field safety corrective actions (FSCAs) and trend reports. The data could be presented in tables, figures and/or in text format. The aim of the data presentation is to provide an accurate summary and appraisal of the Vigilance data for the reported data collection period and to compare with the same types of data from the previous PSURs.
The data should be presented by the device (Basic UDI-DI), device group (CMD) or device group/family level (legacy devices). When justified, the data can be presented for combinations of devices, for example, a device and its accessory.

a) Information concerning Serious Incidents

- The aim is to present the serious incidents and their impact on the overall device safety. This section should characterize the data from at least three different perspectives: the

device problems, the root cause and the health effects on the person(s) affected. In addition to the data, provide a summary text regarding any new types of serious incidents which have occurred since the last report.

- Data regarding serious incidents should be reported using the IMDRF Adverse Event Terminology (AET), when available. With regard to the historical data, the usage of the IMDRF Adverse Event Terminology is not required.
    - The usages of the Level 2 terms/codes are considered sufficient to enable the grouping of the serious incidents;
    - Report both the codes and the terms.
- When applicable report both absolute figures and rate of the serious incidents and split the data by region European Economic Area(EEA), Egypt and worldwide.
- Examples of the data presentation are shared in Annex II of this guidance.
    - The most frequent medical device problems by IMDRF Adverse Event Terminology Annex A – "Medical Device Problem", by year to year- (see Annex II, Table 4).
    - The most common investigation findings as part of the completed "cause investigation" of the serious incidents by IMDRF Adverse Event Terminology Annex C – "Investigation Findings", (see Annex II, Table 5).
    - The health impacts on the person affected as a consequence of the medical device serious incident by IMDRF Adverse Event Terminology Annex F – "Health Impact", including the term and code. It could also be used for the 4- year summary data (starting as of the device MDR certification date or the MDR date of application for legacy devices) and split the data by the IMDRF Adverse Event Terminology Annex D – "Investigation Conclusion" (including term and code). Use only the most relevant investigation conclusion terms/codes which are related to the detected health impacts. Report the most common health impacts as well as any cases resulting into death, regardless if they are included in the most common health impacts. In addition, split the data by region (see Annex II, Table 6).

b) Information from Trend Reporting (non-serious incidents and expected undesirable side effects)

c) Information from Field Safety Corrective Actions (FSCA):

- Provide a summary of the FSCAs for the period of the PSUR and compare with the information from the previous PSURs.
- The summary should include the following information:
    - types of actions.
    - issuing date,
    - scope of the FSCA,
    - status of the FSCA at the time of the PSUR,
    - manufacturer's reference number,
    - a brief description of the reason for action and description of action and impacted regions.

An example of the data presentation is presented in Annex II of this guidance (table 7).

d) Preventive and / or Corrective Actions (CAPA):

- Provide a list of all preventive and / or corrective actions (CAPA)

- The following information should be provided for each CAPA:
    - the type of action,
    - initiation date,
    - scope of the CAPA,
    - status of the action,
    - manufacturer's reference number,
    - CAPA description,
    - the root cause (internal codes with the explanation, IMDRF terms/codes or free text),
    - effectiveness of the CAPA

An example of the data presentation is presented in Annex II of this guidance (table 8).

Post-Market Surveillance: information including general Post-Market Clinical Follow- up (PMCF) information

The data that should be reported in this section consist of other PMS datasets not referred to above and are generated by general methods and procedures of PMCF. The sections below should be completed in alignment with the PMS and PMCF plans.

A list of collected data from other sources of clinical data in the post-market phase should be provided. Safety and performance data generated from these activities should be used also for comparison to other similar devices with the same intended purpose.

a) Feedbacks and complaints from users, distributors and importers

- All feedback from users, distributors and importers and complaints not reported in the Vigilance section above should be considered in this section. The most common complaints should be presented within this section of the PSUR with the following considerations:
    - Grouping of complaints by IMDRF Adverse Event Terminology Annex A – "Medical Device Problem" (including the term and code) or internal event codes including term;
    - Occurrence rate (including reference chosen);
    - Justification for inclusion of these groups of complaints and exclusion of those not presented;
    - Information whether the presented complaints have led to initiation of preventive and / or corrective actions (CAPA).

b) Scientific Literature Review of relevant specialist or technical literature

- For detailed information about literature searches conducted and results generated, the manufacturer may refer to the technical documentation.

c) Public Databases and /or Registry Data

- Provide a list of all registries reviewed including the following information: the name or registry reference, type of registry (Prospective or Retrospective data collection);
- Provide a list of findings in comparison to the devices with same intended use and justify any identified differences. Provide information about any new risks identified from this data set.

d) Publicly Available Information about Similar Medical Devices

- Additional publicly available information may include information gathered from

other manufacturers of similar medical devices, (e.g. results of a manufacturer's specific PMCF study made publicly available in the manufacturer's Summary of Safety and Clinical Performance (SSCP), Cochrane Library or other libraries);

- The type and location of this information should be provided, and when possible a comparison of the devices with same intended purpose should be evaluated with any possible differences in safety and performance reported.

e) Other Data Sources

- The other used data sources could be for example real-world data from electronic health records and digital health-monitoring devices;
- Provide a list of the used data sources and findings with specific reference to safety and performance of the device.

Specific Post-Market Clinical Follow-up (PMCF) Information

This section should include a summary of the findings generated from the analysis of specific PMCF activities performed by the manufacturer. This section is not limited to PMCF studies and should include other specific PMCF activities conducted by the manufacturer.

For this section, the manufacturer should refer to the main findings of the PMCF and, when available, to the conclusions documented in the PMCF Evaluation Report to allow for a comprehensive assessment of the specific PMCF activities it has performed.

Summary of Findings and Conclusions of the PSUR

In this section of the PSUR, the manufacturer should consider the validity of the collected data taking into consideration any deficiencies or bias, and provide a conclusion on the benefits and risks of the device from the gathered data. In the case when these data have had any impact on the overall benefit-risk determination, this should be described. The manufacturer should also outline all actions that have been taken as a result of the analysis of data collected since the last PSUR.

a) Validity of the collected data

- The manufacturer should identify any limitations to the data that have been collected, this could include for example reduced sales or usage of the device, known bias from feedback obtained or enrolment into a PMCF study.
- The manufacturer should consider whether these limitations impact the ability to formulate meaningful conclusions and whether an impact assessment of the overall benefit-risk profile is still possible.

b) Overall conclusions from the analysis of the collected data

- The manufacturer should outline any new or emerging risks identified or when common occurrences of poor performance or claimed benefits have not been achieved within the current reporting period. When there are new or emerging risks that have been identified, the manufacturer should consider any specific patient groups, device models, accessories used, geographical regions impacted, duration of risk etc. Specific information should be provided on the seriousness and the full potential clinical impact of these risks.
- The manufacturer may also describe any new benefits that have been identified from the reporting period.
- The manufacturer should formulate evidence-based conclusions to determine

whether the benefit-risk profile of the device has changed or not.

- Finally, within the conclusion, the manufacturer should declare whether there has been an adverse impact on the benefit-risk profile of the device or the benefit-risk profile remains unchanged.

c)Actions taken by the manufacturer

- The manufacturer should describe any specific actions that have been taken to address any newly identified or emerging risks and occurrences of poor performance.
- The manufacturer should identify all actions initiated during the data collection period as described in Article 83 (3).

Templates for the Presentation of Data in the PSUR

These tables are intended to provide guidance to manufacturer and are only examples. It is up to the manufacturer to present the data in the most appropriate manner depending on the nature of the data and of the device. Please read this Annex II in conjunction with Annex I when forming tables.

Table 1. Volume of sales* by region over time

Basic UDI-DI/ Legacy device name or model					
	Total Number of devices	Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EEA					
Egypt					
Worldwide					

* Indicate according to which criteria the number of devices on the market is provided

Table 2. Estimated size of the population using the device* over time

	Estimated size of population using the device Reporting Day+ preceding 12 months (N)	Estimated size of population using the device N – 12 months (N2)	Estimated size of population using the device N2-12 months (N3)	Estimated size of population using the device N3-12 months (N4)
EEA				
Egypt				
Worldwide				

* When clinically relevant and known by the manufacturer

Table 3. Characteristics of the population using the device* over time

	Characteristic X of population using the device Reporting Day+ preceding 12 months (N)	*Characteristic X* of population using the device N – 12 months (N2)	*Characteristic X* of population using the device N2-12 months (N3)	*Characteristic X* of population using the device N3-12 months (N4)

EEA				
Egypt				
Worldwide				

* Characteristics of the population using the device is defined by the manufacture based on the usage of device

Table 4. Total number (N) and rate (%)*of the serious incidents by IMDRF Adverse Event Terminology (AET) Annex A – Medical Device Problem by time and region over time

Basic UDI-DI/Legacy Device name or model									
IMDRF Adverse Event - Medical Device Problem code (Annex A) and term by region		Reporting Day+ preceding 12 months (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
		N	%	N	%	N	%	N	%
EEA									
Egypt									
Worldwide									
EEA									
Egypt									
Worldwide									

*The denominator is compatible to the number of devices in table 1 or based on manufacturer's reasoning e.g. reusable instruments

Table 5. Total number (N) and rate (%)* and of the serious incidents by IMDRF AET Annex C - Cause Investigation-Investigation Findings by time and region over time

Basic UDI-DI/Legacy Device name or model									
IMDRF Adverse Event - Investigation Findings (Annex C) code and term by region		Reporting Day+ preceding 12 months (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
		N	%	N	%	N	%	N	%
EEA									
Egypt									
Worldwide									
EEA									
Egypt									
Worldwide									

* The denominator is compatible to the number of devices in table 1

Table 6. IMDRF AET Annex F - Health Effects-Health Impact code of the serious incidents by IMDRF Adverse Event Terminology Annex D - Investigation Conclusion in last 4-years

BASIC UDI-DI/Legacy Device name or model						
IMDRF Adverse Event Health Impact (Annex F) code and term by region		Number of serious incidents	Investigation conclusion code+ term $_1$ %	Investigation conclusion code+ term$_2$ %	Investigation conclusion code + term$_3$ %	Investigation conclusion code + term$_4$ %
EEA						
Egypt						
Worldwide						
EEA						
Egypt						
Worldwide						

Table 7. FSCA initiated in current reporting period and open FSCAs *

Type of action	Issuing date	Scope of the FSCA	Status of the FSCA**	Manufacturer Reference number	Rationale and description of action taken	Impacted regions

* Will be further developed when the new FSCA form is in use

**follow-up, final at the time the data collection time ended

Table 8. CAPA initiated in current reporting period and open CAPA

BASIC UDI-DI/Legacy Device name or model							
Type of action	Initiation Date	Scope of the CAPA	Status of the CAPA	Manufacturer Reference number	CAPA description	Root cause*	Effectiveness of the CAPA if closed**

*Internal codes with the explanation, IMDRF codes or free text.

**If CAPA is still open then this is not applicable, if CAPA is closed comment on whether it is resolved, not resolved or comment if additional CAPA has been opened.

Annex 5 National Appendix

Legal Manufacturer fulfillment section	
Name of Reference countries where the Medical device is registered	
Total Number of Countries where the Medical device is Marketed	
Quantity sold in Egypt Egypt (If it was previously marketed in Egypt)	
1st Approval date globally	DD/MM/YY
1st CE	DD/MM/YY
Attach declaration of previous points from legal manufacturer	
PSUR content	
Cover page	
Devices in the PSUR	
PSUR Reference number	
Name of legal manufacturer	
Version number	
First MDR registration number	
Reporting period	
Annually or Every 2 year	
Executive summary	
status of action Taken by the manufacturer	
status of action Taken by the notified body	
Justification for change of data collection period	
Statement for benefit-risk profile impacted	
Description of the devices, **Description and status of actions based on previous PSUR**	

Annex 5 National Appendix

<table>
<tr><td>First date of DOC/ CE/ placed on market/ put on service/ date for first software made available</td><td></td></tr>
<tr><td>Status of MD</td><td></td></tr>
<tr><td>Classification</td><td></td></tr>
<tr><td>Basic UDI</td><td></td></tr>
<tr><td>There is device change in any Basic UDI-DI?</td><td></td></tr>
<tr><td>All trade names of each Basic UDI DI if available</td><td></td></tr>
<tr><td>EMDN (European Medical Device Nomenclature)</td><td></td></tr>
<tr><td>Contraindication</td><td></td></tr>
<tr><td>Indication of use</td><td></td></tr>
<tr><td>Targeted population</td><td></td></tr>
<tr><td>Grouping of the devices</td><td></td></tr>
<tr><td>Grouping justification</td><td></td></tr>
<tr><td>Leading device</td><td></td></tr>
<tr><td>PRESENTATION OF THE DATA AND THEIR EVALUATION</td><td></td></tr>
<tr><td>Volume of sales Worldwide for each Model</td><td>
<table>
<tr><td colspan="6">Basic UDI-DI/ Legacy device name or model</td></tr>
<tr><td></td><td>Total Number of devices</td><td>Current PSUR Period</td><td>Previous PSUR PERIOD (1)</td><td>Previous PSUR PERIOD (2)</td><td>Previous PSUR PERIOD (3)</td></tr>
<tr><td>EEA</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Egypt</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Worldwide</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>Size and Characteristics of the Population Using the Device(s)</td><td></td></tr>
<tr><td>Post-Market Surveillance (PMS): Vigilance and CAPA Information</td><td></td></tr>
<tr><td>Incidents for each Basic UDI not family</td><td>If present attached as ANNEX 1(1,2,3)</td></tr>
</table>

Annex 5 National Appendix

Trending report (Non serious and expected Incidents)	If present attach
Preventive and/or Corrective Actions	If present attached as ANNEX 2
Field Safety Corrective Actions (FSCAs)	If present attached as ANNEX 3
PMS DATA INCLUDING GENERAL PMCF ACTIVITIES	
Feedback and Complaints from the Market	If present attached as annex 1.1
Literature Review	
Public Registry	
Publicly Available Information About Similar Medical Devices	
Other Data Sources	
Specific PMCF Information	
Main Finding of PMCF	
SUMMARY AND CONCLUSIONS OF THE PSUR	
Validity of the Collected Data	
RISKS	
Benefits	
Update to Benefit-Risk Profile	
Actions Taken	
Additional requests	
First date of Egypt License /Registration number	If found: DD/MM/YY attached Egypt License
First Market date in Egypt	DD/MM/YY
Attach Distribution list containing contact details (If it was marketed in Egypt last year)	

Name:

signature with date:

Manufacture Stamp:

Annex 5 National Appendix

Incidents (Annex 1) 1									
Basic UDI-DI/Legacy Device name or model									
IMDRF Adverse Event - Medical Device Problem code (Annex A/C) and term by region		Reporting Day+ preceding 12 months (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
		N	%	N	%	N	%	N	%
EEA									
Egypt									
Worldwide									
EEA									
Egypt									
Worldwide									

Incidents (Annex 1) 2									
Basic UDI-DI/Legacy Device name or model									
IMDRF Adverse Event - Medical Device Problem code (Annex C) and term by region		Reporting Day+ preceding 12 months (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
		N	%	N	%	N	%	N	%
EEA									
Egypt									
Worldwide									
EEA									
Egypt									
Worldwide									

Incidents (Annex 1) 3						
BASIC UDI-DI/Legacy Device name or model						
IMDRF Adverse Event Health Impact (Annex F) code and term by region		Number of serious incidents	Investigation conclusion code+ term $_1$ %	Investigation conclusion code+ term$_2$ %	Investigation conclusion code + term$_3$ %	Investigation conclusion code + term$_4$ %
EEA						
Egypt						
Worldwide						
EEA						
Egypt						

Annex 5 National Appendix

Worldwide						

CAPA ANNEX 2							
	Type of action	Initiation date	Scope of CAPA	STATUS OF CAPA	CAPA description	Root cause	CAPA effectiveness (if closed)
World wide							
Egypt (period)							

Field Safety Corrective Actions (FSCAs) ANNEX 3							
	Type of action	Issuing date	FSCA	FSCA STATUS	Action taken	Affected country	reference FSN number
World wide							
Egypt (period)							

[COMPANY NAME]

(Date)

MANUFACTURER'S COMMITMENT ABOUT SAFETY OF MEDICAL DEVICES

Annex (6) Declaration (2)

Class IIb, III, AND (I, IIa with Regulatory Actions)
Class C, D IVDs

Dear Head of Medical Devices Safety Unit,

For the following medical device applied for registration/re-registration of marketing authorization in the Arab Republic of Egypt:

- **Medical Device/ IVD Acceptance Number:**
- **Medical Device/ IVD Name:**
- **Medical Device/ IVD Models/Codes/Sizes:**

- (Company) undertakes that in case of any regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) raised after the application for registration/reregistration and before granting the marketing authorization of the medical device/ IVD, those regulatory actions concerning the safety of the medical device in respect of (Models/Codes No., Lot/Batch No., or Serial No.) will be informed to the "Medical Device Safety Unit (MDSU)" by (Agent) - the company's agent in the Arab Republic of Egypt.

- (Company) undertakes that since granting the marketing authorization of the medical device / IVD and during the marketing stage, (Company) will be obliged to communicate any incidents (MIRs), Periodic Summary Reports (PSRs), or regulatory actions (Including but not limited to recalls, FSNs, or FSCAs) and also (Company) will be obliged to follow post-market Regulation and (Company) will submit the Periodic Safety report every year (for MD of class IIb, III) or every 2 years (for MD of Class IIa)to the "Medical Device Safety Unit (MDSU)" by (Agent) - the company's agent in the Arab Republic of Egypt, this is according to the Egyptian Guidelines for Medical Device Vigilance System.

- (Company) undertakes that there is a vigilance system in place, oversights the vigilance system of the (Agent) - the company's agent in the Arab Republic of Egypt, and makes sure that (Agent) meets all vigilance requirements (in reference to the Egyptian Guideline for Medical Device Vigilance System), and communicates them with the "Medical Device Safety Unit (MDSU)".

Signature:
Title:
Date

ANNEX 7

Examples of incidents and field safety corrective actions which the manufacturer should report

The following examples are for illustrative purposes only, and are for the guidance of the MANUFACTURER in determining whether a report should be made to MDSD. The examples are intended to show that there is a **considerable judgmental element** in the decision on whether to report.

Examples of the reportable incidents:

1. During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient was not revived.

   Note: If patient was revived, this would be considered a near incident and would also be reportable.

2. A patient receives a burn during the use (in accordance with the MANUFACTURER's instructions) of surgical diathermy. If the burn is significant, this should be reported as such a serious deterioration in state of health is not normally expected.

3. An infusion pump stops, due to a malfunction of the pump, but fails to give an appropriate alarm; there is no patient injury. This should be reported as in a different situation it could have caused a serious deterioration in state of health.

4. An infusion pump delivers the wrong dose because of an incompatibility between the pump and the infusion set used. If the combination of pump and set used was in accordance with the instructions for use for either pump or set, then the INCIDENT should be reported.

5. An aortic balloon catheter leaked because of inappropriate handling of the device in use, causing a situation which was potentially dangerous to the patient. It is believed that the inappropriate handling was due to inadequacies in the labeling.

6. A catheter fractured during insertion, with no suggestion of inappropriate handling. The fracture occurred in such a position that the broken part could easily be withdrawn. However, this was clearly a fortunate circumstance as if the catheter had fractured in a slightly different position then surgical intervention would have been necessary to retrieve the broken end.

7. Glass particles are found in a contact lens vial.

8. Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification. This INCIDENT should be reported.

9. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to MANUFACTURER’s instructions. This INCIDENT should be reported.

10. The premature revision of an orthopedic implant is required due to loosening. Although no cause is yet determined, this INCIDENT should be reported.

11. MANUFACTURER provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.
12. A batch of out-of-specification blood glucose test strips is released by MANUFACTURER. A patient uses the strips according to the MANUFACTURER's instructions, but the readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization. This INCIDENT should be reported.
13. A customer reports a wrong assignment of analytical results to patient codes by an automated analyzer. An evaluation could reproduce the effect and indicated that under specific conditions a data mismatch could occur. Due to the data mismatch a patient suffered from wrong treatment. This INCIDENT should be reported.
14. During maintenance of a self-testing analyzer for patients it was detected that a screw which places the heating unit of the analyzer in exact position had come loose. Due to this fact, it may happen that the heating unit leaves it's position and the measurement is performed under non exact temperature, which would lead to wrong results. As this could lead to wrong treatment of the patient this should be reported.
15. It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. No one was injured in the surgical theatre at that time but a report is necessary (near incident). The system was installed, maintained, and used according to manufacturer's instructions.
16. Sterile, single-use device packaging was labelled with the caution, "Do not use if package is opened or damaged". By incorrect design, the label is placed on the inner packaging. Device was subsequently stored only in the inner packaging, which did not offer a sufficient sterile barrier. Outer package was removed, but device was not used
17. Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs. Burns of adjacent organs due to thin uterine walls were an unanticipated side effect of ablation. Manufacturer does not change the label of the ablation device, and fails to warn users of this side effect which may be produced when the device is working within specification.
18. Health professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.
19. Testing of retained samples identified inadequate manufacturing process, which led to detachment of tip electrode of a pacemaker lead, which did, or could, result in the death or serious deterioration in health of an individual.
20. A user reported that there were insufficient details in the instructions for use regarding cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of variant Creuzfeld-Jacob Disease (vCJD).

Annex 8

Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1

European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Corresponding competent authority

a	Name of receiving national competent authority (NCA)
b	EUDAMED number of NCA
c	Reference number assigned by NCA for this incident
d	Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a	Date of submission (e.g. 2012-10-23)	b	Date of incident (e.g. 2012-10-23) to	c	Manufacturer awareness date (e.g. 2012-10-23)

d Type of report

- ◯ Initial
- ◯ Follow up
- ◯ Combined initial and final
- ◯ Final (Reportable incident)
- ◯ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report (e.g. 2012-10-23)

f Classification of incident

- ◯ Serious public health threat
- ◯ Death
- ◯ Unanticipated serious deterioration in state of health
- ◯ All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a ◯ Manufacturer ◯ Authorised representative ◯ Other, please specify

b Manufacturer's reference number for this incident

c	If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted - NCA's local reference number - EUDAMED's reference number - Manufacturer's reference number		
d	If this incident is covered under an FSCA, please provide the relevant numbers: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - Manufacturer's FSCA reference number		
e	Periodic Summary Report (PSR) ID		
f	If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation		
1.3.2	**Manufacturer information**		
a	Manufacturer organisation name		
b	Single registration number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		
h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code
1.3.3	**Authorised representative information**		
a	Authorised representative organisation name		
b	Single Registration Number		
c	Contact's first name	d	Contact's last name
e	Email	f	Phone
g	Country		

h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code
1.3.4	**Submitter's details if not also manufacturer or authorised representative**		
a	Registered commercial name of company		
b	Contact's first name	c	Contact's last name
d	Email	e	Phone
f	Country		
g	Street	h	Street number
i	Address complement	j	PO Box
k	City name	l	Postal code

Section 2: Medical device information

2.1 Unique Device Identification (UDI)

a	UDI device identifier/Eudamed ID: Unknown	b	UDI production identifier: Unknown
c	Basic UDI-DI/Eudamed-DI: Unknown	d	Unit of use UDI-DI:

2.2 Categorisation of device

a Medical device terminology

◯ EMDN ◯ GMDN ◯ UMDNS(ECRI) ◯ GIVD/EDMS ◯ Other, please specify

b Medical device nomenclature code

2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name)

b Nomenclature text/Description of the device and its intended use

c	Model	d	Catalogue/reference number
e	Serial number	f	Lot/batch number
g	Software version	h	Firmware version
i	Device manufacturing date (e.g. 2012-10-23)	j	Device expiry date (e.g. 2012-10-23)
k	Date when device was implanted (e.g. 2012-10-23) to	l	Date when device was explanted (e.g. 2012-10-23) to

m If precise implant/explant dates are unknown, provide the duration of implantation

Number of years | Number of months | Number of days

n	Implant facility	o	Explant facility

p

	Notified body (NB) ID number(s) (if applicable)	Notified body (NB) certificate number(s) of device (if applicable)
1		
2		

q Please indicate the date of one of the following:

◯ First declaration of conformity
◯ The device first CE marked
◯ First placed on the market
◯ First put into service
◯ If software, date first made available

Year | Month

2.4 Risk class of device when placed on market

a

◯ This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD

b

MDD/AIMDD

◯ active implant
◯ class III
◯ class IIb
◯ class IIa
◯ class I
◯ class Is
◯ class Im
◯ class Ism
◯ custom-made

IVDD

◯ IVD Annex II List A
◯ IVD Annex II List B
◯ IVD devices for self-testing
◯ IVD general

c

MDR

◯ class III
◯ class IIb
◯ class IIa
◯ class I

Type (Multiple choice)

☐ implantable
☐ active device
☐ intended to administer and/or remove a medicinal product
☐ sterile conditions
☐ measuring function
☐ reusable surgical instruments
☐ software
☐ systems
☐ procedure packs
☐ custom-made
☐ non-medical purpose

IVDR

◯ class D
◯ class C
◯ class B
◯ class A

Type (Multiple choice)

☐ self-testing
☐ near-patient testing
☐ professional testing
☐ companion diagnostic
☐ reagent
☐ software
☐ instrument
☐ sterile conditions

2.5 Market distribution of device (region/country)

(according to the best knowledge of the manufacturer)

a

☐ All EEA, Switzerland and Turkey

☐ AT ☐ BE ☐ BG ☐ CH CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI FR ☐ GB
☐ GR ☐ HR ☐ HU ☐ IE IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO
☐ PL ☐ PT ☐ RO ☐ SE SI ☐ SK ☐ TR

Others:

2.6 Use of accessories, associated devices or other devices

a Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

b Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on)

Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

3.1 Nature of incident

a Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization – initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

3.2 Medical device problem information

a IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Medical device problem codes'	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Number of patients involved

c What is the current location of the device?

- ◯ Healthcare facility/carer
- ◯ Distributor
- ◯ Patient/user
- ◯ Discarded
- ◯ In transit to manufacturer
- ◯ Remains implanted
- ◯ Manufacturer
- ◯ Unknown
- ◯ Other:

d Operator of device at the time of the incident

- ◯ Healthcare professional
- ◯ Patient/lay user
- ◯ Other, please describe

e Usage of device (as intended)

- ◯ Initial use
- ◯ Reuse of a single use medical device
- ◯ Reuse of a reusable medical device
- ◯ Re-serviced/refurbished/fully refurbished
- ◯ Problem noted prior use
- ◯ Other:

f Remedial actions taken by healthcare facility, patient or user subsequent to the incident

3.3 Patient information

a IMDRF 'Health Effect' terms and codes (Annex E, F)
Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E)	Code	Code	Code	Code	Code	Code
IMDRF 'Health impact' codes (Annex F)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b Age of patient at the time of the incident
years ☐ months ☐ days ☐

c Gender ◯ Female ◯ Male ◯ Unknown ◯ Not applicable

d Body weight (kg)

e List any of the patient's prior health condition or medication that may be relevant to this incident

3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a Role of initial reporter
◯ Healthcare professional ◯ Patient ◯ Lay user ◯ Other, please specify

b Name of healthcare facility where incident occurred

c Healthcare facility report number (if applicable)

d Contact's first name

e Contact's last name

f Email

g Phone

h Country

i Street

j Street number

k Address complement

l PO Box

m City name

n Postal code

Section 4: Manufacturer analysis

4.1 Manufacturer's preliminary comments

a For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation

b Initial actions (corrective and/or preventive) implemented by the manufacturer

c What further investigations do you intend in view of reaching final conclusions?

4.2 Cause investigation and conclusion

a **For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible root causes/causative factors and conclusion

b **For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable

c Is root cause confirmed?

◯ Yes ◯ No

d Has the risk assessment been reviewed?

◯ Yes ◯ No If 'No', rationale for no review required:

If the risk assessment has been reviewed, is it still adequate?

◯ Yes ◯ No

Results of the assessment:

e IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

Coding with IMDRF terms is a mandatory requirement.	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6	Choice 7	Choice 8
IMDRF Cause investigation: Type of investigation (Annex B)	Code	Code	Code	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation findings (Annex C)	Code	Code	Code	Code	Code	Code

IMDRF Cause investigation: Investigation conclusion (Annex D)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

	Choice 1 *(most relevant)*	Choice 2	Choice 3	Choice 4	Choice 5	Choice 6
IMDRF 'Component' codes (Annex G)	Code	Code	Code	Code	Code	Code

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

(For a FSCA, fill in the FSCA form)

h Time schedule for the implementation of the identified actions

i Final comments from the manufacturer on cause investigation and conclusion

4.3 Similar incidents (for Final (Reportable incident))

4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a

Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes
Tick-mark which code or combination of codes were used for identifying similar incidents.

	Choice 1
IMDRF code relating to most relevant 'Medical device problem' (Annex A)	☐
IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation')	☐

☐ Other – enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a

If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

	Choice 1	
Code/term for most relevant medical device problem	Code	
	Term	
Code/term for most relevant root cause evaluation	Code	
	Term	

☐ Other – enter description of what similar incidents are based on and the rationale why the above codes were not used

4.3.3 Number of similar incidents and devices on the market

a

Indicate on which basis similar incidents were identified regarding the device or device variant:

◯ Model ◯ Software ◯ Lot/Batch ◯ Product platform ◯ Other variant

Details of the selection made above

b

Indicate to what criteria the number of devices on the market (also known as denominator data) is based on (tick the most appropriate):

◯ Devices placed on the market or put into service
◯ Units distributed within each time period
◯ Number of tests performed
◯ Number of episodes of use (for reusable devices)
◯ Active installed base
◯ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
◯ Number of devices implanted
◯ Other -describe

c	Enter the number of similar incidents and devices on the market for the indicated time periods You must use yearly time periods unless: A: a different time period has been specified by the European vigilance Working Group B: the device has not been on the European market for more than three years

	Time period (N) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start date								
End date								
	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market	Number of similar incidents	Number of devices on market
Country of incident								
EEA + CH + TR								
World								

d	Comments on how similar incidents and associated number of devices on the market were determined

Section 5: General comments

Coded summary of report (will be auto populated from previous selections)

Medical device name

Basic UDI-DI	Unknown
UDI device identifier	Unknown
UDI production identifier	Unknown

IMDRF adverse event reporting terms and codes

IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

IMDRF clinical signs, symptoms, conditions codes								
IMDRF health impact codes								
IMDRF Medical device problem codes								
IMDRF Component codes								
IMDRF Cause investigation: Type of investigation								
IMDRF Cause investigation: Investigation findings.								
IMDRF Cause investigation: Investigation conclusion.								

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form | Save as PDF

Date

Signature/Digital Signature

Send as XML file — Submit XML by Email

Send as PDF file — Submit PDF by Email

ANNEX 9

EXAMPLES OF USE ERROR AND ABNORMAL USE

1. Potential use errors:

Complaint reports received of events occurring despite proper instructions and proper design according to manufacturer's analysis. Examples include the following:

- Operator presses the wrong button.
- Operator misinterprets the icon and selects the wrong function.
- Operator enters incorrect sequence and fails to initiate infusion.
- Operator fails to detect a dangerous increase in heart rate because the alarm limit is set too high and operator is over-reliant on alarm system.
- Operator cracks catheter connector when tightening.
- A centrifugal pump is made from material that is known to be incompatible with alcohol according to the labeling, marking, and product warnings provided with the pump. Some pumps are found to have cracked due to inadvertent cleaning with alcohol.
- Unintentional use of pipette out of calibration range.
- Analyzer placed in direct sunlight causing higher reaction temperature than specified.
- MRI system and suite have large orange warning labels concerning bringing metal near the magnet. Technician brings an oxygen tank into presence of magnet and it moves swiftly across the room into the magnet.

2. Potential abnormal uses:

Complaint reports received of events occurring despite proper instructions, and proper design and proper training according to manufacturer's analysis determined to be beyond any reasonable means of the manufacturer's risk control. Examples include the following:

- Use of a directly medical device in installation prior to completing all initial performance checks as specified by the manufacturer.
- Failure to conduct device checks prior to each use as defined by the manufacturer.
- Continued use of a medical device beyond the manufacturer defined planned maintenance interval as a result of operator's or user's failure to arrange for maintenance.
- Contrary to the instructions for use, the device was not sterilized prior to implantation.
- Pacemaker showed no output after use of electro cautery device on the patient despite appropriate warnings.
- Product analysis showed that the device was working in accordance to specifications, further investigation revealed that the operator was inadequately trained due to failure to obtain proper training.

- During placement of a pacemaker lead, an inexperienced physician or other nonqualified individual perforates the heart.
- The labeling for a centrifugal pump clearly indicates that it is intended for use in bypass operations of less than 6 hours in duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bled to death.
- Safety interlock on a medical laser removed by operator or user.
- Filter removed and intentionally not replaced resulting in particulate contamination and subsequent device failure.
- Tanks delivered to a health care facility are supposed to contain oxygen but have nitrogen in them with nitrogen fittings. The maintenance person at the health care facility is instructed to make them fit the oxygen receptacles. Nitrogen is delivered by mistake resulting in several serious injuries.
- Use of an automated analyzer regardless of the warnings on the screen that calibration is to be verified.
- Pacemaker patient placed into MRI system with the knowledge of the physician.
- Ventilator alarm is disabled, preventing detection of risk condition.
- Patient's relative intentionally altered infusion pump to deliver a lethal overdose of the infusing drug to the patient.
- Home care worker uses bed rails and mattress to suffocate patient.

Annex 10
Manufacturer's Periodic Summary Report (PSR)

1. Administration Information
To which NCA(s) is this report being sent?
Date of this report
Reference number assigned by the manufacturer
Reference number assigned by NCA
Type of report ☐ Initial report ☐ Follow up report Follow up Number s ☐ Final report

2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :

3. Manufacturer information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

4. Authorised Representative information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5. Submitter's information (if different from section 3 or 4)

Submitter's name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

6. Medical Device Information

Class ☐ AIMD Active Implants ☐ MDD Class III ☐ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I	☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General
Nomenclature system (preferable GMDN)	Nomenclature code
Nomenclature text	
Notified Body (NB) ID – Number	

Model number(s) or Family Name	Catalogue number(s)

7. PSR Information

PSR Type:	
☐ Incidents described in a Field Safety Notice If Incidents described in a Field Safety Notice, Manufacturers reference number for FSN/FSCA	☐ Common and well documented incidents

Stage of PSR reporting based on:

☐ Observed Failure mode ☐ Root cause

Nature of problem agreed for PSR reporting

Summary period agreed:

☐ Every month ☐ Every 2 months ☐ Every 3 months ☐ Every 6 months ☐ Every 12 months

The figures in the table below relate to:	☐ EEA + CH+ TR	☐ All PSR recipients NCA's identified in Section 1	☐ Single Member State Please name:-

Date of PSR	**New incidents this period**	**Total number incidents via PSR**	**Total number resolved**	**Total number in progress**

8. Manufacturer's comments / investigation results

Investigation update for this period

Initial corrective actions / preventive actions implemented by the manufacturer

Recommended actions for this period, if any

Expected date of next PSR report

9. Distribution

The medical device has been distributed to the following Countries

Within EEA, Switzerland and Turkey:

☐ AT ☐ BE ☐ BG ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES
☐ FI ☐ FR ☐ GB ☐ GR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT
☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE ☐ SI
☐ SK ☐ TR

Candidate Countries:
☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

10. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

……

Name City date

ANNEX 11
Report Form Manufacturer's Trend Report

1. Administration Information	
Recipient (Name of National Competent Authority NCA)	
Address of National Competent Authority	
Date of this report	
Reference number assigned by the manufacturer	
Reference number assigned by NCA	
Type of report ☐ Trend Initial ☐ Trend Follow up ☐ Trend Final	
Do these incidents / trend represent a serious public health threat? ☐ Yes ☐ No	
Identify to what other NCAs this report was **also** sent	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☐ Authorised Representative within EEA, Switzerland and Turkey ☐ Others: (identify the role) :	
3. Manufacturer information	
Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country
4. Authorised Representative information	

Name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

5. Submitter's information (if different from section 3 or 4)

Submitter's name	
Contact name	
Address	
Postcode	City
Phone	Fax
E-mail	Country

6. Medical Device Information

Class

☐ AIMD Active Implants
☐ MDD Class III
☐ MDD Class IIb
☐ MDD Class IIa
☐ MDD Class I
☐ IVD Annex II List A
☐ IVD Annex II List B
☐ IVD Devices for self-testing
☐ IVD General

Nomenclature system (preferable GMDN)	Nomenclature code
Nomenclature text	
Commercial name/ brand name / make	
Model number(s) or Family name	Catalogue number(s)
Serial number range (if applicable)	Lot/batch number range(if applicable)
Software version number (if applicable)	
Accessories / associated devices (if applicable)	

Notified Body (NB) ID – Number
7. Information on Trend Report
Date the trend was identified
Description narrative for identified trend
Time period of trend analysis
Established trigger level
Have any of the trended events been submitted individually as reportable events under vigilance? ☐ Yes ☐ No
If yes, please list how many and to which Competent Authority
8. Manufacturer's preliminary comments
Manufacturer's preliminary analysis into causes of trend
Initial corrective actions / preventive actions implemented by the manufacturer
Expected date of next report
9. Results of manufacturer's final investigation into trend
The manufacturer's trend analysis results
Remedial action / corrective action / preventive action / Field Safety Corrective Action
Time scheduled for the implementation of the identified actions
Final comments from the manufacturer
Further investigation
10. The medical device has been distributed to the following Countries
Within EEA, Switzerland and Turkey: ☐ AT ☐ BE ☐ BG ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GB ☐ GR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK ☐ TR Candidate Countries: ☐ HR ☐ All EEA, Candidate Countries, Switzerland and Turkey Others:
11. Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.
I affirm that the information given above is correct to the best of my knowledge.

……..

Name City date

ANNEX 13

Company letter header

Urgent Field Safety Notice *(if appropriate)*

Commercial name of the affected product,

Field Safety Corrective Action (FSCA)-identifier *(e.g. date)*

Type of action:

Date:

Attention: ///////////////

Details on affected devices:

Specific details to enable the affected product to be easily identified e.g.

- type of device:
- model name and number:
- batch/ serial numbers of affected devices:
- *Insert or attach list of individual devices*

(Possible reference to a manufacturer web site.)

Description of the problem:

A factual statement explaining the reasons for the FSCA, including:

- *description of the device deficiency or malfunction,*
- *clarification of the potential hazard associated with the continued use of the device*
- *the associated risk to the patient, user or other person.*
- *Any possible risk to patients associated with previous use of affected devices.*

Advise on action to be taken by the user:

Include, as appropriate:

- *identifying and quarantining the device,*
- *method of recovery, disposal or modification of device*
- *recommended patient follow up, e.g implants, IVD*
- *timelines.*
- *Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products).*

Company letter footer

Company letter header

Transmission of this Field Safety Notice: *(if appropriate)*

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. *(If appropriate)*

Please transfer this notice to other organizations on which this action has an impact. *(If appropriate)*

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. *(If appropriate)*

Contact reference person:

Name,

Organization,

Address,

Contact details.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

(Closing paragraph)

Signature

******Note: the fields in italic font in this form is to be replaced by the actual information***