



# **MEDICAL DEVICE GUIDANCE**

MEDICAL DEVICE MANDATORY ADVERSE EVENT  
REPORTING

## **PREFACE**

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The medical device regulatory Authority of ASEAN member states accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

## **CONTACT INFORMATION**

For further information, please contact:

ASEAN AMDC Heads of Delegation

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## **1. INTRODUCTION**

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Member State market meet the ASEAN Agreement on Medical Device Directive (AMDD) and its regulations requirements by investigating reports of adverse events involving medical devices and, where appropriate, ensuring corrective and preventive actions are taken to reduce the risk of hazard and repetition.

## **2. BACKGROUND**

This guidance document is made pursuant ASEAN Agreement on Medical Device Directive (AMDD), pertaining to Annex 5 of AMDD: Post Market Alert System (PMAS) requirements.

Mandatory adverse event reporting is part of a post-marketing risk assessment measure to ensure the continued safe use of medical devices and is an important part of the post-market surveillance system. The objective of this reporting system and subsequent evaluations is to improve protection of the health and safety of patients, users and others by disseminating information that may reduce the likelihood of, or preventive repetition of adverse events, or alleviate consequences of such repetition.

## **3. SCOPE**

This guidance document provides requirements for mandatory adverse event reporting of any adverse event related to a medical device. This guidance document applies to dealers of medical devices as defined in the AMDD.

Adverse events and corrections for products which are subject to clinical investigation are not in the scope of this document.

## 4. TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions in AMDD, the regulations under it and the following terms and definitions apply.

**4.1. COMPLAINT:** Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed in the market.

**4.2. ADVERSE EVENT:** Adverse event means either a malfunction or a deterioration in the characteristics or performance of a supplied medical device or use error or inadequacy in its labelling, which either has caused or could have caused or contributed to death, or injury to health of patients or other persons.

**4.3. FIELD SAFETY CORRECTIVE ACTION (FSCA):** means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include:

- a) the return of a medical device to the product owner or its representative;
- b) device modification;
- c) device exchange;
- d) device destruction;
- e) advice given by product owner regarding the use of the device.

**4.4. FIELD SAFETY NOTICE (FSN):** A communication sent out by a product owner or its representative to the medical device users in relation to an FSCA.

**4.5. CORRECTIVE ACTION:** Action to eliminate the cause of a detected nonconformity or other undesirable situation to prevent reoccurrence.

**4.6. DEALER :** any person, which could include the product owner, physical manufacturer, authorised representative or authorised distributor in a Member State, who has either manufactured , imported , placed on the market or put into service a medical device in that Member State.

**4.7. DEVICE/DRUG COMBINATION PRODUCT:** A medical device incorporating a medicinal product or substance where the action of the medicinal product or substance is ancillary to that of the device.

**4.8. HARM:** Physical injury or damage to the health of people, or damage to property or the environment.

**4.9. INDIRECT HARM:** In the majority of cases, there are medical devices which, due to their intended use, will 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.

Indirect harm may be caused by

- imprecise results
- inadequate quality controls
- inadequate calibration
- false positive or
- false negative results.
- for self-testing devices, a medical decision may be made by the User of the device who is also the patient.

**4.10. INTENDED PURPOSE:** The use for which the device is intended according to the data supplied by the product owner on the labelling, in the instructions and/or in promotional materials.

**4.11. PRODUCT OWNER (as defined in AMDD):** in relation to a medical device, means any person who:

- (i) supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- (ii) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

**4.12. TREND REPORTING:** A reporting type used by the product owner when a significant increase in adverse events not normally considered to be reportable adverse events for which pre-defined trigger levels are used to determine the threshold for reporting.

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

**4.14. USE ERROR:** A use error refers to a situation in which the outcome of device use was different than intended, but not due to malfunction of the device. The error may have been due to a poorly designed device, or it may have been used in a situation that promoted incorrect usage.

**4.15. USER:** The health care institution, healthcare institution personnel, professional, carer or patient using or maintaining medical devices

## **5. GENERAL REQUIREMENT**

All dealers shall be required to report adverse events involving medical devices, which they have placed in the market.

Dealers are required to establish and maintain the following, for medical devices it deals with, related to mandatory adverse event reporting.

In assessing the type of adverse event, the user involved or healthcare professional should be consulted wherever practicable. All dealers who place medical devices in the market should be vigilant for any changes in trends or frequency of occurrences of adverse events with regards to medical devices they deal in.

The act of reporting an adverse event to the Regulatory Authority is not to be construed as an admission of liability for the adverse event and its consequences. Written reports may carry a disclaimer to this effect.

When placing in the market of a particular model of medical device ceases, the dealers' post market surveillance and vigilance obligations remain. However, a dealer's legal trading arrangements may change with any business activities such as mergers and acquisitions, etc. Where the vigilance and other post market surveillance obligations are being transferred to another legal entity, it is important that post market surveillance and vigilance activities continue and that the Regulatory Authority are informed of the arrangements and provided with new contact details, so that any detrimental effects on the functioning of the vigilance system are minimized.

## **5.1 ADVERSE EVENT REPORTING CRITERIA**

**5.1.1** As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reportability of an adverse event. Any adverse event, which meets the three basic reporting criteria listed below, is considered as reportable. The criteria are that:-

- a) an adverse event has occurred;
- b) the medical device is associated with the adverse event; and
- c) the adverse event led to one of the following outcomes;
  - i) a serious threat to public health;
  - ii) death of a patient, user or other person;
  - iii) serious deterioration in state of health, user or other person; or
  - iv) no death or serious injury occurred but the adverse event might lead to death or serious injury of a patient, user or other person if the adverse event recurs.

**5.1.2** An adverse event or other occurrence relating to a medical device represents a serious threat to public health if one or more of the following occur:

- a) The adverse event or other occurrence is a hazard arising from a systematic failure of the medical device that becomes known to the dealers related to the medical device;
- b) The adverse event or other occurrence may lead to the death of, or a serious injury to, a patient, a user of the medical device or any other person;
- c) The probable rate of occurrence of or degree of severity of harm caused by the hazard was not previously known or anticipated by the product owner of the medical device;
- d) It becomes necessary for the dealer of the medical device to take prompt action (including the recall of the medical device) to eliminate or reduce the risk of the hazard.

**5.1.3** A serious deterioration in state of health can include:



- a) life-threatening illness or injury;
- b) permanent impairment of a body function or permanent damage to a body structure;
- c) a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

**5.1.4** In assessing the link between the device and the adverse event the dealer should take account of:

- a) the opinion, based on available evidence, of healthcare professionals; the results of the dealer's own preliminary assessment of the adverse event: evidence of previous, similar adverse event; other evidence held by the dealer.
- b) This judgement 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 adverse event.

**5.1.5** Not all adverse events that shall be reported involve a death or serious deterioration in health that actually occurred. The non-occurrence of an adverse effect might have been due to other fortunate circumstances or to the timely intervention of health-care personnel. In such cases, it is sufficient that either:

- a) an adverse event is associated with a medical device happened, and in such that, if it occurred again, it might lead to death or serious deterioration in health; or
- b) testing, examination of the medical device, information supplied with the medical device, or any scientific literature indicated some factor (e.g. a deterioration in characteristics or performance, or a shortcoming in the information) which could lead to an adverse event involving death or serious deterioration in health.

### 5.1.6 Adverse event involving in vitro diagnostic devices

Most IVD medical devices do not come into contact with patients and so it is not easy to establish direct harm to patients, unless the IVD medical device itself causes deterioration in the state of health in a patient. However, an adverse event involving an IVD medical device could result in indirect harm as a result of an action taken or not taken on the basis of an incorrect reading obtained with an IVD medical device.

There should always be a predisposition to report even though it may not be easy to establish that a serious deterioration in the state of a patient's health was the result of an erroneous test result obtained with an IVD medical device, or if the harm was the result of an error by the user or third party.

Information supplied by the product owner when inadequate, can lead users, patients or third parties to harm and should be reported. For self-testing IVD medical devices, where a medical decision may be made directly by the user who is the patient, insufficient information on the product presentation could lead to an incorrect use of the IVD medical device or a misdiagnosis. Hence, adverse events involving IVD medical devices will most likely result from a consequence of a medical decision or action taken, or not taken, on the basis of result(s) provided by the IVD medical device.

Examples of these types of adverse events include (non-exhaustive list):

- misdiagnosis;
- delayed diagnosis;
- delayed treatment;
- inappropriate treatment;
- transfusion of inappropriate materials.

Adverse events for IVD medical devices may arise due to (non-exhaustive list):

- shortcomings in the design or manufacture (activity of manufacturing) of the IVD medical device itself;
- inadequate instructions for use;
- inadequate servicing and maintenance;
- locally initiated modifications or adjustments;
- inappropriate user practice;
- inappropriate management procedures;
- inappropriate environment in which an IVD medical device is used or stored;
- selection of the incorrect IVD medical device for the purpose.

## 5.2 Responsibilities

### 5.2.1 Dealers

- a) The dealers shall report to the Regulatory Authority about adverse events when the reporting criteria are met.
- b) The dealer has the responsibility for investigating adverse events and for taking any corrective action as appropriate.
- c) The product owner shall ensure that these requirements are made known to their authorized representatives, persons responsible for placing devices in the market and any other person authorized to act on their behalf for purposes related to medical devices vigilance, so that the dealer's responsibilities may be fulfilled.
- d) The product owner shall ensure that their authorized representative and persons responsible for placing devices in the market and any other person authorized to act on their behalf for purposes relating to medical devices vigilance, are kept informed of adverse event reports as appropriate.

- e) Where an adverse event occurs with the combined use of two or more separate devices (and/ or accessories) from different dealer, each product owner and their dealers shall submit a report to the Regulatory Authority.
- f) In the case of potential errors by users or third parties, labelling and instructions for use shall be carefully reviewed for any possible inadequacy.
- g) Product Owner shall keep the Regulatory Authority and Certification Body advised of issues occurring in the post production phase which may affect the certification. This would include relevant changes derived from the vigilance system.

### 5.2.2 Dealers of IVD medical devices

Any adverse event which meets the basic reporting criteria as in clause 5.1.5 are considered an adverse event and shall be reported to the Regulatory Authority. Where the dealer of an IVD diagnostic medical device identifies such an adverse event that has or could result in indirect harm and that led or might have led to death or serious deterioration in state of health, they shall submit the adverse event report to the Regulatory Authority.

### 5.3 Adverse event Reporting Timeline

- a) All adverse events should be reported immediately and shall be:
  - i) not later than **48 hours** for adverse events that represent a serious threat to public health;
  - ii) not later than **10 days** for adverse events that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person;
  - iii) not later than **30 days** for adverse events where a recurrence of which might lead to the death, or a serious deterioration in the state

- of health, of a patient, a user of the medical device or any other person;
- b) The timeline for reporting starts as soon as any personnel of the medical device dealers, including sales personnel, is made aware of the adverse event. If there is uncertainty about whether the adverse event is reportable, the dealers shall still submit a report within the timeframe stipulated.
  - c) Dealers should not unduly delay the reporting of adverse event (s) if information is incomplete. The initial report of an adverse event should contain as much relevant detail as is immediately available, and should not be delayed for the sake of gathering additional information. Refer Annex A on the template for initial/final report.
  - d) Dealers are to follow up with a final report within 30 days of the initial report or within a timeframe as allowed by the Regulatory Authority, detailing the investigation into the adverse event and the outcome. Refer Annex A on the template for initial/final report.

## 6. **EXAMPLES OF CONDITIONS WHERE REPORTING IS NOT REQUIRED**

The following are examples of conditions where reporting is not required:

### **a) Deficiency of a device found by the user prior to its use**

Regardless of the existence of provisions in the instructions for use provided by the product owner, deficiencies of devices that are always detected (that could not go undetected) by the user prior to its use do not need to be reported under the vigilance system.

Examples:

- i) The packaging of a sterile single use device is labeled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.
- ii) Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.
- iii) A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.
- iv) In an IVD testing kit, a bottle labelled lyophilised is found to be fluid, this is discovered by the user prior to use.

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

- i) When the only cause for the adverse event was that the device exceeded its service life or shelf-life as specified by the product owner and the failure mode is not unusual, the adverse event does not need to be reported.
- ii) The service life or shelf-life shall be specified by the device product owner and included in the master record [technical file] and, where appropriate, the instructions for use (IFU) or labelling, respectively. Service life or shelf-life can include e.g.: the time or usage that a device is intended to remain functional after it is manufactured, put into service, and maintained as specified. Reporting assessment shall be based on the information in the master record 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 explantation 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 labelled but exceeded.
- A patient is admitted to hospital with hypoglycaemia 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 product owner.

### **c) Protection against a fault functioned correctly**

Adverse 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 (in accordance with relevant standards or documented design inputs), do not need to be reported. As a precondition, there must be no danger for the patient to justify not reporting. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.

Examples:

- i) 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.
- ii) 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.
- iii) During radiation treatment, the automatic exposure control is engaged.

- iv) Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.
- v) A laboratory analyzer stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the user. An intervention by the user or an immediate remote intervention by the product owner allowed the analyzer to resume the analysis, resulting in correct results.

**d) Expected and foreseeable side effects**

Expected and foreseeable side effects which meet all the following criteria:

- i) clearly identified in the product owner's labelling; clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended; documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the adverse event and clinically acceptable in terms of the individual patient benefit are ordinarily not reportable.
- ii) It is recommended that the product owner involves a clinician in making this decision.
- iii) If the product owner 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 shall be considered as deterioration in the characteristics of the performance of the device. A trend report shall be submitted to the Regulatory Authority by the dealer.

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.
- 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.
- Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.

**e) Negligible likelihood of occurrence of death or serious deterioration in state of health:**

- i) Adverse events where the risk of a death or serious deterioration in state of health has been quantified and found to be negligibly small need not be reported if no death or serious deterioration in state of health occurred and the risk has been characterized and documented as acceptable within a full risk assessment.
- ii) If an adverse event resulting in death or serious deterioration in state of health has happened, the adverse event is reportable and a

reassessment of the risk is necessary. If reassessment determines that the risk remains negligible small previous adverse events of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Changes in the trend, usually an increase, of these non-serious outcomes shall be reported.

Example:

- Dealer of a pacemaker released in the market identified a software bug and quantified the probability of occurrence of a serious deterioration in state of health with a particular setting to be negligible. No patients experienced adverse health effects.

## 7. USE ERROR

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Use error related to medical devices, which did result in death or serious deterioration in state of health or caused serious public health threat, shall be reported by the dealers to the Regulatory Authority.

Use errors become reportable by the dealer to the Regulatory Authority when a product owner:

- a) notes a significant change in trend (usually an increase in frequency), or a significant change in pattern of an issue that can potentially lead to death or serious deterioration in state of health or public health threat) ;or
- b) initiates a FSCA to prevent death or serious deterioration in state of health or causes a serious public health threat.

### **i) Use error which is not reportable**

Use error related to medical devices, which did not result in death or serious deterioration in state of health or causes a serious public health threat; need not be reported to the Regulatory Authority. Such adverse events should be handled within the product owner's quality and risk management system. A decision not to report shall be justified and documented.

**ii) Consideration for handling Off-label use of medical device.**

Off-label use needs not be reported by the dealer to the Regulatory Authority. Off-label use should be handled by the healthcare facility and appropriate regulatory authorities under specific appropriate schemes not covered by this document.

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

## **8. OUTCOME OF AN INVESTIGATION AND FOLLOW-UP**

The dealer shall take the action necessary following the investigation, including consultation with the Regulatory Authority and performing any corrective action. The Regulatory Authority may take any further action it deems appropriate, consulting with dealer or authorized representative where possible.

### **9.1 Follow-up report**

The dealers shall provide a follow-up-report to the Regulatory Authority if the investigation time reaches the time line given.

### **9.2 Final report**

There shall be a final report which includes a written statement of the outcome of the investigation and of any action.

Examples of actions may include:

- a) no action;
- b) additional surveillance of devices in use is needed;
- c) preventive action on future production; and
- d) FSCA.

The report shall be made by the dealer to the Regulatory Authority.

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Annex A  
(normative)



**Medical Device Adverse Event (AE) Report Form**

AR Report Ref
Regulatory Authority Report No.

<b>I. ADMINISTRATIVE INFORMATION</b>	
<p><u>1. Report Type (select one):</u></p> <p><input type="checkbox"/> Initial    <input type="checkbox"/> Follow-up    <input type="checkbox"/> Final    <input type="checkbox"/> Trend</p>	
<p><u>2. Classification of Event:</u></p> <p><input type="checkbox"/> Serious Deterioration in State of Health</p> <p><input type="checkbox"/> Death</p> <p><input type="checkbox"/> Other Reportable Event</p>	
<p>3. Date of this report (dd-mmm-yyyy)</p>	
<p>4. Date of adverse event (dd-mmm-yyyy)</p>	
<p>5. Dealer awareness date (dd-mmm-yyyy)</p>	
<p>6. Expected date of next report (dd-mmm-yyyy)</p>	
<p><u>Particulars of the Dealer submitting this Report:</u></p>	
7. Name	
8. Company	
9. Address	
10. Mobile Phone No.	
11. Fax	
12. Email	
<p><u>13. Other Regulatory Authorities to which this report was also sent</u></p>	
<b>II. CLINICAL EVENT INFORMATION</b>	
<p><u>1. Event Description:</u></p>	

<b>III. HEALTHCARE FACILITY INFORMATION</b>			
1. Name of the Facility			
2. Name of Contact Person			
3. Facility Report No. (if available)			
4. Address			
5. Phone		6. Fax	
7. E-mail			
<b>IV. DEVICE INFORMATION</b>			
<u>Device Information:</u>			
1. Device Name			
2. Dealer License No.			
3. Product Registration No.			
4. Nomenclature System		AMDNS / UMDNS Code:	
		GMDN Code:	
5. Catalogue No.			
6. Serial No.			
7. Lot/Batch No.			
<u>Product Owner Information:</u>			
8. Name			
9. Contact Person			
10. Address			
11. Phone		12. Fax	
13. E-mail			
<u>14. User of device at the time of the event:</u>			
<input type="checkbox"/> Healthcare Professional <input type="checkbox"/> Patient <input type="checkbox"/> Others <input type="checkbox"/> None			
<u>15. Usage of Device:</u>			
<input type="checkbox"/> Initial Use <input type="checkbox"/> Reuse of Single-Use Device			

2. No. of affected people involved		3. No. of devices involved	

Reuse of Reusable Device     Re-serviced / Refurbished  
 Other, please specify: \_\_\_\_\_

16. Device Disposition / Current Location:

**V. RESULT OF MANUFACTURER'S INVESTIGATION**

1. Product Owner's Device Analysis Results:

2. Remedial Action / Corrective Action / Preventive Action:

**VI. INFORMATION OF PATIENT**

1. Age at time of event (years, months)			
2. Gender (M/F)		3. Weight (kg)	

4. List of devices involved with the patient (see Section IV):

5. Corrective action taken relevant to the care of the patient:

6. Patient outcome:

**VII. OTHER REPORTING INFORMATION**

Any events with this device with the same root cause?

Yes, please specify the rate: \_\_\_\_\_     No

**VIII. COMMENTS**

**IX. SUBMISSION OF REPORT**

By Mail:

By Fax.: (     )                              By e-mail:

**X. DISCLAIMER**

Submission of this report does not constitute an admission of manufacture, AR, user, or patient liability for the event and its consequences. It does not, in itself, represent a conclusion by the AR that the content of this report is complete or confirmed, that the device(s) listed failed in any manner. It is also not a conclusion that the device(s) caused or contributed to the adverse event.

**GUIDANCE FOR FILLING IN THE ADVERSE EVENT REPORT FORM**

<b>GENERAL</b>	For details on reportable and non-reportable events, please refer to the related guidance notes.
All fields must be completed with appropriate information or "NA" if not applicable to the event or "unknown when the data is not available.	<u>3 – 6. Dates of this report, date of adverse event, AR, awareness date, and expected date of next report:</u>
"AR Report No." on the top right hand corner of the first page is the unique number assigned by the AR to identify the report in the AR's internal system.	All dates must be formatted as follows: 2 digit day, 3 letter month, 4 digit year e.g., 01-JAN-2001
Reasonable effort must be made to address all elements. However failure or inability to do so in not justification for failing to submit a report within the established timeframes.	Expected date of next report: the date when further information will be provided. This should be "NA" for final report.
<b>I. ADMINISTRATIVE INFORMATION</b>	<u>7 – 12. Particulars of the AR Submitting this Report</u>  Please fill in the contact details of the AR's report.
<u>1. Report Type:</u>  Initial: defined as the first information submitted by the AR about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate submission.  Follow-up: defined as a report that provides supplemental information about a reportable event that was not previously available.  Final: defined as the last report that the AR expects to submit about the reportable event. A final report may also be the first report.  Trend: A reporting type used by the product owner when a significant increase in adverse events not normally considered to be reportable adverse events for which pre-defined trigger levels are used to determine the threshold for reporting.	<u>13. Other Regulatory Authorities to which this report was also sent:</u>  Please identify to what other regulatory authorities, such as the FDA (US), MHRA (UK), this report was also sent.
<u>2. Classification of Event:</u>  Adverse events that resulted in (i) Serious Threat To Public Health shall be reported within 48 hours, (ii) death, (iii) Serious Deterioration in State of Health shall be reported as soon as possible, but not later than <i>10 elapsed calendar days</i> following the awareness of the event.  All other reportable events shall be reported as soon as possible, but not later than <i>30 elapsed calendar days</i> following the awareness of the event.  Please note that the following use errors are reportable events: refer to Section 7 of Guidance Document on AMDD Adverse Event Reporting.	<b>II. CLINICAL EVENT INFORMATION</b>  <u>1. Event Description :</u>  Clarification or relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in the report. E.g. "the patient was confused prior to becoming trapped in the bedsides": " the patient was a very low birth weight premature delivery and had a central line placed three days before onset of cardiac tamponade": "the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event", etc.
<b>III. HEALTHCARE FACILITY INFORMATION</b>	<u>2. No. of affected people</u>  Includes any affected individual, e.g. user, patient, or third party.
Please provide information about the place of the event. It could include home care, transport or emergency care site. Information in this section is optional. If information is not available, justification should be provided.	<u>3. No. of devices</u>  Please state the number of devices involved in this event.
<b>IV. DEVICE INFORMATION</b>	<b>VI. INFORMATION OF PATIENT</b>
<u>1 -13. Device Information:</u>  Please provide information on the device involved. Please repeat this	Please provide individual patient information (including information of any affected individual, e.g. user, patient, or third party) for each element as appropriate. Please repeat this section for each patient involved in separate sheets. If information is not available, justification should be provided.  Please note that in some cases, the patient's age, gender and weight may be irrelevant. In some cases, they are essential, e.g. the age and weight of the

section for each device in separate sheets.
<p><b>14. User of device at the time of the event:</b></p> <p>Please indicate the type of User of the device at the time of the event.</p> <p>"None" means that the problem is noted prior to use.</p>
<p><b>15. Usage of Device:</b></p> <p>Please indicate the usage of the device involved.</p>
<p><b>16. Device Disposition / Current Location:</b></p> <p>Please provide information on where and in what state the device is at the time of the report, e.g. " the device has been destroyed"; "the device remains implanted in the patient"; "the device was returned to the manufacturer"; the device remains under investigation", etc.</p>
<p><b>V. RESULT OF MANUFACTURER'S INVESTIGATION</b></p>
<p><b>1. Product Owner's Device Analysis Results:</b></p> <p>Specify, for this event, details of investigation methods, results, and conclusions</p> <p>Alternatively, product owner's device analysis report may be submitted.</p>
<p><b>2. Remedial Action / Corrective Action / Preventive Action:</b></p> <p>Specify if action was taken by product owner and/or AR for the reported specific event or for all similar types of products. Include what action was taken by the product owner and/or AR to prevent recurrence. Clarify the timeframes for completion of various action plans.</p>

<p>patient in regards to some implants.</p> <p>Some events are caused by the combined action of two or more devices, medical or non-medical. Please provide a brief list of devices involved.</p> <p>Information in this section is optional.</p>
<p><b>VII. OTHER REPORTING INFORMATION</b></p>
<p>If the product owner or the AR is aware of similar events with this device with the same root cause, please provide the number of such events. The number should be specified in terms of event per unit sold, or the number of event per unit sold / in use in a region, etc.</p>
<p><b>VIII. COMMENTS</b></p>
<p>Please provide any additional details that are relevant and not requested elsewhere in this report.</p>

DRAFT