ASEAN MEDICAL DEVICE DIRECTIVE

AMDD Supporting Documents

东盟医疗器械技术指南_ＡＭＤＤ配套汇编

Compilation of official guidance documents from asean.org:

1. CSDT - Common Submission Dossier Template (12 pages)
2. Post-Market Information Exchange System (14 pages)
3. Adverse Event Reporting Format (24 pages)

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内容：　ＣＳＤＴ　通用申报档案模板　/　上市后信息交换系统　/　不良事件报告格式

国瑞中安ＧＲＺＡＮ　-　全球法规库



ASEAN Consultative Committee for Standards & Quality

Medical Device Product Working Group

Common Submission Dossier Template

1.0 Introduction

The document is intended to provide guidance for submission of device information to the regulatory authorities; structured in the format of one common template acceptable by all ASEAN regulators. It is envisaged that a Common Submission Dossier Template (CSDT) will harmonize the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of this guidance document in ASEAN will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities.

2.0 Scope

This guidance document describes the format for an ASEAN harmonized common submission dossier template and provides general recommendation on the content of the formatted elements. This document does not recommend any new or additional technical documents above and beyond what should be created by the product owner to comply with existing requirements to demonstrate conformity to the Essential Principles [GHTF SG1/N041], and to address any country-specific requirements.

This document applies to all products that fall within the definition of a medical device.

Essentially, the CSDT contains elements of the Summary Technical Documentation (STED) [GHTF SG1/N011R17] for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices.

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.

3.0 Executive Summary

An executive summary shall be provided with the common submission dossier template, which shall include the following information:

- an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT;
- commercial marketing history;
- intended uses and indications in labelling;
- list of regulatory approval or marketing clearance obtained;
- status of any pending request for market clearance; and
- important safety/performance related information.

4.0 Elements of the Common Submission Dossier Template

4.1 Relevant Essential Principles and Method Used to Demonstrate Conformity

The CSDT should identify the Essential Principles of Safety and Performance of Medical Devices that are applicable to the device. The CSDT *should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.*

The CSDT should *identify the specific documents related to the method used to demonstrate conformity to the Essential Principles.*

4.1.1 Essential Principles and Evidence of Conformity

The *evidence of conformity can be provided in tabular form with supporting documentation available for review as required.* A sample of the essential principles conformity checklist is included in Appendix A.

For example, a completed Essential Principles conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. As such, CSDT would then include a declaration of conformity to the standard, or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does

not include performance requirements. When the **product owner** uses international or other standards to demonstrate conformity with the Essential Principles, the CSDT should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the **product owner** uses other means, such as internal standards, the CSDT should describe the means.

Not all the essential principles will apply to all devices and it is for the **product owner** of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.

4.2 *Device Description*

4.2.1 *Device description* & features

Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. A complete description of each functional component, material or ingredient of the device should be provided, with *labelled pictorial representation of the device* in the form of *diagrams, photographs or drawings*, as appropriate.

4.2.2 *Intended use*

This means the use for which the medical device is intended, for which it is suited according to the data supplied by the **product owner** in the instructions as well as the functional capability of the device.

4.2.3 *Indications*

This is a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the device is intended.

4.2.4 *Instructions of use*

These are all necessary information from the **product owner** including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging by other formats / forms.

4.2.5 *Contraindications*

This is a general description of the disease or condition and the patient population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are

conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

4.2.6 Warnings

This is the specific hazard alert information that a user needs to know before using the device.

4.2.7 Precautions

This alerts the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.

4.2.8 Potential adverse effects

These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.

4.2.9 Alternative therapy

This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

4.2.10 *Materials*

A description of the materials of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device.

4.2.11 Other Relevant *Specifications*

The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles.

4.2.12 Other Descriptive Information

Other important descriptive characteristics not detailed above, to the extent necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

NOTE: For simple, low risk devices, the above information will typically be contained in already existing sales brochures, instructions for use, etc.

4.3 Summary of Design Verification and Validation Documents

This section *should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device*:

Such documentation should typically include:

- *declarations/certificates of conformity to the "recognized" standards listed as applied by the* **product owner***; and/or*
- *summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.*

EXAMPLE: *The completed Table of Conformity to the Essential Principles that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle*. Section 3.0 of the CSTD would then *include a declaration of conformity to the standard, or other certification permitted by the relevant Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements.*

The data summaries or tests reports and evaluations would typically cover, as appropriate to the complexity and risk class of the device:

- *a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the device with reference to the Essential Principles;*
- *engineering tests;*
- *laboratory tests;*
- *biocompatibility tests;*
- *animal tests;*
- *simulated use;*
- *software validation.*

4.3.1 Pre-clinical Studies

Details must be provided on all biocompatibility tests conducted on materials used in a device. At a minimum, tests must be conducted on samples from the finished, sterilized device. All materials that are significantly different must be characterized. Information describing the tests, the results and the

analyses of data must be presented.

Complete pre-clinical physical test data must be provided, as appropriate. The report must include the objectives, methodology, results and **product owner's** conclusions of all physical studies of the device and its components. Physical testing must be conducted to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, long-term use and all known and possible failure modes.

Pre-clinical animal studies used to support the probability of effectiveness in humans must be reported. These studies must be undertaken using good laboratory practices. The objectives, methodology, results, analysis and **product owner's** conclusions must be presented. The study conclusion should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

4.3.1.1 Software Verification and Validation Studies (if applicable)

The correctness of a software product is another critical product characteristic that cannot be fully verified in a finished product. The **product owner** must provide evidence that validates the software design and development process. This information should include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, as well as representative data generated from both testing environments.

4.3.1.2 Devices Containing Biological Material

Results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

4.3.2 *Clinical Evidence*

This section *should indicate how any applicable requirements of the Essential Principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class devices, or for devices where there is little or no clinical experience.*

4.3.2.1 Use of Existing Bibliography

Copies are required of all literature studies, or existing bibliography, that the **product owner** is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

4.4 Device *Labelling*

This is the descriptive and informational product literature that accompanies the device any time while it is held for sale or shipped, such as any physician's manuals, pack labeling, promotional material and product brochures etc. This section *should summarize or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labelling"*:

- Labels on the device and its packaging
- Instructions for use
- Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform (if applicable).

4.4.1 Samples of Labels on the Device and its Packaging

This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

4.4.2 Instructions for Use

The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the device.

4.5 *Risk Analysis*

This section *should summarize or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.*

4.5.1 Results of Risk Analysis

A list of possible hazards for these devices must be prepared. Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. The evaluation of these risks against the claimed benefits of the device and the method(s) used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyze risk must be specified, to ensure that it is appropriate for the device and the risk involved.

4.6 *Manufacturer Information*

This section *should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the device.*

4.6.1 Manufacturing Process

Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output.

EXAMPLE: The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, storage of the device. Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any.

If multiple facilities are involved in the manufacture of device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the device under contract to **the product owner** may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The **product owner** should inform these contractors of the need to supply detailed information on the device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical device) that contributes towards the manufacture of the finished device itself.

References

SG1/N009 *Labeling for Medical Devices*

SG1/N015 *Medical Devices Classification*

SG1/N029 *Information Document Concerning the Definition of the Term 'Medical Device'.*

SG1/N041 *Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)*

SG1/N043 *Labeling for Medical Devices (including In Vitro Diagnostic Devices)*

SG1/N011R17 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*

APPENDIX A - Example of an Essential Principles Conformity Checklist

Essential Principle	Applicable to the device?	Method of Conformity[1]	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: • identify hazards and the associated risks arising from the intended use and foreseeable misuse, • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • inform users of the residual risks due to any shortcomings of the protection measures adopted.	Yes		
3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	Yes		
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the	Yes		

[1] Select from: recognised standard/other international standard/national standard/company standard/validated test/ etc.

manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.			
5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes		
6. The benefits must be determined to outweigh any undesirable side-effects for the performances intended.	Yes		
7.1. The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I of the 'General Requirements'. Particular attention should be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
7.2. The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.			



MEDICAL DEVICE GUIDANCE

MEDICAL DEVICE POST MARKET INFORMATION EXCHANGE FOR ASEAN MEMBER STATES

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Preface

This document is produced to ASEAN Member States (AMS) and intended to provide general guidance. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the ASEAN Medical Device Committee (AMDC) or the ASEAN Secretariat. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. Neither the medical device regulatory authority of AMS nor the ASEAN Secretariat accept 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 any 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 Secretariat

1. Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices to be placed in the market meet appropriate standards of safety, quality and performance, and that they are used safely. This document is made pursuant to the ASEAN Medical Device Directive (AMDD) for post market alert and the need for information exchange among AMS.

This guidance document has been adapted from IMDRF/NCAR WG/N14FINAL:2022 (Edition 3) - *Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form*.

2. Scope and application

This guidance provides guidance on exchange of post market information among AMS.

3. References

The references are as follows:

ASEAN Medical Device Directive (AMDD)

IMDRF/NCAR WG/N14FINAL:2022 (Edition 3) - Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form

4. Terms and definitions

For the purpose of this document, the terms and definitions given in ASEAN Medical Device Directive (AMDD).

5. Requirements on exchange of post market information

In order to facilitate the AMS in implementing the post market surveillance activities, AMDC agreed that all AMS are allowed to exchange post market information, including information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions.

5.1 The concerns or potential trends that individual authorities have observed in their jurisdictions are as according to the following:

5.1.1 Events leading or highly likely to lead to unanticipated public health threat

Reportable events, associated with a medical device that have led or are highly likely to lead to unanticipated serious public health threat and fulfil the following criteria:

a. Death of a patient, user or other person;

b. Serious injury of a patient, user or other person; or

c. 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. Some jurisdictions refer to these events as near incidents.

Notes:
1. The interpretation of "serious" in the context of serious public health threat may be difficult to assess and should be determined in consultation with a medical practitioner when appropriate.
2. Post market report from any AMS should not be used for advising of single incidents, unless those incidents have a clear implication for public health.

Examples:
a) A contaminated eye rinsing solution is used during eye surgery. The possible outcome is serious vision impairment or blindness. The issue was not identified until testing was conducted following several reports of patients having infection and visual problems. The size of the concerned batch is such that the contaminated solution is likely to be distributed in different geographical areas/regions.
b) A spinal disc prosthesis is inserted between two cervical vertebrae to treat the pain and numbness associated with the collapse of the disc space. Cases of implanted patients suffering from paralysis several months following surgery have been reported. The investigation concluded that the root cause of the paralysis is mechanical failure of the disc, resulting in the disc moving out from between the vertebrae. Subsequent investigation shows that there is no warning for when the disc might break. Advice provided is that all implanted patients should have the disc replaced.
c) An IVD product owner had identified a problem with his HIV test which can result in the generation of false negative results. The problem is not detected by the device control and therefore the incorrect false negative result could be given to medical staff and the patient. The device is widely used across the world, and in some jurisdictions, it is used for testing prior to blood / organ donation.

5.1.2 Observations from national trend analysis

A trend noticed by an AMS is circulated to the other AMSs when:

a) The frequency of the event associated with the device is significantly higher than the frequency recorded in the product owner's file or significantly higher than the frequency observed with similar devices; and

b) The event has led or is highly likely to lead to a serious public health threat.

Examples:

a) The review of data from a national registry, complemented by adverse event data indicates a potential concern regarding high revision rates for hip prosthesis that have Metal on Metal (MoM) articulations. The consequence for implanted patients can be permanent impaired mobility and/or the need for surgical re-intervention to avoid further impairment.
b) Review of adverse event data and literature for a specific atrial septal occluder device indicated an increase in tissue erosion compared with other devices in this category. This type of device failure has not been seen in similar devices to treat this condition. This erosion can require immediate interventional surgery to remove the device and repair the erosion.

5.1.3 Request and/or share of information

5.1.3.1 An AMS may request and/or share information about a specific device or class/group of devices concerning:

a) An adverse event;

b) An increased seriousness or frequency to what was previously reported to the AMS;

c) Major weaknesses and/or major deviations regarding a product owner's Project Management System (PMS) / Quality Management System (QMS); and

d) Regulatory status changes of a device(s).

The consequences of which:

a) Have led or are highly likely to lead to serious public health threat; and

b) May affect other jurisdictions.

5.1.3.2 The concerned AMS can ask whether other AMSs have similar experience and what actions were initiated or are being discussed to address the issue, e.g. recalls or Field Safety Corrective Actions (FSCA).

Examples:

a) An AMS has received an increasing number of reports for thrombosis in association with a particular Left Ventricular Assist Device (LVAD). These devices are used in very ill patients who depend on these devices for survival. If the LVAD is stopped or slowed because of thrombosis the patient requires immediate treatment such as thrombolytics or surgical intervention to avoid patient death. The root cause is not identified.

b) The AMS requests information and assistance if other jurisdictions have encountered this issue and have any additional information that might be useful in determining a root cause.

c) Several reports have been received of embolus, which has led to or could lead to the death of the patient during an operation, for devices delivering fibrin to seal the gut during surgery. It is unclear whether the device or the drug is responsible for the observed event. The competent authority circulates the report and requests information from other competent authorities regarding any reported adverse events associated with fibrin and embolus.

d) An AMS notes a series of field actions that have been conducted by a product owner. The field actions all relate to one specific device that is used both in the High Dependency Unit setting and palliative care settings. The large number of field actions and the manner in which the product owner has managed the identified issues raise questions about the product owner's quality management system. The competent authority seeks information from other authorities relating to their experience with the product owner and the product.

e) An AMS restricts the importation of a medical device(s) due to concerns about device safety that could result in a serious public health threat.

5.2 The exchange of post market information among AMS shall be reported based on the reporting template as attached in ANNEX A. The report shall be submitted to the ASEAN Secretariat which shall circulate it to all AMS. All information in the report shall be treated confidential and shall accordingly be managed or disclosed in accordance with Article 16 of the AMDD.

The ASEAN Secretariat, in ensuring/maintaining the quality and consistency of the circulated report, shall respect confidentiality arrangements of information among AMS. Except for the circulation of the report, no confidential information shall be disclosed by the ASEAN Secretariat.

5.3 The explanation on how to fill up the reporting template can be referred in ANNEX B of this document.

ANNEX A

(normative)

REPORTING TEMPLATE FOR EXCHANGE OF POST MARKET INFORMATION AMONG AMS

Completed forms shall not be released to any other party. All information contained in this form is considered confidential.

1. Report Number: <reference number>

☐ New
☐ Amended

2. PURPOSE of the EXCHANGE:

☐ Share Information
- ☐ Events leading or highly likely to lead to unanticipated serious public health threat.
- ☐ Observations from national trend analysis
- ☐ Share of Information as outlined in Clause 5.1.3

☐ Request Information
☐ Summary of query findings

DETAILS OF INITIATING COUNTRY

3. Authoring Country:	<name of country>		
4. Contact Person:	<name of contact person>	**5. Designation:**	
6. E-mail:	<email address>	**7. Telephone:**	<telephone number>
8. Circulated:	<date circulated - dd/mm/yyyy>		

DEVICE DETAILS

9. Generic name / kind of device:	
10. Nomenclature Type:	**11. No / Code:**
12. Medical Speciality Area:	

13. Trade Name and Model:	
14. Device also marketed as (trade name), if known:	
15. If Applicable, UDI No.:	**16. Software version (If Applicable):**
17. Serial number(s):	**18. Lot / batch number(s):**

Regulated Parties

19. Product Owner: **Country:** **Full Address:** **Contact:** **Telephone:** **Email:**	**20. Authorised Representative:** **Country:** **Full Address:** **Contact:** **Telephone:** **Email:**	**21. If Applicable, CAB / Notified Body No.:**

BACKGROUND INFORMATION AND REASON FOR THIS REPORT

22. <background of report >

Is the Investigation of the report Complete : ☐ Yes ☐ No

Attachments : ☐ Yes ☐ No

(… include information on relevant manufacturing sites)

QUESTIONS AND RESPONSES (If Applicable)
23. Deadline for response: <dd/mm/yyyy>

Question	**Answer**	**Rationale / Remarks**
24.		

ADDITIONAL RATIONALE AND REMARKS
25.
DETAILS OF RESPONDING COUNTRY

26. Responding Country:	<name of country>		
Contact Person:	<name of contact person>	**Telephone:**	<telephone number>
E-mail:	<email address>	**Fax**	<fax number>

FINAL SUMMARY / COMMENTS
27.

ANNEX B
(informative)

INSTRUCTIONS FOR FILLING UP REPORTING TEMPLATE FORM

B.1 GENERAL

1. The form should be completed in English.

2. The point of contact identified in Field 3 of the report form is considered to be the author of the report. The author is responsible for:
   i. ensuring that the report is issued in accordance with exchange criteria as mentioned in this guidance;
   ii. the accuracy, completeness and relevance of the content; and
   iii. the scope of its distribution.

3. Reports should not to be used for advising of single incidents, unless those incidents have a clear implication for public health. In such cases, the implied recommendation is for other AMSs to be aware and take such local actions they find appropriate.

4. If the report involves a specific product owner's device, then the product owner or authorized representative may be consulted regarding the reports content and distribution of the device prior to it being sent to ASEAN Secretariat – preferably by providing a copy for the product owner or authorized representative to comment on. This will help to ensure the accuracy, particularly the technical content, of the report. An appropriate timeframe for receiving product owner's comments should be communicated.

FIELD:

Number	Explanatory notes
1	Use the rules for numbering reports (use the ISO 3166 for country codes) which incorporates a two-letter code of the issuing country to fill in this item. For example: MY-2005-10-19-002 is a report from Malaysia sent 19 October 2004 and is the 2nd report for 2005. Each new report should be given a unique report number. If a report relates to a previously exchanged report ensure that the "Amended" box has been checked.
2	Check the box associated with the purpose of the exchange.
3-5	Identify person and organization sending the report. This should be the single point of contact, previously identified to the ASEAN Secretariat.
6-7	Telephone and e-mail of person in (3) above.
8	Add the date this report has been circulated
9	Kind of device or generic descriptor

10	Identify the nomenclature system used (e.g. Global Medical Device Nomenclature [GMDN] etc.).
11	Number or code to identify the device based on the nomenclature system.
12	State medical speciality area. No/Code of medical speciality areas are as follows: 1- Anaesthesia; 2- Cardiovascular; 3- Chemistry; 4- Dental; 5- Ear, nose and throat; 6- Gastroenterology/urology; 7- General and plastic surgery; 8- General hospital; 9- Haematology; 10- Immunology; 11- Microbiology; 12- Neurology; 13- Obstetrics and gynaecology; 14- Ophthalmology; 15- Orthopaedics; 16- Pathology; 17- Physical medicine; 18- Radiology; 19- Clinical toxicology; and 20- Paediatrics 21- Other (Please specify)
13	Trade name/ brand name and model number
14	List the marketed trade name(s) in other countries, if different.
15	State UDI information.
16-18	If there are many lot/ batch numbers or serial numbers (i.e., more than 3 or 4), a detailed list should be appended to the bottom of the report.
19	Product owner of device - full address, including country, phone number(s) and email.
20	Identify the natural or legal entity in reporting country who is responsible for placing the subject device on the market where the incidents occurred, full address, including country, phone number(s) and email.
21	Indicate name of Conformity Assessment Body / Notified Body involved, if applicable.
22	Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (Clause 5), describe the reason for the report and why you want to inform other AMSs about these events. Such information will lead to a better understanding by the recipient on what is considered to be appropriate follow-up. Identify any investigation taken by the product owner and also whether there has been any regulatory, legal or company-initiated action taken in advance of sending out the report. Indicate if the investigation of the report is complete or not.

	Check either the 'Yes' or 'No' boxes to indicate whether there are any attachments associated with this report.
23	Indicate a date for which the sending AMS would like to receive responses from recipients of the report.
24	List questions under the heading 'Questions'. Number the questions for ease in replying.
25	Add any information that is relevant and will assist the receiver of the information to undertake action or to be able to answer the questions appropriately.
26	Provide the name of the AMS, the name of the person that the sending AMS can contact if they need to clarify any responses, a telephone number and an email address for the contact person.
27	This section is used by the sending AMS to inform other report members of the outcome of enquires related to a 'Request for Information' under the heading Purpose of the Exchange' (Field 2).



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

FINAL

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.

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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 CORRECTICE 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 reoccurance.

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.

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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.

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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:

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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.

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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

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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.

FINAL

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.

FINAL

7. USE ERROR

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.

FINAL

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**.**

FINAL

Annex A
(normative)

Medical Device Adverse Event (AE) Report Form

AR Report Ref	
Regulatory Authority Report No.	

I. ADMINISTRATIVE INFORMATION

1. Report Type (select one):

☐ Initial ☐ Follow-up ☐ Final ☐ Trend

2. Classification of Event:

☐ Serious Deterioration in State of Health

☐ Death

☐ Other Reportable Event

3. Date of this report (dd-mmm-yyyy)	
4. Date of adverse event (dd-mmm-yyyy)	
5. Dealer awareness date (dd-mmm-yyyy)	
6. Expected date of next report (dd-mmm-yyyy)	

Particulars of the Dealer submitting this Report:

7. Name	
8. Company	
9. Address	
10. Mobile Phone No.	
11. Fax	
12. Email	

13. Other Regulatory Authorities to which this report was *also* sent

II. CLINICAL EVENT INFORMATION

1. Event Description:

III. HEALTHCARE FACILITY INFORMATION

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			

IV. DEVICE INFORMATION

Device Information:

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.		

Product Owner Information:

8. Name			
9. Contact Person			
10. Address			
11. Phone		12. Fax	
13. E-mail			

14. User of device at the time of the event:

☐ Healthcare Professional ☐ Patient ☐ Others ☐ None

15. Usage of Device:

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

☐ Initial Use ☐ Reuse of Single-Use Device
☐ 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.

FINAL

GUIDANCE FOR FILLING IN THE ADVERSE EVENT REPORT FORM

GENERAL

All fields must be completed with appropriate information or "NA" if not applicable to the event or "unknown when the data is not available.

"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.

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.

I. ADMINISTRATIVE INFORMATION

1. Report Type:

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.

2. Classification of Event:

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 *10 elapsed calendar days* following the awareness of the event.

All other reportable events shall be reported as soon as possible, but not later than *30 elapsed calendar days* 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.

III. HEALTHCARE FACILITY INFORMATION

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.

IV. DEVICE INFORMATION

For details on reportable and non-reportable events, please refer to the related guidance notes.

3 – 6. Dates of this report, date of adverse event, AR, awareness date, and expected date of next report:

All dates must be formatted as follows: 2 digit day, 3 letter month, 4 digit year e.g., 01-JAN-2001

Expected date of next report: the date when further information will be provided. This should be "NA" for final report.

7 – 12. Particulars of the AR Submitting this Report

Please fill in the contact details of the AR's report.

13. Other Regulatory Authorities to which this report was also sent:

Please identify to what other regulatory authorities, such as the FDA (US), MHRA (UK), this report was also sent.

II. CLINICAL EVENT INFORMATION

1. Event Description :

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.

2. No. of affected people

Includes any affected individual, e.g. user, patient, or third party.

3. No. of devices

Please state the number of devices involved in this event.

VI. INFORMATION OF PATIENT

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.

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Please provide information on the device involved. Please repeat this section for each device in separate sheets.

14. User of device at the time of the event:

Please indicate the type of User of the device at the time of the event.

"None" means that the problem is noted prior to use.

15. Usage of Device:

Please indicate the usage of the device involved.

16. Device Disposition / Current Location:

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.

V. RESULT OF MANUFACTURER'S INVESTIGATION

1. Product Owner's Device Analysis Results:

Specify, for this event, details of investigation methods, results, and conclusions

Alternatively, product owner's device analysis report may be submitted.

2.Remedial Action / Corrective Action / Preventive Action:

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.

irrelevant. In some cases, they are essential, e.g. the age and weight of the patient in regards to some implants.

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.

Information in this section is optional.

VII. OTHER REPORTING INFORMATION

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.

VIII. COMMENTS

Please provide any additional details that are relevant and not requested elsewhere in this report.

FINAL