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MEDICAL DEVICE GUIDANCE DOCUMENT

MANDATORY PROBLEM REPORTING

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following:

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012*;* and

c) Medical Device (Duties and Obligation of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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MANDATORY PROBLEM REPORTING

0 Introduction

Mandatory problem 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. Mandatory problem reporting is also referred as adverse event reporting in ASEAN Medical Device Directive (AMDD). 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 incidents, or alleviate consequences of such repetition.

All medical device establishments shall comply with all requirements relating to mandatory problem reporting stipulated in the Act 737 and its regulations to continuously ensure the safety and performance of the medical devices that have been placed in the Malaysian market. The requirements include submit mandatory problem report to the Authority when incident relating to the medical device occurred, carry out investigation to determine the root cause of incident and, carry out corrective and preventive actions to eliminate or reduce the risk of recurrence of incident.

This guidance document is made pursuant to Section 40 of Medical Device Act 2012 (Act 737) and Regulations 5 of Medical Device (Duties and Obligation of Establishments) Regulations 2019, pertaining to mandatory problem reporting.

1 Scope and application

This guidance document elaborate requirements pertaining to mandatory problem reporting of any incident related to a medical device as stipulated in Section 40 of Act 737 and Regulation 5 of Medical Device (Duties and Obligations of Establishments) Regulations 2019. This guidance document applies to:

a) medical device as defined in Section 2 of Act 737; and

b) establishments.

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

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

2.1 active medical device

Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy,

substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

2.2 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.

2.3 corrective action

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

2.4 drug/ device 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.

2.5 field corrective action (FCA)

FCA means any action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include:

a) the return of a medical device to the manufacturer or its representative;

b) device modification;

c) device exchange;

d) device destruction;

e) advice given by manufacturer regarding the use of the device.

2.6 field safety notice (FSN)

A communication sent out by a manufacturer or its representative to the medical device users in relation to an FCA.

2.7 harm

Physical injury or damage to the health of people, or damage to property or the environment.

2.8 immediately

Immediately means without any delay that could not be justified.

2.9 Incident

An event that causes, or has a potential to cause, unexpected or unwanted effects involving the safety of any person who use a medical device or any person associated with the use of a medical device

2.10 indirect harm

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

Examples of indirect harm include

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

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.

2.11 intended purpose

The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

2.12 off-label use

Act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer in accordance with the medical device registration.

2.13 operator

Person handling equipment.

2.14 serious public health threat

Any incident which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action. This would include:

- incidents that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus

(HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the Authority or the manufacturer.

- the possibility of multiple deaths occurring at short intervals.

2.15 trend reporting

A reporting type used by the manufacturer or authorized representative when a significant increase in incidents not normally considered to be incidents for which pre-defined trigger levels are used to determine the threshold for reporting.

2.16 unanticipated

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

2.17 use error

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

2.18 user

The health care institution, healthcare institution personnel, healthcare professional, operator or patient using or maintaining medical devices.

3 Mandatory Problem Reporting

3.1 General requirements

As required by Section 40 of Act 737 and Regulation 5(1) of Medical Device (Duties and Obligations of Establishments) Regulations 2019, every establishment shall report any incident involving its medical device which comes to establishment's attention occurring inside or outside Malaysia to the Authority only if the medical device is registered in Malaysia.

The establishment shall investigate the cause of incident and conduct field corrective action if necessary, to prevent recurrence of the incident to ensure safety and performance of the medical device as specified in Regulation 5(2) of Medical Device (Duties and Obligations of Establishments) Regulations 2019. The Authority will evaluate the investigation report and if the report and action taken are satisfactory, the Authority will inform the establishment in writing to close the matter.

The requirement to submit a mandatory report shall not apply to any incident that occurs outside Malaysia if that incident has been reported by the establishment to the regulatory agency of the country in which the incident occurred and a field corrective action has been taken by the manufacturer or establishment in the country where the incident occurred and on all the affected devices placed in the Malaysian market as specified by Regulation 5(7) of Medical Device (Duties and Obligations of Establishments) Regulations 2019.

Establishments are required to establish and maintain the following, for medical devices it deals with, related to mandatory problem reporting:

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

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

c) When placing in the market of a particular model of medical device ceases, the manufacturer's post market surveillance and vigilance obligations under the Medical Device Act 2012 (Act 737) and its regulations remain. However, when a manufacturer's legal trading arrangements 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 Authority are appraised of the implications and provided with new contact details as soon as possible, so that any detrimental effects on the functioning of the vigilance system are minimised.

3.2 Reporting Criteria

3.2.1 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 incident. Any incident, which meets the three basic reporting criteria listed below, is considered as reportable. The criteria are that: -

a) an incident has occurred;

b) the medical device is associated with the incident; and

c) the incident led to one of the following outcomes;

i) serious deterioration in state of health, user or other person. A serious deterioration in state of health can include: -

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

ii) death of a patient, user or other person;

iii) a serious threat to public health; or

iv) no death or serious injury occurred but the incident might lead to death or serious injury of a patient, user or other person if the incident recurs.

3.2.2 Incidents involving in vitro diagnostic devices

a) 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 incident 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.

b) 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.

c) Information supplied by the manufacturer 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, Incidents 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 incidents include (non-exhaustive list):

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

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

- shortcomings in the design or manufacture 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.

3.2.3 Use error

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

a) Use error which is reportable

Use errors become reportable by the manufacturer and its authorised representative to the Authority when a manufacturer:

i. 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

ii. initiates a FCA to prevent death or serious deterioration in state of health or causes a serious threat to public health.

b) Use error which is not reportable

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

c) Off-label use of medical device

Off-label use needs not be reported by the manufacturer to the 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 manufacturers become aware of instances of off-label use, they may bring this to the attention of other appropriate organizations and healthcare facility personnel. Use of medical device indicated for children on adults or vice versa is an example of off-label use.

3.2.4 In assessing the link between the device and the incident the manufacturer should take account of:

a) the opinion, based on available evidence, of healthcare professionals; the results of the manufacturer's own preliminary assessment of the incident: evidence of previous, similar incidents; other evidence held by the manufacturer.

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 incident.

Not all incidents 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 an incident 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. However, this does not include the testing, examination of medical devices or information supplied with the medical device that have not yet been put on the service in the user's site or handed over to the user.

3.3 Responsibilities of manufacturers and authorised representatives

3.3.1 The manufacturer or its authorised representative shall report to the Authority about incidents when the reporting criteria are met. Importer and distributor shall immediately report any incident that come to their attention to the manufacturer/AR.

3.3.2 Where an incident occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different manufacturers, each manufacturer or authorised representative shall submit a report to the Authority.

3.3.3 The manufacturer and AR shall establish appropriate communication channels to address all requirements pertaining to MPR to other establishment involved in the supply chain.

3.4 Reporting timeline

3.4.1 As soon as any personnel of the medical device manufacturers or its authorised representative, including sales personnel, are made aware of the incident, the timeline for reporting starts as follows;

a) within 30 days after the establishment becomes aware of an incident that is related to the failure of the medical device or a deterioration in its effectiveness, or any inadequacy in its labeling or in its instruction for use, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, or

b) within 10 days after the establishment becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were the incident to recur; or

c) within 48 hours after the establishment becomes aware that the incident is a serious threat to public health;

3.4.2 If there is uncertainty about whether the incident is reportable, the manufacturers or the authorised representative shall still submit a report within the timeframe stipulated.

3.4.3 Establishments shall not unduly delay the reporting of incident(s) if information is incomplete. The initial report of an incident should contain as much relevant detail as is immediately available, but shall not be delayed for the sake of gathering additional information. Refer Annex A for the reporting template.

4 Investigation of an incident

4.1 General requirements

The establishment shall investigate the cause of incident and conduct field corrective action if necessary, to prevent recurrence of the incident to ensure safety and performance of the medical device as specified in Regulation 5(2) of Medical Device (Duties and Obligations of Establishments) Regulations 2019.

4.2 Responsibilities of manufacturers and authorised representatives in investigation

4.2.1 The manufacturer and AR have the responsibility for investigating incidents and for taking any corrective action as appropriate. The manufacturer or authorised representative shall take the action necessary following the investigation of an incident, including consultation with the Authority and performing any FCA. The Authority may

take any further action it deems appropriate, consulting with manufacturer or authorised representative where possible.

4.2.2 The manufacturer and AR shall establish appropriate communication channels to ensure effective investigation and FCA can be carried throughout the supply chain of the medical device involved in the incident.

4.2.3 In the case of potential errors by users or third parties, labelling and instructions for use shall be carefully reviewed for any possible inadequacy.

4.3 Investigation report & reporting timeline

After completion of investigation, the establishment shall prepare the investigation report to address all findings and outcomes of the investigation and actions to be taken to eliminate or reduce the risk of incident recurrence. This report needs to be attached together with the completed Investigation Form (refer Annex B).

The investigation report and form shall be submitted to the Authority within 30 days after the submission of Mandatory Problem Report. However, the Authority may grant an extension time to the establishment to submit the investigation report if requested by the establishment.

5 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 manufacturer, 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.

This is without prejudice to the fact that the user should inform the manufacturer of any deficiency identified prior to the use of a medical device.

Examples:

i) The packaging of a sterile single use device is labelled 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 incident was that the device exceeded its service life or shelf-life as specified by the manufacturer and the failure mode is not unusual, the incident does not need to be reported.

ii) The service life or shelf-life is specified by the device manufacturer 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:

i) Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explanation of pacemaker required.

ii) 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.

iii) 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 manufacturer.

c) Protection against a fault functioned correctly

Incidents 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,
treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.

iv) A laboratory analyser 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 manufacturer allowed the analyser 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 manufacturer'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, with an appropriate risk assessment, prior to the occurrence of the incident and clinically acceptable in terms of the individual patient benefit are ordinarily not reportable.

ii) It is recommended that the manufacturer involves a clinician in making this decision.

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

Examples:

i) 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.

ii) 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.

iii) A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.

iv) 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.

v) 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) Incidents 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 incident resulting in death or serious deterioration in state of health has happened, the incident is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligible small previous incidents 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:

Manufacturer 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.

Annex A
(informative)

PART 1: MANDATORY PROBLEM REPORTING FORM
Section 40, Medical Device Act 737 (2012)

Notes:
1. This reporting form may be used by establishment as a template (medical device manufacturer (local)/ authorised representative/ distributor) to submit online reporting to any incident involving its medical device recorded inside or outside Malaysia only if the medical device is registered in Malaysia.
2. Although the format of the form might differ from one establishment to another, the contents of this form are mandatory. It is mandatory to complete all the information.

MPR Reference No.		
To be filled by the Authority		
Location of Incident		
Where the incident occurred*	☐ In Malaysia ☐ Outside Malaysia	
If incident occurred in Malaysia:		
Type of affected facility	☐ Government hospital/ clinic ☐ Private hospital/ clinic ☐ Unknown ☐ Others	
Name of institution*		
Address		
Telephone no.		
Fax no.		
Contact person at site of incident		
Name of institution*		
If incident occurred outside Malaysia:		
Name of country where the incident occurred	<List of all countries>	
Device Information		
Classification Device	General Medical Device ☐ Class A ☐ Class B ☐ Class C ☐ Class D	IVD Medical Device ☐ Class A ☐ Class B ☐ Class C ☐ Class D
Medical device registration no.*		
Device name		
Brand name		
Manufacturer name		
Device available in Malaysian market?*	☐ Yes ☐ No ☐ Others , please justify : _____	

Details of affected devices	Batch no.	Lot no.	Serial no.	Expiry Date
Please provide attachment if the row provided is insufficient.				
Background Information				
Report category* (please tick)	☐ Failure of device effectiveness ☐ Deterioration of device effectiveness ☐ Inadequacy in labelling or IFU ☐ Led to death of a patient, user or other person, ☐ Led to serious deterioration in the state of health of a patient, user or other person, ☐ may led to death or serious deterioration in the state of health of a patient, user or other person or could do so were the incident to recur ☐ Serious threat to public health			
Date of incident				
Date of establishment aware about the incident				
Incident Information				
Incident occurred related to:*	☐ Patient Device Interaction Problem ☐ Manufacturing, Packaging or Shipping Problem ☐ Chemical Problem ☐ Material Integrity Problem ☐ Mechanical Problem ☐ Optical Problem ☐ Electrical /Electronic Property Problem ☐ Calibration Problem ☐ Output Problem ☐ Temperature Problem ☐ Computer Software Problem ☐ Connection Problem ☐ Communication or Transmission Problem ☐ Infusion or Flow Problem ☐ Activation, Positioning or Separation Problem ☐ Protective Measures Problem ☐ Compatibility Problem ☐ Contamination / decontamination Problem ☐ Environmental Compatibility Problem ☐ Installation-Related Problem ☐ Labelling, Instructions for Use or Training Problem ☐ Human-Device Interface Problem ☐ Use of Device Problem ☐ Adverse Event Without Identified Device or Use Problem ☐ No Apparent Adverse Event ☐ Insufficient Information ☐ Appropriate Term/Code Not Available			
Description of incident*				

Device operator during time of incident (please tick)	☐ Healthcare Professional ☐ Patients ☐ Others: _____
Usage of device (please tick)	☐ Initial Use ☐ Single Use / Disposables ☐ Reuse of Single Use ☐ Reuse of Reusable ☐ Re-serviced/ Refurbished ☐ Others
Device disposition/ current location (please tick) *Note: Information on state of device is at the time of the report*	☐ Remain implanted ☐ Explanted ☐ Disposed ☐ Quarantined at user's site ☐ Quarantined at establishment's site ☐ Returned to manufacturer ☐ Others, please specify: _____ *(Example: Device has been destroyed, device remains implanted in the patient, device has been quarantined)*
List of other devices involved in the incident (if applicable)	
Immediate Action taken by the establishment during incident.	*Example: Recommendation to stop usage, advice to quarantine, additional CME to cater related issues)*

Submission of Investigation Report
☐ Within 30 days after submission of MPR ☐ Request for extension time; ☐90 days after submission of MPR ☐120 days after submission of MPR ☐150 days after submission of MPR ☐Longer than the above; Please specify: _____

Attestation	
I attest that the information provided by the user/ manufacturer submitted is true and correct.	
Signature:	
Name of reporting person:	
Date of this notification:	
Establishment stamp:	

Annex B
(informative)

PART 2: INVESTIGATION FORM
SECTION 40, MEDICAL DEVICE ACT 737 (2012)

Notes:
1. This form shall be accompanied with the investigation report otherwise the form will not be accepted.
2. This investigation form may be used by establishment as a template (medical device manufacturer (local)/ authorised representative/ distributor) to submit report on investigation involving any incidents related to its medical device recorded inside or outside Malaysia only if the medical device is available in Malaysian market.
3. Although the format of the form might differ from one establishment to another, the contents of this form are mandatory. It is mandatory to complete all the information.

MPR Reference No.	
To be filled by the Authority	
Results of Manufacturer Investigation	
Investigation findings	☐ Biological Problem Identified ☐ Electrical Problem Identified ☐ Electromagnetic Compatibility Problem Identified ☐ Interoperability Problem Identified ☐ Labelling and Instructions for Use/Maintenance ☐ Material and/or Chemical Problem Identified ☐ Mechanical Problem Identified ☐ Optical Problem Identified ☐ Clinical Imaging Problem Identified ☐ Software Problem Identified ☐ Thermal Problem ☐ Protective System Problem Identified ☐ Operational Problem Identified ☐ Patient Sample Problem ☐ Environment Problem Identified ☐ Manufacturing Process Problem Identified ☐ Maintenance Problem Identified ☐ Transport/Storage Problem Identified ☐ No Device Problem Found ☐ No Findings Available ☐ Results Pending Completion of Investigation ☐ Appropriate Term/Code Not Available
Please click more than one if there are more findings	
Root cause of the incident	

Corrective Action and Preventive Action has been taken by the manufacturer	☐ Yes ☐ No, please justify: _____	
IN MALAYSIA, this incident will lead towards:	☐ FCA ☐ Recall ☐ No action required	
Was this incident reported to other Regulatory Authorities?	☐ Yes, please select the Competent Authority the incident has been reported to: ☐ US FDA ☐ EU ☐ Australia ☐ Canada ☐ Japan ☐ Others, please specify: _____	
	☐ No	

Patient Information *(when information not available, please indicate as N/A)*	
Age	
Gender	
Patient outcome	☐ Death ☐ Life threatening ☐ Hospitalized ☐ Congenital anomaly ☐ Required intervention to prevent permanent impairment/ damage ☐ Others, please specify: _____

Other additional Information about incident

Attestation	
I attest that the information provided by the user/ manufacturer submitted is true and correct.	
Signature:	
Name of reporting person:	
Date of this notification:	
Establishment stamp:	

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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