Guidance for Medical Device Industry

Reporting of Device Defects, Adverse Events and Field Safety Corrective Actions

Health Product Vigilance Center
Strategy and Planning Division, Thai Food and Drug Administration
Ministry of Public Health

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1. Introduction

Medical devices are one of important products for the diagnosis, treatment and prevention of diseases. The Thai Food and Drug Administration (FDA), as a government agency responsible for regulating such products, has issued measures to ensure standard, quality and safety of medical devices marketed in Thailand. One of the measures is medical device vigilance, where, since 2016, marketing authorization holders, premises registrants and specification providers whose businesses are related to medical devices have been obliged to report the following problems regarding medical devices: medical device defects or adverse events occurring to consumers, and field safety corrective actions thereof. The Thai FDA prepared the Guidance for Medical Device Industry on Reporting of Device Defects, Adverse Effects and Field Safety Corrective Actions in September 2016.

For the purposes of ensuring its applicability, its relevance to the current situation and its usefulness for the benefit of consumer health protection and safety monitoring, as well as providing data record for appropriate medical device risk management which meets the objective of the monitoring and is in line with the Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions for Medical Devices, B.E. 2563 (2020) (Annex 1), the Thai FDA subsequently revises the medical device industry guidance on medical device vigilance.

2. Objective

The objective of this document is to serve as guidance for marketing authorization holders, business premises registrants and specification providers on the reporting of medical device defects or adverse events which occur to consumers as well as the reporting of field safety corrective actions thereof as required by the Notification of the Ministry of Public Health.

3. Scope

This guidance applies to all types of medical devices under the Medical Devices Act, B.E. 2551 (2008), as amended by the Medical Devices Act (No.2), B.E. 2562 (2019), which cover medical devices for human or animal use. These consist of medical devices used for diagnosis outside the body (in vitro diagnostic medical devices: IVDs) and medical devices not used for diagnosis outside the body (non- in vitro diagnostic medical devices: non-IVDs). Areas where reporting is required are:

(1) the reporting of medical device defects or adverse events occurring to customers for domestic cases;

(2) the reporting of device defect and adverse event summaries for foreign cases;

(3) the reporting of field safety corrective actions for both domestic and foreign cases.

4. Definitions

"Medical device"[1] means:

(1) any instrument, apparatus, appliance, implant inserted into the human or animal body, reagent, software, material or other similar or related article, intended by the manufacturer or product owner to be used for any one or more of the following purposes on human beings or animals, whether independently from, in conjunction with, or as an accessory of any other article:

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, correction, modification, or support in relation to anatomy or a physiological process of the body;

(d) supporting or sustaining life;

(e) birth control or assisted reproduction;

(f) alleviating or compensating incapacities or disability;

(g) providing information by means of in vitro examination of specimens derived from the human or animal body ,for a medical purpose or diagnosis;

(h) disinfection or sterilization of medical devices;

(2) supplementary equipment to be used in conjunction with a medical device under (1);

(3) instrument, appliance, apparatus, product or any other object prescribed in the Notification of the Minister as a medical device;

provided that the medical device dose not achieve its principal intended action described in (1) in or on human or animal body primarily by pharmacological, immunological or metabolic mean.

"Supplementary equipment" means an article, appliance or product specifically intended by the manufacturer or owner to be used in conjunction with a medical device in order to cause or facilitate such medical device to be usable for its intended purpose.

"Manufacture" means an act of making, assembling, inventing, divisional repackaging, bundling, improving, transforming, modifying or sterilizing.

"Sell" means an act of selling, distributing, supplying, providing, giving, exchanging, lending, granting a lease, granting a lease on a hire-purchase basis or transferring rights or possession to another person, for the purpose of trade, and shall also include an act of having in possession for sale.

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[1] The definition of medical device refers to that under the Medical Devices Act, B.E. 2551 (2008) as amended by the Act (No. 2), B.E. 2562 (2019)

“Import” means an act of bringing or ordering (product) into the country.

“Marketing authorization holder” means a person to whom a license is granted under the Medical Devices Act, B.E. 2551 (2008), as amended by the Medical Devices Act (No.2), B.E. 2562 (2019), and, in the case where a juristic person is granted a license, shall also include a person appointed or entrusted by the juristic person to operate the business.

“Specification provider” means a person to whom a specification provision acknowledgment license is granted under the Medical Devices Act, B.E. 2551 (2008), as amended by the Medical Devices Act (No.2), B.E. 2562 (2019), and, in the case where a juristic person is granted a specification provision acknowledgment license, shall also include a person appointed or entrusted by the juristic person to operate the business.

“Notifier” means a person to whom a notifier license is granted under the Medical Devices Act, B.E. 2551 (2008), as amended by the Medical Devices Act (No.2), B.E. 2562 (2019), and, in the case where a juristic person is granted a notification certificate, shall also include a person appointed or entrusted by the juristic person to operate the business.

“Business premises registrant” means a person to whom a business premises registration license is granted under the Medical Devices Act, B.E. 2551 (2008), as amended by the Medical Devices Act (No.2), B.E. 2562 (2019), and, in the case where a juristic person is granted a business premises registration license, shall also include a person appointed or entrusted by the juristic person to operate the business.

“Consumer” means a patient, a sick animal, a user of medical device, or any person affected by a medical device.

“Physical manufacturer” means a person or a juristic person who performs the activity of manufacturer.

“Product owner” means a natural person or a justice person who:

(1) sells a medical device under his or her own name or under a trademark, design, trade name, other name or other mark which he or she owns or controls, and;

(2) is responsible for designing, manufacturing, assembling, processing, display of label, packaging, refurbishing or modifying a medical device, whether on his or her own or by entrusting other to do so.

"Device defect" means a malfunction or deterioration in characteristic or performance of a medical device, or display of incorrect/erroneous result, or result which deviates from a specification, or a defect in design of a medical device, or incorrect or incomplete statement on the label, package insert or instruction for use, or use error.

"Adverse event (AE)" means any event resulting from a malfunction or deterioration in characteristic or performance of a medical device or a use error which causes, may be a cause of or contributes to the death or injury of a consumer.

"Field safety corrective action (FSCA)" means an action taken by a product owner to reduce risk from a serious threat to public health or risk of consumer's death or serious harm which results from the use of a medical device.

"Serious threat to public health" means an event resulting in imminent risk of death, serious deterioration in state of health or serious illness which requires a remedial action. This includes the following events:

(1) an event that is of significant and unexpected nature such that it became alarming as potential public health hazard, such as human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD), etc. or

(2) an event of multiple deaths occurring at short intervals.

"Serious injury" means any of the following conditions of a consumer:

(1) life-threatening illness or injury

(2) permanent impairment of body function or permanent damage to a body structure;

(3) a condition necessitating medical or surgical intervention to prevent disability, permanent impairment of a body function or permanent damage to a body structure.

"Corrective action" means an action to prevent recurrence of an adverse event.

"Preventive action" means an action to prevent occurrence of an adverse event.

"Health hazard evaluation report" means a report which evaluates health hazards associated with a medical device. This consists of estimation of the probability of any device defects, its severity and probability of adverse events occurring to consumers who are exposed to or use the medical device.

5. Persons Responsible for Report Submission

The following persons are required to submit reports of any device defects or adverse events occurring to consumers, medical device defect and adverse event summary reports and field safety corrective action reports:

5.1 Business premises registrant for manufacture or import of the medical device;

5.2 Market authorization holder for manufacture or import of the medical device;

5.3 Specification provider for manufacture or import of the medical device;

5.4 Notifier for manufacture or import of the medical device.

Note: In the case of an entrusted person to report on one's behalf, please proceed according to the "User Manual for the Information System of the Health Product Vigilance Center". For more details, please visit the website https://hpvcth.fda.moph.go.th/. Select "Publications", topic "Manual & Guidance" and then sub-topic "for entrepreneurs".

6. Guidance on Reporting of Medical Device Defects or Adverse Events Occurring to Customers for Domestic Cases

6.1 What to Report

The responsible person in Article 5 must report device defects or adverse events occurring to consumers in Thailand (domestic cases), in accordance with the following criteria:

(1) an incident occurs in Thailand (including situations where testing was performed on the device (according to the manufacturer's quality assurance system), examination of the information supplied with the device (i.e. label/package insert/instruction for use) or any scientific data or evidence indicates some factor that could lead to an event; **and**

(2) the medical device is suspected to be related to such incident, **and**;

(3) the incident leads to one of the following cases:

- serious threat to public health;
- death or serious injury;
- where there is scientific data or evidence indicating that a recurrence of the incident may lead to death or serious injury of a consumer.

In case of doubt on whether to report an incident or not, the reporter should report it as a general principle. (details of the decision tool for the reporting of medical device defect or adverse event and examples of incidents where reporting is required and not required can be found under Annex 2 and Annex 3).

6.2 Minimum Criteria for Reporting

Every report should be completed with required information as much as possible so that the cause of device defect or adverse event which occurs to a consumer can be adequately evaluated. Following is the minimum required information in each report.:

(1) **information regarding the reporter**: business premises registration number/seller's license number, name of business premises, name, telephone number and email address of the reporter;

(2) **details of the medical device**: trade name, GMDN code, type of medical device, class of medical device according to risk classification, indication/intended use, market authorization number/number of specification provision acknowledgment license/number of notifier license, serial number/lot or batch number, name and country of the physical manufacturer, and name and country of the product owner;

(3) **information regarding the place where the defect/adverse event occurs**: name of the place and contact person at the place of occurrence;

(4) **information regarding the device defect/adverse event**: classification of the incident, device defect (medical device problem) (IMDRF Annex A), or health effects - clinical signs, symptoms and conditions (IMDRF Annex E), date of occurrence, date of reporter's awareness, the user at the time of occurrence, the way the device was used; and number of people affected by the incident;

(5) **Information regarding each person affected by the incident** (only for adverse event): information and details of each affected individual, age, gender, and patient outcome.

Note: In the case of a final report, the following details of the investigation/inspection result conducted by the manufacturer/product owner must be given: type of investigation (IMDRF Annex B), investigation findings (IMDRF Annex C), investigation conclusion (IMDRF Annex D), remedial action/corrective action/preventive action, and details of the FSCA.

6.3 Documentation for Report Submission shall be submitted in accordance with the Medical Device Defect or Adverse Event Report Form for a Domestic Case (Form Ror Mor Por 1) under Annex 4.

6.4 Reporting Timeframes

The reporter should report the incident relating to medical device defect or adverse event occurring to a customer in Thailand to the Thai FDA as soon as possible within the timeframes for initial report and follow-up report specified in the table.

Types of Reports	Timeframe (As from the Awareness Date)
1) Initial report 1.1) Serious threat to public health	Immediately or not later than 48 hours
1.2) Death or serious injury	Immediately or within 10 days
1.3) scientific data or evidence indicating that a recurrence of the incident may lead to death or serious injury of a consumer	Within 30 days
2) Follow-up report	Within 30 days as from the submission date of the initial report

6.5 Reporting Channels

(1) Reporting the Ror Mor Por 1- report in PDF format to adr@fda.moph.go.th.

(2) Hard copy of the Ror Mor Por 1- report can be mailed or handed in person to the Strategy and Planning Division, Health Product Vigilance Center, Thai Food and Drug Administration, Ministry of Public Health, Talat Kwan Sub-district, Muang District, Nonthaburi 11000.

(3) Reporting the Ror Mor Por 1- report through the AE Online Reporting on the Health Product Vigilance Center website.

6.6 Follow-up report

After the submission of the initial report, the responsible person must follow up and gather additional relevant information and investigate the cause and assess the risk/harm to human. Follow-up reports and investigation results must be submitted within the timeframes specified in 6.4. The number of the follow-up, company's reference number and the Thai FDA reference number given to the initial report (if known) should be clearly identified.

7. Guidance on Reporting of Device Defect and Adverse Event Summary for Foreign Cases

7.1 What to Report

The responsible person must submit a device defect and adverse event summary report in the following cases:

(1) the medical device is registered, manufactured and used in Thailand, or imported into Thailand, **and**;

(2) the medical device is suspected to be related to an incident which occurs during the periodic reporting cycle (including situations where testing was performed on the device (according to the manufacturer's quality assurance system), examination of the information supplied with the device (i.e. label/package insert/instruction for use) or any scientific data or evidence indicates some factor that could lead to an event);

(3) the incident leads to one of the following cases:

- serious threat to public health;
- death or serious injury;
- where there is scientific data or evidence indicating that a recurrence of the incident may lead to death or serious injury of a consumer

7.2 Minimum Criteria for Reporting

Every report should be completed with required information as much as possible so that the cause of device defect or adverse event which occurs to a consumer can be adequately evaluated. The following is the minimum required information.

(1) **information regarding the reporter**: business premises registration number/seller's license number, name of business premises, name, telephone number and email address of the reporter;

(2) **details of the medical device**: trade name, GMDN code, indication/intended use, market authorization number/number of specification provision acknowledgment license/number of notifier license, name and country of the physical manufacturer, and name and country of the product owner;

(3) **information regarding the sale of medical device of such model number**: number of devices supplied globally (including Thailand) and number of devices supplied in Thailand, in the smallest unit of measurement possible;

(4) **information regarding the defect defect/adverse event of such model number**: by identifying the number of reports of device defect/adverse event (IMDRF Annex A and E) which occurs in Thailand and abroad, categorized by the seriousness of the outcomes: serious threat to public health, death, and serious injury, together with any corrective action carried out by relevant regulatory agency in the country of the product owner, as well as identifying whether each of these incidents is a trending report.

7.3 Documentation for Report Submission

(1) Medical Device Defect and Adverse Event Summary Report Form (Form Ror Mor Por. 2) under Annex 4.

7.4 Reporting Timeframes

(1) Any incidents occurring between January and June should be reported by August.

(2) Any incidents occurring between July and December should be reported by February of the next year

7.5 Reporting Channels

(1) Reporting the Ror Mor Por 2- report in PDF format to adr@fda.moph.go.th.

(2) Reporting the Ror Mor Por 2- report through the AE Online Reporting on the Health Product Vigilance Center website.

8. Guidance on Reporting of Field Safety Corrective Action (FSCA) for both Domestic and Foreign Cases

8.1 What to Report

The responsible person must report corrective actions to ensure product safety in the following cases:

(1) any actions taken by the product owner, either in the country or outside the country, such as product recall, device modification, device replacement, device destruction, safety notification, etc., and

(2) purpose of action is to eliminate/reduce the risks associated with device defects or adverse events occurring to consumers which could result in serious threat to public health, imminent risks of death or serious injury from such medical device and;

(3) there is business premises registration, specification provision acknowledgement license, notifier license or market authorization number for import or sales of the medical device in Thailand; in case the aforementioned is no longer valid, a report is required only when the medical device is still in use.

Medical device modification includes retrofit or changes to the labelling or instructions for use (permanent or temporary), software upgrades, and changes to the clinical management of patients.

8.2 Minimum Criteria for Reporting

Every report should be completed with required information as much as possible for the benefit of assessing whether the action taken is sufficient, appropriate, and cable of preventing the risks or harm to consumers' health. Following is minimum required information:

(1) **type of FSCA**: information regarding product recall, device modification, device replacement, device destruction, safety notification, and other related activities;

(2) **information regarding the reporter**: business premises registration number/ seller's license number, name of business premises, name, telephone number and email address of the reporter;

(3) **details of the medical device**: trade name, GMDN code, type of medical device, class of medical device according to risk classification, indication/intended use, market authorization number/number of specification provision acknowledgment license/number of notifier license, serial number/lot or batch number, name and country of the physical manufacturer, and name and country of the product owner;

(4) **FSCA information**: reason for the FSCA (device defect or adverse event), health hazard evaluation report, FSCA strategy, communication of the FSCA, description of the FSCA, number of affected medical devices, number of medical devices distributed/exported, number of remaining medical devices, and number of medical devices expected to be imported.

Note: A report can constitute the initial and final report submitted in the case where no corrective action is taken in Thailand.

8.3 Documentation for Report Submission

(1) Field Safety Corrective Action Report Form Both Domestic and Foreign Cases (Form Ror Mor Por. 3) under Annex 4.

(2) FSCA strategy to accompany the initial report.

(3) Health hazard evaluation report to accompany the initial report (if any).

(4) Field Safety Notice (FSN) to accompany the initial report.

8.4 Reporting Timeframes

The reporter should report the FSCA to the Thai FDA according to the timeframes below:

After the business premises registrant, the market authorization holder, the specification provider or notifier has conducted the risk evaluation of such medical device and has carried out the FSCA. The reporter should report the FSCA to the Thai FDA according to the timeframes as specified in the table.

Types of Reports	Timeframe
1) Initial report	Within 48 hours as from the awareness date of the implementation of the FSCA
2) Follow-up/final report	Within 21 days as from the submission date of the previous report

8.5 Reporting Channels

(1) Reporting the Ror Mor Por 3- report in PDF format to adr@fda.moph.go.th.

(2) Hard copy of the Ror Mor Por 3- report can be mailed or handed in person to the Strategy and Planning Division, Thai Food and Drug Administration, Ministry of Public Health, Talat Kwan Sub-district, Muang District, Nonthaburi, 11000.

(3) Reporting the Ror Mor Por 3- report through the AE Online Reporting on the Health Product Vigilance Center website.

8.6 Follow-up report and final report

After the submission of the initial report, the responsible person must follow up and gather additional relevant information, implement the FSCA strategy, and report the progress of the corrective action under the heading “Product status” of the medical device in Thailand, all the results of which should be reported within the timeframes specified under 8.4. The number of the follow-up, company’s reference number and the Thai FDA reference number given to the initial report (if known) should be clearly identified.

In the case of final report, the responsible person must identify the date of completion as well as the result of the final risk evaluation (where it differs from that of the initial evaluation), recommendations for the prevention of reoccurrence, instructions for the handling of affected medical devices, such as the return of affected medical devices to the product owner, device destruction, or any other actions, which will be accompanied by relevant documents and evidence.

Annexes

Annex 1 Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions for Medical Devices, B.E. 2563 (2020)

Annex 2 **Flowchart 1** Decision Tool for the Reporting of Device Defect or Adverse Event Occurring to a Consumer

Flowchart 2 Decision Tool for Field Safety Corrective Action Reporting

Annex 3 Examples of Incidents of Medical Device Defects or Adverse Events and Field Safety Corrective Actions

Annex 4 Notification of the Thai Food and Drug Administration Re: Prescription of Report Forms under the Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions for Medical Devices, B.E. 2563 (2020)

Form Ror Mor Por 1 Medical Device Defect or Adverse Event Report Form for a Domestic Case

Form Ror Mor Por 2 Device Defect and Adverse Event Summary Report Form for Foreign Cases

Form Ror Mor Por 3 Field Safety Corrective Action Report Form Both Domestic and Foreign Cases

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH RE: CRITERIA, PROCEDURES AND CONDITIONS FOR PREPARATION OF REPORTS ON MEDICAL DEVICE DEFECTS OR ADVERSE EVENTS OCCURRING TO CONSUMERS AND REPORTS ON FIELD SAFETY CORRECTIVE ACTIONS FOR MEDICAL DEVICES, B.E. 2563 (2020)*

Whereas it is expedient to revise the Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions to ensure that it is suitable to and compatible with the present situations, with a view to safeguarding the health and safety of consumers as well as to gather information for appropriate risk management of medical devices;

By virtue of the provisions of section 5 paragraph one of the Medical Devices Act, B.E. 2551 (2008) and section 41 (4) of the Medical Devices Act, B.E. 2551 (2008) as amended by the Medical Devices Act (No. 2), B.E. 2562 (2019), the Minister of Public Health hereby issues the Notification as follows.

Clause 1. The Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions dated the 22nd day of March B.E. 2559 (2016) shall be repealed.

Clause 2. In this Notification:

"consumer" means a patient, a sick animal, a user of the medical device or any other person affected by a medical device;

"device defect" means a malfunction or deterioration in characteristic or or performance of a medical device, or display of inccorect/erroneous result, or result which deviates from a specification, or defect in design of a medical device, or incorrect or incomplete statement on the label, package insert or instruction for use, or use error;

"adverse event" means any event resulting from a malfunction or deterioration in characteristic or performance of a medical device or a use error which causes, may be a cause of or contributes to the death or injury of a consumer;

"field safety corrective action" means any action taken by the product owner to reduce risk from a serious threat to public health or risks of consumer's death or serious harm which are resulted from the use of a medical device;

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* Published in the Government Gazette, Vol. 137, Special Issue, Part 286d, page 5, dated 7th December B.E. 2563 (2020)

"serious threat to public health" means an event resulting in imminent risk of death, serious deterioration in state of health or serious illness which requires a remedial action; this includes the following events:

(1) an event that is of significant and unexpected nature such that it became alarming as potential public health hazard, such as Human Immunodeficiency Virus (HIV), Creutzfeldt-Jacob Disease (CJD); or

(2) an event of multiple deaths occurring at short intervals;

"serious injury" means any of the following conditions of a consumer:

(1) life-threatening illness or injury;

(2) permanent impairment of body function or permanent damage to a body structure;

(3) a condition necessitating medical or surgical intervention to prevent, permanent impairment of a body function or permanent damage to a body structure

"product owner" means a natural person or a juristic person who:

(1) sells a medical device under his or her own name or under a trademark, design, trade name, other name or other mark which he or she owns or controls, and;

(2) is responsible for designing, manufacturing, assembling, processing, display of label or packaging, irrespective of whether it is done by him or her or by another person entrusted to act on his or her behalf.

Clause 3. The business premises registrant, market authorization holder, specification provider or notifier shall prepare reports on device defects or adverse events occurring to consumers as well as reports on field safety corrective actions for medical device, whether the device defects or adverse events occur within or outside the country, in compliance with the following criteria:

(1) a report on medical device defects or adverse events occurring to consumers with one of the following outcomes:

(a) a serious threat to public health;

(b) death or a serious injury;

(c) a case where there is scientific data or evidence indicating that a recurrence of the incident may lead to the death or a serious injury of consumers;

(2) a report on field safety corrective actions for medical device taken by the product owner to reduce risks from medical device defects or adverse events occurring to consumers.

Clause 4. The business premise registrant, marketing authorization holder, specification provider or notifier shall prepare reports under clause 3 for submission to the Thai Food and Drug Administration within the prescribed period as follows:

(1) reporting of device defects or adverse events occurring to consumers:

(a) cases of events occurring within the country:

1) initial report:

1.1 in cases of serious threat to public health, the report shall be submitted immediately or within forty-eight hours at the latest from the awareness date;

1.2 in cases of death or a serious injury, the report shall be submitted immediately or within ten days at the latest from the awareness date;

1.3 in cases where there is academic data or evidence indicating that a recurrence of the incident may lead to the death or a serious injury of consumers, the report shall be submitted within thirty days from the awareness date;

2) the follow-up report shall be submitted within thirty days from the date of submission of the initial report;

(b) cases of events occurring outside the country: the report shall be submitted twice a year. A report on events occurring between January and June shall be submitted by August, and a report on events occurring between July and December shall be submitted by February. The events shall also be reported as requested by the Thai Food and Drug Administration, except for those concerning a medical device manufactured and sold in the country which shall be reported in accordance with (a);

(2) reporting of field safety corrective actions for medical device both in the country and outside the country:

(a) The initial report shall be submitted within forty-eight hours from the date on which the field safety corrective action for the medical device is known to have been carried out;

(b) The follow-up report or final report shall be submitted within twenty-one days from the date of the previous report.

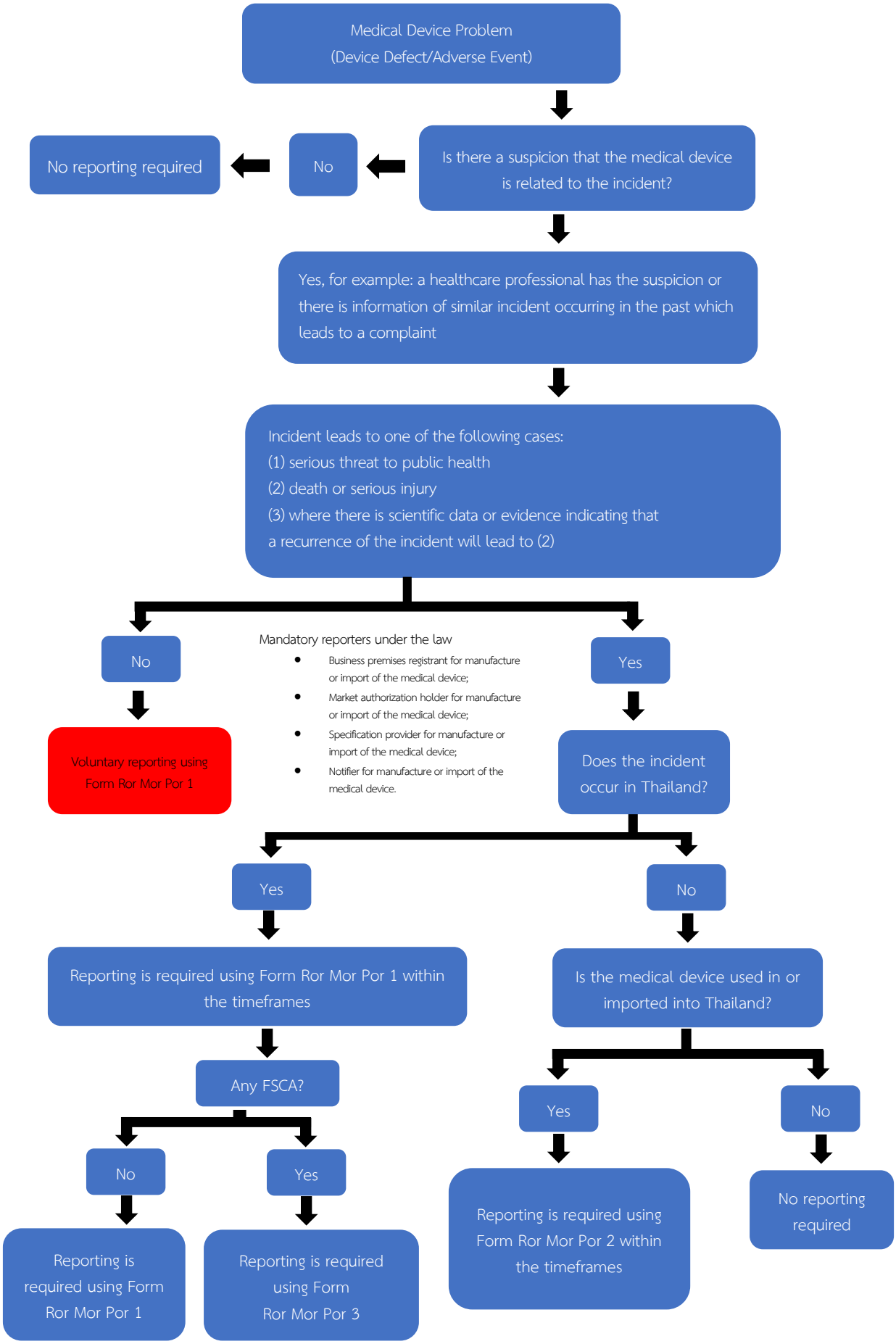
Clause 5. The report shall be made in the form of report specified in the Notification by the Secretary-General of the Thai Food and Drug Administration.

Clause 6. This Notification shall come into force after the expiration of sixty days from the date of its publication in the Government Gazette.

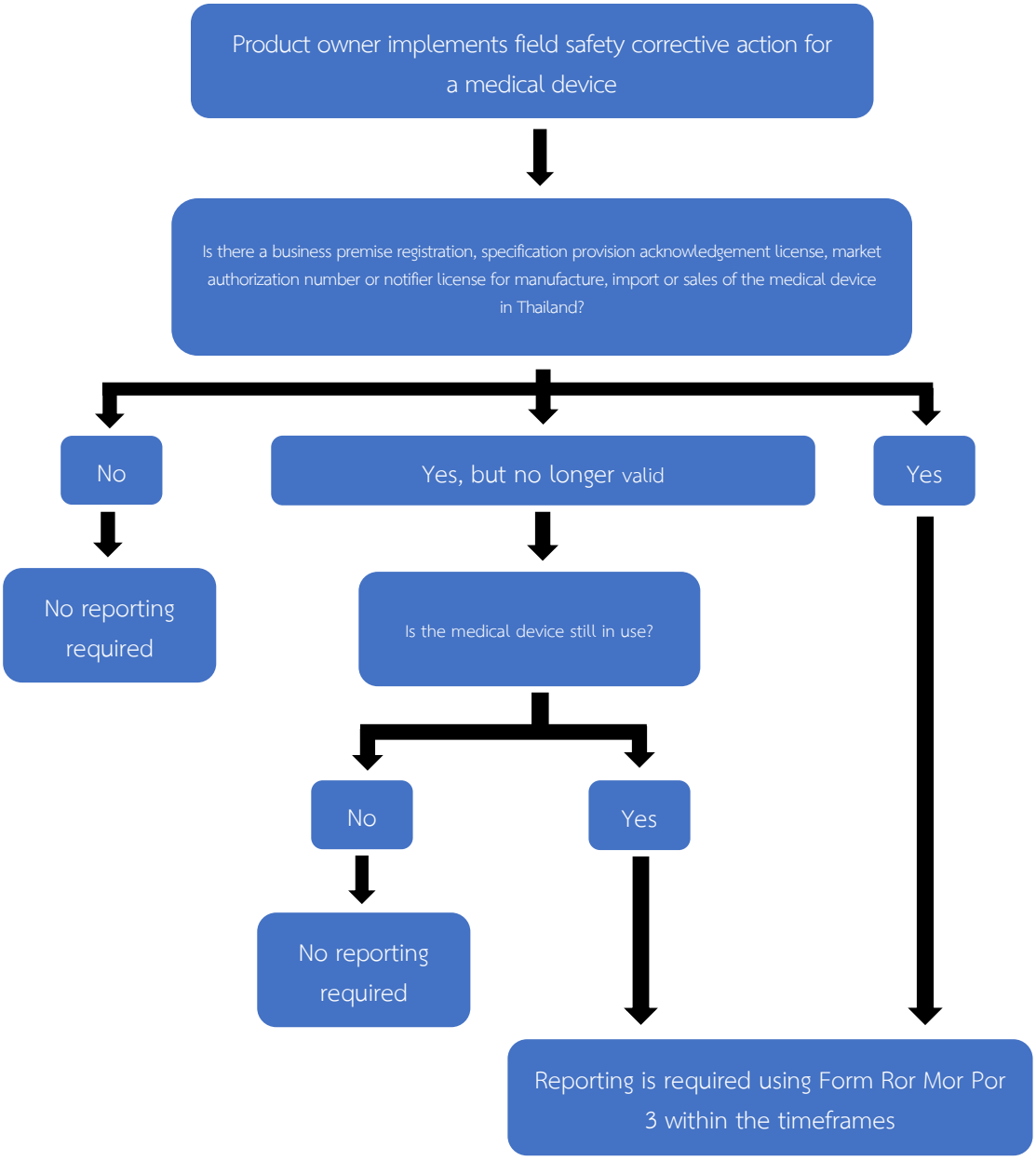
Announced on the 22nd day of October B.E. 2563 (2020)

Anutin Charnvirakul

Minister of Public Health



Flowchart 1 Decision Tool for the Reporting of Device Defect or Adverse Event Occurring to a Consumer



Flowchart 2 Decision Tool for the Field Safety Corrective Action Reporting

Examples of Incidents of Medical Device Defects or Adverse Events and Field Safety Corrective Actions

1. Examples of reportable medical device defects or adverse events

1.1 Loss of sensing in a defibrillator and the indicator did not show results as specified in the instruction. The incident results in death.

1.2 Sterile single use device packaging is labelled with the caution 'do not use if package is opened or damaged'. The label is placed by incorrect design on inner packaging. Outer package is removed but device is not used during procedure. Device is stored with inner packaging only which does not offer a sufficient sterile barrier.

1.3 A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

1.4 An infusion pump stops, due to a malfunction, but fails to give an alarm. Patient receives under-infusion of needed fluids and requires extra days in hospital to correct.

1.5 Healthcare professional reported that during implant of a heart valve, the sewing cuff is discovered to be defective. The valve was abandoned and a new valve was implanted and pumping time during surgery was extended.

1.6 During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to malfunction. Patient died

1.7 Fatigue testing performed on a commercialized heart valve bio prosthesis demonstrates premature failure, which resulted in risk to public health.

1.8 Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

2. Examples of non-reportable medical device defects or adverse events

2.1 Deficiency of a new device found by the user prior to its use

(1) User performs an inflation test prior to inserting the balloon catheter in the patient as required in the instructions for use accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured.

(2) Sterile single use device packaging is labeled with the caution 'do not use if package is opened or damaged'. Open package seals are discovered prior to use. Device is not used.

2.2 Adverse effect caused by patient conditions

(1) Early revision of an orthopedic implant due to loosening caused by the patient developing osteoporosis

(2) A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.

(3) Death of a patient not associated with an implant or device.

2.3 Use of a medical device beyond its service life

(1) A user is exposed to infected blood as result of his using expired gloves

(2) A drill bit was used beyond end of specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.

2.4 Protection against a fault functioned correctly and where no death or serious injury occurs

(1) 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.

(2) Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm and there was no injury to the patient.

2.5 Remote likelihood of occurrence of death or serious injury

(1) Manufacturer of pacemaker released on the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is remote. No patients experienced adverse health effects.

(2) A particle was detected in one piece of contact lens, and there was remote likelihood of serious injury. No patient was affected.

2.6 Expected and foreseeable side effects

(1) 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.

(2) Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.

2.7 Adverse effects described in a previous advisory notice

(1) Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration did not have to be reported if they did not cause any serious injury or death.

3. Examples of <u>reportable</u> field safety corrective action

3.1 Fatigue testing performed on a commercialized heart valve bio prosthesis demonstrates premature failure, which resulted in a risk to public health. The FSCA should be reported.

3.2 A defect is discovered in one (hitherto unopened) sample of a batch (lot) of a contact lens disinfecting agent that could lead to incidence of microbial keratitis in some patients. The manufacturer initiates a FSCA of this batch. The FSCA should be reported.

3.3 A manufacturer of an immunohematology analyzer received complaints of an ABO blood grouping system results being attributed to the wrong patient identification. The error proved to be due to the analyzers software, which was subsequently updated. The FSCA should be reported.

3.4 IVF/ART manufacturer informs users of an error on the labelling of their device which indicates a shelf life longer than the validated shelf life for the product. The FSCA should be reported.

NOTIFICATION OF THE THAI FOOD AND DRUG ADMINISTRATION RE: PRESCRIPTION OF REPORT FORMS UNDER THE NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH RE: CRITERIA, PROCEDURES AND CONDITIONS FOR PREPARATION OF REPORTS ON MEDICAL DEVICE DEFECTS OR ADVERSE EVENTS OCCURRING TO CONSUMERS AND REPORTS ON FIELD SAFETY CORRECTIVE ACTIONS FOR MEDICAL DEVICES, B.E. 2563 (2020)*

By virtue of the provision of clause 5 of the Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions for Medical Devices, B.E. 2563 (2020), dated 22nd October B.E. 2563 (2020), the Secretary-General of the Thai Food and Drug Administration hereby issues the Notification as follows:

Clause 1. Business premise registrants, market authorization holder s, specification providers, or notifiers shall prepare the reports on medical device defects or adverse events occurring to consumers, as well as the reports on field safety corrective actions for medical devices to be submitted to the Thai Food and Drug Administration using the forms annexed to this Notification, as follows:

(1) Medical Device Defect or Adverse Event Report Form for a Domestic Case, in accordance with Form Ror Mor Por 1;

(2) Device Defect and Adverse Event Summary Report Form for Foreign Cases, in accordance with Form Ror Mor Por 2;

(3) Field Safety Corrective Action Report Form Both Domestic and Foreign Cases, in accordance with Form Ror Mor Por 3.

Clause 2. This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

Announced on the 20th day of January B.E. 2564 (2021)
Paisan Dankum
Secretary-General of the Thai Food and Drug Administration

* Published in the Government Gazette, Vol. 138, Special Issue, Part 27d, page 17, dated 4th February B.E. 2564 (2021)

Company's reference No. .....
HPVC-MD1- .....

Medical Device Defect or Adverse Event Report Form for a Domestic Case

○ Device defect	○ Adverse event		
Report type	☐ Initial ☐ Follow-up No. ..... ☐ Final ☐ Trend		
1. Company information			
Type of reporter	☐ Manufacturer ☐ Importer ☐ Seller License holder ☐ Other, specify		
Establishment License No./Seller's License No.			
Company's name			
Address			
Reporter		Position	
Telephone No.		E-mail	
Other regulatory authorities to which this report was also sent			
2. Device details			
Trade name			
Common name			
GMDN code			
Type of medical device	○ IVD ○ Non-IVD	Risk classification	○ Class I ○ Class II ○ Class III ○ Class IV
Indication/intended use			
Device regulatory status	○ Licensed medical device No. ..... ○ Notified medical device No. ..... ○ Listed medical device No. ..... ○ Other, specify		
Catalogue No.		Model No.	Lot/Batch No.
Serial No.		Software version	
Accessories			
Physical manufacturer			
Address			
Country		E-mail	
Product owner			
Address			
Country		E-mail	
3. Healthcare facility information			
Facility's name			
Address			
Contact person's name		Position	
Telephone No.		E-mail	
Current location of device			

4. Information of device defect/adverse event			
Classification of incident	○ Serious ○ Serious threat to public health ○ Death ○ Serious injury ○ Non-serious		
Medical device problem (IMDRF Annex A)			
Clinical signs, symptoms and conditions (IMDRF Annex E)			
Event description			
Date of incident		Company awareness date	
Have any of the similar events occurred?	○ Yes (specify the country) ..... ○ No ○ Unknown		
Have any of other AE occurred by using the medical device for the same cause?	○ Yes, country ..... frequency of occurrence ..... ○ No ○ Unknown		
User of device at the time of the event	○ Healthcare professional ○ Patient ○ Patient/sick animal caregiver ○ Other, specify		
Usage of device	○ Initial use ○ Reuse of a single use device ○ Reuse of a reusable device ○ Re-service/Refurbished ○ Other, specify		
Number of patients involved		Number of devices involved	
5. Patient information (only for adverse event)			
Affected person	○ Patient ○ Sick animal ○ Patient/sick animal caregiver ○ Healthcare professional ○ Other, specify ..... ○ Unknown		
Gender	○ Male ○ Female ○ Unknown		
Age at the time of the incident	..... (year/month/day) ○ Unknown		
Weight	..... kg.		
Health impact (IMDRF Annex F)			

Treatment of affected person	
Patient outcome	○ Death (Date: ...../...../.....) ○ Not yet recovered ○ Recovered (Date: ...../...../.....) ○ Other, specify .....
6. Results of investigation/inspection from manufacturer/product owner	
Type of investigation (IMDRF Annex B)	
Investigation findings (IMDRF Annex C)	
Investigation conclusion (IMDRF Annex D)	
Component (IMDRF Annex G)	
Is there any policy created for Field Safety Corrective Action?	
○ No ○ Yes (HPVC-MD3-.....)	
Remedial action/corrective action/preventive action	
7. Other information	

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....

Company's reference No. .....
HPVC-MD2- .....

Device Defect and Adverse Event Summary Report Form for Foreign Cases

Reporting period ○ Jan-Jun ○ Jul-Dec in the year .....

1. Company information			
Type of reporter	☐ Manufacturer ☐ Importer ☐ Seller License holder ☐ Other, specify		
Establishment License No./Seller's License No.			
Company's name			
Address			
Reporter		Position	
Telephone No.		E-mail	
2. Device details			
Trade name			
Common name			
GMDN code			
Indication/intended use			
Device regulatory status	○ Licensed medical device No. ..... ○ Notified medical device No. ..... ○ Listed medical device No. ..... ○ Other, specify		
Physical manufacturer		Country	
Product owner		Country	

Model number												
No. of devices supplied by model												
No. of devices supplied worldwide (including Thailand)												
No. of devices supplied in Thailand												
No. of Device Defect/Adverse Event (AE) by model												
Device Defect/AE	①		②		③		**Total**		**% Rate**		**RA action**	**Trending report**
	WW	**TH**	**WW**	**TH**	**WW**	**TH**	**WW**	**TH**	**WW**	**TH**		
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA

Model number												
No. of devices supplied by model												
No. of devices supplied worldwide (including Thailand)												
No. of devices supplied in Thailand												
No. of Device Defect/Adverse Event (AE) by model												
Device Defect/AE	①		②		③		**Total**		**% Rate**		**RA action**	**Trending report**
	WW	**TH**	**WW**	**TH**	**WW**	**TH**	**WW**	**TH**	**WW**	**TH**		
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA
											Y/N/NA	Y/N/NA

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....

Notes:

1. ① = serious threat to public health, ② = death, ③ = serious injury, WW = worldwide, TH = Thailand.
2. %Rate = "(No. of Device Defect/AE ÷ No. supplied) × 100".
3. RA action = are there any regulatory/corrective actions/notification by the manufacturer? (Y = Yes, N = No, NA = Not available).
4. Trending Report = Is %Rate exceeding the threshold? (Y = Yes, N = No, NA = Not available).
5. One brand name/report.

Company's reference No. .....
HPVC-MD3- .....

Field Safety Corrective Action Report Form Both Domestic and Foreign Cases

Report type	☐ Initial ☐ Follow-up No. ..... ☐ Final			
1. Type of Field Safety Corrective Action (FSCA)				
☐ Product recall ○ Class I ○ Class II ○ Class III ☐ Device modification ☐ Retrofit ☐ Change to the labeling or design change ○ Permanent ○ Temporary ☐ Software upgrades ☐ Modification to the clinical management of patients			☐ Device exchange ☐ Device destruction ☐ Advice given by product owner regarding the use of the device ☐ Other, specify	
2. Company information				
Type of reporter	☐ Manufacturer ☐ Importer ☐ Seller License holder ☐ Other, specify			
Establishment License No./Seller's License No.				
Company's name				
Address				
Reporter			Position	
Telephone No.			E-mail	
3. Device details				
Trade name				
Common name				
GMDN code				
Type of medical device	○ IVD ○ Non-IVD	Risk classification	○ Class I ○ Class II ○ Class III ○ Class IV	
Indication/intended use				
Device regulatory status	○ Licensed medical device No. ..... ○ Notified medical device No. ..... ○ Listed medical device No. ..... ○ Other, specify			
Catalogue No.				
Model No.				
Lot/Batch No.				
Serial No.				
Software version				
Accessories				

Physical manufacturer			
Address			
Country		E-mail	
Product owner			
Address			
Country		E-mail	

4. FSCA information

Reason for the FSCA	☐ Device Defect ..... ☐ Adverse Event ..... ☐ Other, specify .....
Health Hazard Evaluation Report	
FSCA strategy	

The FSCA communication of corrective action that sent to all consignees

☐ In Thailand	☐ Food and Drug Administration Date sent ..... ☐ Medical center/Healthcare professional/Patient Expected date to be sent ..... Completed date .....
☐ Other countries	Date sent .....

Corrective action for safety

☐ In Thailand	Expected date of action ..... Date of action ..... Expected date to be completed .....
☐ Other countries	Expected date of action ..... Date of action .....

Number of affected medical device	
Number of affected medical device sold/distributed	
Number of affected medical device remaining	
Number of affected medical device expected to be imported	

Product status (only follow-up and final report)

Model No.	Batch No. & Manufacturing or expiry date	Quantity manufactured or imported	Quantity exported	Quantity remaining in warehouse	Quantity sold	Quantity recalled	Quantity corrected

5. Final report	
FSCA has been completed on	
Effectiveness checks on operational conduct of FSCA	
Final risk evaluation (if different from the initial risk evaluation)	
Summary of product owner's corrective and preventative action and effectiveness checks	

6. Action taken on affected products

I confirm that the action has been completed on .....

I will be

- ○ returning the affected stocks to the product owner as approved by the Thai FDA
- ○ destroying the affected stocks as approved by the Thai FDA at (location & date) .....
- ○ taking other action(s) as approved by the Thai FDA, please specify

.....

7. Other information

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....