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 : .....