Change Notification Guideline

1st March, 2022

Change Notification Guideline

Listing Medical Device

- **Jor.Jor.Nor. 3 (จ.จ.น.3) and Jor.Jor.Phor. 3 (จ.จ.ผ.3)** are allowed to amend the following list.

Jor.Jor.Nor. 3	Jor.Jor.Phor. 3
1. Name and address of manufacturer in the event that there is not change location. (In case of importer)	-
2. Name of product owner in case of merger.	1. Name of product owner in case of merger.
3. Name and address of product owner. (Manufacturer remains the same.)	2. Name and address of product owner. (Manufacturer remains the same.)
4. Declaration of conformity issued by manufacturer or product owner	3. Declaration of conformity issued by manufacturer or product owner
5. Details of the text on the label or IFU that does not change the intended use or indications for use.	4. Details of the text on the label or IFU that does not change the intended use or indications for use.
6. Grouping e.g., adding color/size, adding or removing the list of medical devices in the same grouping without changing in a grouping category.	5. Grouping e.g., adding color/size, adding or removing the list of medical devices in the same grouping without changing in a grouping category.

- **Jor Jor Nor. 4 (จ.จ.น.4) and Jor Jor Phor. 4 (จ.จ.ผ.4)** are allowed to amend the following list.

1. Decrease shelf life or increase the degree of strictness of storage.
2. Label or IFU, without affecting the efficiency or safety of the medical device, such as changing colors, adding/cancelling/changing formats, images, symbols, barcodes or altering text without affecting its overall meaning.
3. Label or IFU, to improve safety of medical devices, such as adding or replacing warnings, precautions, contraindications and/or adverse effects.
4. Product code, which is still the same medical device by changing only the product code number, for example, modifying the product code to indicate the distribution zone.
5. Amend the description of medical devices or accessories due to the typo.

Procedure:

- The applicant submits a request for amendment in the Skynet system (Thai FDA online system), attaches the required attachments → submits the request

Processing time: automatic approval system

Cost: free of charge

Documentation

- **Jor Jor Nor. 3 and Jor Jor Phor. 3**

Topics	Documents
1. Name and address of manufacturer in the event that there is not change location. (In case of importer)	- Label and IFU - Declaration letter issued by product owner certifying that the location of manufacturer has not changed - Declaration of conformity
2. Name of product owner in case of merger.	- Label and IFU (optional) - Declaration of conformity - Letter of authorization - Declaration letter issued by product owner certifying that the location of manufacturer has not changed
3. Name and address of product owner. (Manufacturer remains the same.)	- Label and IFU (optional) - Declaration of conformity - Letter of authorization - Declaration letter issued by product owner certifying that the location of manufacturer has not changed
4. Declaration of conformity issued by manufacturer or product owner	- Declaration of conformity
5. Details of the text on the label or IFU that does not change the intended use or indications for use.	- Label and IFU (If any) - Declaration letter issued by product owner outlining the details of the label and IFU changes
6. Grouping e.g., adding color/size, adding or removing the list of medical devices in the same grouping without changing in a grouping category.	- Label - IFU - Product specification - Declaration of conformity - Letter of authorization

– **Jor Jor Nor. 4 and Jor Jor Phor. 4**

Topics	Documents
1. Decrease shelf life or increase the degree of strictness of storage.	- Design verification and validation - Risk analysis - Clinical evidence (optional) - The latest version of label and IFU, with the change highlighted
2. Label or IFU, without affecting the efficiency or safety of the medical device, such as changing colors, adding/cancelling/changing formats, images, symbols, barcodes or altering text without affecting its overall meaning.	- The latest version of label and IFU, with the change highlighted - Declaration letter issued by product owner explaining that the change has no effect on the efficiency or safety of medical devices
3. Label or IFU, to improve safety of medical device, such as adding or replacing warnings, precautions, contraindications and/or adverse effects.	- The latest version of label and IFU, with the change highlighted - Declaration letter issued by product owner clarifying that the change is being made to improve safety of medical devices - Clinical evidence (optional) - Risk analysis
4. Product code, which is still the same medical device by changing only the product code number, for example, modifying the product code to indicate the distribution zone.	- Document from product owner describing a comparison of the old and updated product code - The latest version of label and IFU, with the change highlighted - Declaration of conformity - Letter of authorization - Declaration letter issued by product owner clarifying that the medical device has not changed its appearance, shape, intended use, technical specifications and/or sterilization process
5. Amend the description of medical devices or accessories due to the typo.	- Declaration letter clarifying that the filling in the information on the system is incorrect from the importer or local manufacturer

Notification Medical Device and Licensing Medical Device

The level of change; 2 levels

1. Major change: change that needs to be <u>reviewed by external Specialist (Non IVD/IVD) or Thai FDA official (IVD)</u> prior to approval as follows:

1) Risk classification: only Class 2 and 3, which does not affect the license category.
2) Add Indication/Intended use
3) Change the principal ingredients or components that does not affect the product specification
4) Product specification
5) Increase shelf life or decrease the degree of strictness of storage
6) Primary packages that affect the quality of medical devices or Sterile primary packaging
7) Manufacturing procedure that affects the efficiency and safety of medical devices

<u>Procedure:</u>

- The applicant submits a request for amendment in the Skynet system (Thai FDA online system), attaches the required attachments → Applicant submits the request → Thai FDA official reviews and informs applicant to revise or submit supplemental documents → The official accepts a request → Applicant pays for Specialist Review fee → The official delivers documents to specialist → The official reviews and complete documents in the system → The official requests senior to sign → The official approves in the system → Applicant pay for the amendment fee → Issue a license with attachment of details of amendment

<u>Processing time:</u> 35 working days

Cost:

Category	Fees (THB)		
	Submission fee	**Specialist review fee**	**Total**
Notification category			
Notified medical device manufacturing license	500	19,200	19,700
Notified for medical device import license	500	24,000	24,500
Category	**Fees (THB)**		
	Submission fee	**Specialist review fee**	**Total**
Licensing category			
Licensed medical device manufacturing license	500	24,000	24,500
Licensed medical device import license	500	30,000	30,500

2. Minor change: change that needs to be reviewed by Thai FDA official prior to approval as follows:

1) Increasing/decreasing/changing sterilization facilities where the sterilization process has not changed
2) Add or remove the list of medical devices in the same medical device group without changing in a grouping category
3) Change physical manufacturer, but legal manufacturer/product owner remains the same.
4) Name or address of the product owner without changing a physical manufacturer
5) Name of physical manufacturer without changing the location
6) Decrease shelf life or increase the degree of strictness of storage.
7) Label or IFU without affecting the efficiency or safety of the medical device
8) Label or IFU, to improve safety of medical devices
9) Product code, still the same medical device.
10) Software change (only change that does not affect efficiency and safety of medical device)

Procedure:

- The applicant submits a request for amendment in the Skynet system (Thai FDA online system), attaches the required attachments → Applicant submits the request → Thai FDA official reviews and informs applicant to revise or submit supplemental documents → The official accepts a request → The official requests senior to sign → The official approves in the system → Applicant pay for the amendment fee → Issue a license with attachment of details of amendment

Processing time: 5 working days

Cost:

Category	Fees (THB)	Total
Notification category		
Notified medical device manufacturing license	500	500
Notified for medical device import license	500	500
Licensing category		
Licensed medical device manufacturing license	500	500
Licensed medical device import license	500	500

Documentation

1. Major change: change that needs to be <u>reviewed by external Specialist (Non IVD/IVD) or Thai FDA official (IVD)</u> prior to approval as follows:

Topics	Documents
1) Risk classification: only Class 2 and 3, which does not affect the license category.	
E.g., Adding indication or intended use etc.	- Change notification approval for adding/amending indication from regulatory bodies in other countries (In case of adding indication) - Declaration of conformity (If there is a change in applied standard or classification) - Device verification and validation - Clinical Evidence - Risk Analysis
2) Add Indication/Intended use	
2.1) Amend an approved indication or add a new indication, for example, a change in design characteristics, medical device characteristics (adding approved indication)	- Change notification approval for adding/amending indication from regulatory bodies in other countries - The latest version of label and IFU, with the change highlighted - Declaration of conformity (If there is a change in applied standard) - Device verification and validation - Clinical Evidence - Risk Analysis - Product specification (optional)
2.2) Amend an approved indication or add a new indication due to a software change (for active medical device) affecting the main mechanism of operation, the sterilization process of primary packaging, and/or change in the design of the medical device, e.g. - Feature or software application change that affects diagnosis or treatment	- Change notification approval for adding/amending indication from regulatory bodies in other countries - The latest version of label and IFU, with the change highlighted - Declaration of conformity (If there is a change in applied standard) (optional) - Design verification and validation e.g., Summary of software changes, Overview of all verification, validation,

Topics	Documents
- Software change made to improve algorithms that affect diagnosis or treatment - Software change by increasing or decreasing the notification system which affects patient treatment - Software change, including changing in the operating system, in comparison to the previous registered software version - Software change that affects the operational control of medical devices and causes change in the result of diagnosis or treatment.	and testing, Summary all unresolved anomalies in the release version of the software, Evidence to demonstrate that the software issue has been resolved - Clinical Evidence - Risk Analysis
3) Change the principal ingredients or components that does not affect the product specification.	
3.1) Change in the type, origin, production process of biological materials (including cells, tissues and/or derivatives of animal, human, microbial or recombinant origin) without changing the purpose of use of biological materials	- Design verification and validation - Clinical Evidence (optional) - Biological safety data - Information of sources/donors - List of material(s) making direct/ indirect contact with human body)
3.2) Change in raw material or raw material supplier	- Design verification and validation - Clinical Evidence (optional) - List of material(s) making direct/ indirect contact with human body)
4) Product specification	
- Non-IVD medical device, medical device with measuring function, IVD: change in sensitivity, specificity, linearity, measuring range **-** Modification affecting control mechanism, key operating function, sterilization process of primary packaging and/or altering the design of the medical device - Updated software version	- Design verification and validation as relevant e.g., physical test - Risk Analysis - Clinical Evidence (optional) - The latest version of label and IFU, with the change highlighted - Product specification

Topics	Documents
- Amendment of product specifications, including shelf life, stability, and expiration date	
5) Increase shelf life or decrease the degree of strictness of storage	
	- Design verification and validation as relevant e.g., stability test - Risk Analysis - Clinical Evidence (optional) - The latest version of label and IFU, with the change highlighted (optional)
6) Primary packages that affect the quality of medical devices or Sterile primary packaging	
	- Design verification and validation as relevant e.g., stability test - Risk Analysis - Clinical Evidence (optional) - The latest version of label and IFU, with the change highlighted (optional)
7) Manufacturing procedure that affects the efficiency and safety of medical devices	
E.g., manufacturing process change that result in any change in product specification	- Quality system certificate ISO 13485 or GMP (optional) - The latest version of label and IFU, with the change highlighted (optional) - Design verification and validation - Risk Analysis (optional) - Product specification
E.g., sterilization method change	- Quality system certificate ISO 13485 or GMP - The latest version of label and IFU, with the change highlighted - Sterilization validation report including an EO residuals report (if applicable) and evidence of continuous sterilization validation - Design verification and validation e.g., post-sterilization functional report, Biocompatibility

2. Minor change: change that needs to be <u>reviewed by Thai FDA official</u> prior to approval as follows:

Topics	Documents
1) Increasing/decreasing/changing sterilization facilities where the sterilization process has not changed	
	- Quality system certificate ISO 13485 or GMP (optional) - The latest version of label and IFU, with the change highlighted (optional) - Declaration letter issued by product owner certifying that the medical device has not changed its appearance, shape, including its intended use, technical specifications and/or sterilization process. - Sterilization validation report including an EO residuals report (if applicable) and evidence of continuous sterilization validation (optional) - Sterilization test report from new sterilization facilities (optional)
2) Add or remove the list of medical devices in the same medical device group without changing in a grouping category	
- Family: add/remove size, specification, volume - System: add/remove accessories - Family of system: add/remove main unit, size, specification, volume, accessories	- Label - IFU - Product specification (optional) - Declaration of conformity - Letter of authorization - Quality system certificate ISO 13485 or GMP (optional)
3) Change physical manufacturer, but legal manufacturer/product owner remains the same.	
E.g., adding a production site, relocation of production site	- Declaration letter issued by product owner certifying that the medical device has not changed its appearance, shape, including its intended use, technical specifications and/or sterilization process. - Declaration of conformity

Topics	Documents
	- Quality system certificate ISO 13485 or GMP of the new physical manufacturer. - The latest version of label and IFU, with the change highlighted (optional)
4) Name or address of the product owner without changing a physical manufacturer	
E.g., - Change the company name - Relocating according to the acquisition or merger - The street name, county, zip code has been changed by the state government, in which located in the original location.	- Label and IFU (optional) - Declaration of conformity - Letter of authorization - Declaration letter issued by product owner certifying that the location of manufacturer has not changed
5) Name of physical manufacturer without changing the location	
E.g., - Change the company name according to the acquisition or merger - The street name, county, zip code has been changed by the state government, in which located in the original location.	- Label and IFU - Declaration of conformity - Quality system certificate ISO 13485 or GMP (optional) - Declaration letter issued by product owner certifying that the location of manufacturer has not changed - Letter certificate from a governmental or local authority indicating a change in the name of the owner or product without changing the place of manufacture - In case of city plan change: attach documents from the host country of the product owner or manufacturer - In case of merger: attach evidence of merger contract (optional)

Topics	Documents
6) Decrease shelf life or increase the degree of strictness of storage.	
	- Design verification and validation - Risk Analysis - Clinical Evidence (optional) - The latest version of label and IFU, with the change highlighted (optional)
7) Label or IFU without affecting the efficiency or safety of the medical device	
E.g., changing colors, adding/cancelling/changing formats, images, symbols, barcodes, packing size or altering text without affecting its overall meaning.	- The latest version of label and IFU, with the change highlighted (optional) - Description and picture showing packing style (in case of changing packing size) - Declaration letter issued by product owner explaining that the change has no effect on the efficiency or safety of medical devices
8) Label or IFU, to improve safety of medical devices	
E.g., adding or replacing warnings, precautions, contraindications and/or adverse effects	- The latest version of label and IFU, with the change highlighted - Risk Analysis - Clinical Evidence (optional) - Declaration letter issued by product owner clarifying that the change is being made to improve safety of medical devices
9) Product code, still the same medical device.	
E.g., amending the product code to indicate the zone of sale.	- Document from product owner describing a comparison of the old and updated product code - The latest version of label and IFU, with the change highlighted - Declaration of conformity - Letter of authorization - Declaration letter issued by product owner clarifying that the medical device has not changed its appearance, shape, intended use, technical specifications and/or sterilization process

Topics	Documents
10) Software change (only change that does not affect efficiency and safety of medical device)	
E.g., - Software has fixed error that does not add new functionality and does not affect safety and is intended to function as specified in the specification. - Software changes related to the operation of other non-medical devices, such as printers. - Software that changes the interface that appears to the user without affecting the diagnosis or treatment of the medical device.	- Change notification approval issued by regulatory agency - The latest version of label and IFU, with the change highlighted - Declaration of conformity (If there is a change in applied standard) (optional) - Device verification and validation e.g., Summary of software changes, Overview of all verification, validation, and testing, Summary all unresolved anomalies in the release version of the software, Evidence to demonstrate that the software issue has been resolved

Description of the documents

- **Design verification and validation**

  Summary of the design verification and validation documents of a product, i.e. pre-clinical studies such as test report of physical test, chemical test, biocompatibility, stability test etc. Test report needs to be submitted in the relevant part of submitting an amendment request.

- **Clinical Evidence**

  Clinical evaluation document for a medical device product produced in the form of a Clinical Evaluation Report in accordance with MEDDEF 2.7/1 Revision 4, Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC through systematic reviews of existing bibliography, clinical experience of the same or similar medical device, or clinical investigation of a medical device product that has submitted an amendment request together with a copy of clinical trials report used as reference to support the effectiveness and safety of clinical assessment reports.

- **Risk Analysis**

  Risk Management Report prepared in accordance with ISO 14971:2007 Medical Devices - Application of Risk management to Medical Devices with attached references as follows:

  1) Risk management plan: consists of the scope of risk management at which stage life cycle of the medical device, intended use and the details of the operation of the medical device, role and responsibility of the risk management team, risk tolerance criteria, the work plan for collecting production and post-production information.
  2) Risk management table: consists of risk analysis, risk evaluation, risk control (if applicable), residual risk evaluation (if applicable). overall residual risk evaluation (if applicable)
  3) Risk management report: consists of all activities taken in accordance with the risk management plan, overall residual risk within an acceptable range, and a data collection system for production and post-production information.

- **The latest version of label and IFU, with the change highlighted**

  Attach 2 copies of label and IFU;

  1) Label and IFU to be changed, highlighting the changed text.

  2) The latest version of label and IFU that are available for sale to consumers.