Notification of the Office of the Food and Drug Administration

re: Rules, Procedures, and Conditions in Applying for Amendment of Registered Information

B.E. 2564 (2021)

It is appropriate to determine the rules, procedures, and conditions in applying for amendment of the registered information if there is a change in order to keep the information up to date.

By virtue of section 31/1, paragraph two of the Medical Device Act, B.E. 2551 (2008), as amended by Medical Device Act No. 2, B.E. 2562 (2019), the secretary-general of the Food and Drug Administration therefore issues the following notification.

Clause 1 A medical device manufacturing or import registrant who wishes to amend the following registered information must submit to the licensor an Application for the Amendment of Registered Particulars Regarding Manufacturing of Medical Devices using Form Jor.Jor.Phor. 3 or an Application for the Amendment of Registered Particulars Regarding Import of Medical Devices using Form Jor.Jor.Nor. 3 and the evidence as specified in the schedule to this Notification:

(1) the name and location of the manufacturer outside Thailand if there is not a change in location (for import);

(2) the name of the product owner, in case of a merger or acquisition;

(3) the name and location of the product owner;

(4) a declaration of conformity from the manufacturer or the product owner;

(5) the details provided on the label or medical device documentation, whereby the change must not be related to the intended use or the indication; or

(6) the grouping of the medical devices.

Clause 2 A medical device manufacturing or import registrant who wishes to amend any particulars apart from those specified in Clause 1 must notify the licensor via the Notification Form for Amendment of Registered Particulars Regarding Manufacturing of Medical Devices (Form Jor.Jor.Phor. 4) and the Notification Form for Amendment of Registered Particulars Regarding Import of Medical Devices (Form Jor.Jor.Nor. 4) attached to this Notification.

Clause 3 The permission to amend the registered information in Clause 1 can be shown at the end of the application or as an attachment to the certificate of registration, or by notifying the registrant in writing.

Clause 4 A medical device manufacturing or import registrant who is permitted to amend the permitted particulars on the registration certificate for the establishment for manufacturing of medical devices or the registration certificate for the establishment for import of medical devices will be deemed to be permitted to amend the registered particulars on the certificate of registration for the manufacturing or import of medical devices from the date that he or she is permitted to amend the particulars of the registration certificate for the establishment for manufacturing of medical devices or the registration certificate for the establishment for import of medical devices, as the case may be.

Clause 5 The filing of the application and notification for the amendment of the registered particulars under this Notification should be done electronically. While it cannot be done electronically, the application and notification for amendment of the registered particulars must be filed at the Office of the Food and Drug Administration, the Ministry of Public Health, or at any other place as specified by the secretary-general in the *Government Gazette*.

Clause 6 The secretary-general of the Food and Drug Administration will be in charge of this Notification. If there is any problem in considering a matter under this Notification, the secretary-general of the Food and Drug Administration will have the final decision.

Clause 7 This notification is effective from 17 March 2021 onward.

Issued on 2 February 2021

Paisan Dankum

Secretary-General of the Food and Drug Administration

(Translation)

Form Jor.Jor.Phor. 3

Receipt No. .....
Date .....
Recipient .....
(for officials only)

Application for the Amendment of Registered Particulars Regarding Manufacturing of Medical Devices

Written at .....

Date.....Month.....B.E.....

I/We, ..., medical device manufacturing registrant under Registration Certificate No. .....,

with ..... as the person acting on behalf of the juristic person, wish to amend the following registered particulars for the manufacturing of medical devices.

□ The declaration of conformity from the manufacturer or the product owner

□ Details on the medical device label or documentation

□ Medical device grouping

.....
.....

Together with this application, I/we have attached the evidence related to the registered particulars for which the amendment is requested.

(Signature) ..... Applicant

(.....)

No. SorThor

The Office of the Food and Drug Administration

The Ministry of Public Health

Date ..... Month .....B.E. .....

The amendment to the registered particular(s) for the manufacturing of medical devices is permitted.

(Signature) .....

Position .....

Licensor

(Translation)

Form Jor.Jor.Nor. 3

Receipt No. .....
Date .....
Recipient .....
(for officials only)

Application for the Amendment of Registered Particulars Regarding Import of Medical Devices

Written at .....

Date.....Month.....B.E.....

I/We, ..., medical device import registrant under Registration Certificate No. ....., with ....., as the person acting on behalf of the juristic person, wish to amend the following registered particulars for the import of medical devices.

□ Declaration of conformity from the manufacturer or the product owner
□ Details on the medical device label or documentation
□ Medical device grouping, such as adding color(s) or size(s)
□ The name/address of the manufacturer outside Thailand (same location)
□ The name of the product owner (same manufacturer)

.....
.....

Together with this application, I/we have attached the evidence related to the registered particulars for which the amendment is requested.

(Signature) ..... Applicant
(.....)

No. SorThor

The Office of the Food and Drug Administration
The Ministry of Public Health

Date ..... Month .....B.E. .....

The amendment to the registered particular(s) for the import of medical devices is permitted.

(Signature) .....
Position .....
Licensor

(Translation)

Form Jor.Jor.Phor. 4

Receipt No. .....
Date .....

Notification Form for Amendment of Registered Particulars Regarding Manufacturing of Medical Devices

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Written at .....

Date ..... Month .....B.E. .....

I/We, ..., medical device manufacturing registrant under Registration Certificate No. ....., with ....., as the person acting on behalf of the juristic person, wish to notify the amendment to the registered particulars for the manufacturing of medical devices, as follows.

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.....

Together with this notification form, I/we have attached the evidence related to the registered particulars for which the amendment is requested.

(Signature) .....the Notifying Person

(.....)

(Translation)

Form Jor.Jor.Nor. 4

Receipt No. .....
Date .....

Notification Form for Amendment of Registered Particulars Regarding Import of Medical Devices

Written at .....

Date ..... Month .....B.E. .....

I/We, ..., medical device import registrant under Registration Certificate No. ....., with ....., as the person acting on behalf of the juristic person, wish to notify the amendment to the registered particulars for the import of medical devices, as follows.

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Together with this notification form, I/we have attached the evidence related to the registered particulars for which the amendment is requested.

(Signature) .....the Notifying Person

(.....)