Notification of the Office of the Food and Drug Administration
re: Rules, Procedures, and Conditions for the Renewal of the Medical Device Certificate of Registration and the Permission for the Renewal of the Medical Device Certificate of Registration
B.E. 2564 (2020)

It is appropriate to determine the rules, procedures, and conditions for the renewal of the medical device certificate of registration and the permission for the renewal of the medical device certificate of registration.

By virtue of section 30/1, 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 manufacturing or import registrant who wishes to renew the certificate of registration must submit the application to the licensor prior to the expiration date of the certificate of registration and pay the renewal fee, and provide at least the following information to the licensor.

(1) the number of registration certificate of the medical device manufacturing or import establishment;

(2) the number of the medical device manufacturing certificate of registration and the medical device import certificate of registration;

(3) the name and location of the medical device manufacturing or import facility; and

(4) in the case of an attorney, the power of attorney and the certification document of the company or partnership, as the case may be, must be attached.

Clause 2 After receiving the application, the licensor must review the information, documents, and evidence. If they are correct and complete, the licensor will issue the application receipt to the registrant. If they are incorrect or incomplete, the licensor will immediately notify the registrant. If the incorrectness or incompletion can be resolved at the time, the licensor will inform the registrant to amend or submit the information, documents, or evidence. If this cannot be resolved at the time, the licensor will note down the mistake and inform the registrant to amend or submit the information, documents, or evidence within a time period specified by the licensor.

If the registrant does not amend or submit the information, documents, or evidence within the time period specified by the licensor, it will be deemed that the registrant does not wish to continue the action, and the licensor will discard the registrant's application.

Clause 3 To permit the renewal of certificate of registration, a new certificate of registration for the manufacturing or import of medical devices will be issued.

If the licensor does not permit the renewal, the licensor will issue a letter to the registrant, specifying the reasons and the right to appeal to the minister within fifteen days from the date on which the order is issued.

Clause 4 The application for the renewal of the certificate of registration must be based on Form Jor.Jor.Phor. 2 and Form Jor.Jor.Nor. 2, as attached to this Notification.

Clause 5 The filing of the application under this Notification should be done electronically. While it cannot be done electronically, the application 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 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. 2

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

Application for the Renewal of the Medical Device Manufacturing Certificate of Registration

Written at .....

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

I/We, ...
the registrant for the manufacturing of the medical device under Certificate of Registration No. ....., expiring on date ..... month .....B.E.....
at the medical device manufacturing facility named .....,
located at No. ..... Lane/Soi.....
Road ..... Moo. .....Subdistrict .....District.....
Province ..... Postal code ..... Telephone ..... Fax .....,
with ....., as the person acting on behalf of the juristic person, wish to renew the medical device manufacturing certificate of registration from Date ..... Month .....B.E....., via this application. I/We certify that the registered particulars remain the same.

Signature .....Applicant

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Remark: If the registrant for the manufacturing of medical devices is exempt from submitting information, documents, or evidence at the time of application, the registrant must submit all information, documents, or evidence pursuant to the Ministerial Regulation On the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), along with this application.

(Translation)

Form Jor.Jor.Nor. 2

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

Application for the Renewal of the Medical Device Import Certificate of Registration

Written at .....

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

I/We, ...,
the registrant for the import of the medical device under Certificate of Registration No. .....,
expiring on date ..... month .....B.E.....
at the medical device import facility named .....,
located at No. ..... Lane/Soi.....
Road ..... Moo. .....Subdistrict .....District.....
Province ..... Postal code ..... Telephone ..... Fax .....,
with ....., as the person acting on behalf of the juristic person, would like to renew the medical device import certificate of registration from Date ..... Month .....B.E....., via this application. I/We certify that the registered particulars remain the same.

Signature .....Applicant

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Remark: If the registrant for the import of medical devices is exempt from submitting information, documents, or evidence at the time of application, the registrant must submit all information, documents, or evidence pursuant to the Ministerial Regulation On the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), along with this application.