Gazette Volume 141 Special Section 169 D *June 20th, 2024*

Notification of the Ministry of Public Health

Re: Medical devices that require a controller of manufacturing, import or sale, and the qualifications, number, and duties of the controller.

BE. 2567 (2024)

Whereas it is appropriate to specify the medical devices that must be provided with a controller, as well as specify the qualifications, number and duties of the controllers in order for the control of medical devices to be effective and of standard quality, which is to protect consumers.

By virtue of Section 5, paragraph one, and Section 6 (7) of the Medical Devices Act, B.E. 2551 (2008), the Minister of Public Health, with the advice of the Medical Devices Committee, issues the following statement:

Clause 1 This announcement shall come into force the day after its publication in the Royal Gazette onwards.

Clause 2 The establishment/licensed/notified/listing license holder must appoint at least one manufacturing controller with the following qualifications and duties:

(1) Qualifications

(a) Educational qualifications:

1) A bachelor's degree or higher in Science, Pharmacy, Medicine, Engineering, Medical Technology, Veterinary Medicine, or other related scientific fields. or

2) A bachelor's degree in any field with at least one year of experience in quality management system for medical devices.

(b) Residing in Thailand

(2) Duties

(a) Control and supervise production or sales to ensure that the compliance with the manufacturing quality system of medical devices.

(b) Control and supervise the production or sale of every production batch to be in accordance with the law, including verifying the control records of manufacturing process at the medical device manufacturing establishment.

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(c) Control the preparation of labels or IFU, which must not display false or exaggerated information and must be completed correctly before sale, in accordance with Section 44 and Section 45 of the Medical Device Act B.E. 2551 and as amended.

(d) Perform duties as assigned by the establishment/licensed/notified/listing license holder.

Clause 3 The establishment/licensed/notified/listing license holder must appoint at least one import controller with a bachelor's degree, residing in Thailand and with the following duties;

(1) Control the import and sale to be in accordance with the quality system for importing and sale of medical devices.

(2) Control the preparation of labels or IFU, which must not display false or exaggerated information and must be completed correctly before sale, in accordance with Section 44 and Section 45 of the Medical Device Act B.E. 2551 and as amended.

(3) Perform duties as assigned by the establishment/licensed/notified/listing license holder.

Clause 4 The sales license holder must appoint at least once sales controller a bachelor's degree, residing in Thailand and with the following duties;

(1) Control the sales to be in compliance with the quality system for medical devices sales.

(2) Control the sales to be in compliance with the criteria, method and conditions in accordance with the Section 6 (3) (9) and (10) of the Medical Device Act B.E. 2551

Clause 5 If the establishment is registered for manufacturing, import, or sales, the manufacturing, import, or sales controller can be the same person, but they must meet the qualifications and duties outlined in this notification.

Clause 6 If the operator on behalf of an establishment/licensed/notified/listing license holder, whoever, has all of the qualifications and fully performs the duties as a production, import, or sales controller under this notification, such person may be designated as a manufacturing, import, or sales controller as well.

Clause 7 If a manufacturing, import, or sales controller does not wish to continue as a controller, the licensor must be notified within thirty days of the termination of duty.

Clause 8 If a manufacturing, import, or sales controller is temporarily unable to perform their duties, the registrant of an establishment/licensed/notified/listing license shall appoint a person with the same qualifications as a manufacturing, import, or sales controller at the premise to perform the duties in their place.

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Clause 9 Any establishment/licensed/notified/listing license holder who registered prior to the effective date of this notification shall arrange for a manufacturing, import, or sales controller, as the case may be, in accordance with this notification, and shall notify the information, documents, and evidence related to the controller to the licensor within one year from the effective date of this notification

Clause 10 Any notification or communication, issuance of documents shall be carried out in accordance with the law on electronic procedures.

If it is not possible to proceed using electronic methods as described in paragraph one, it must be executed at the Food and Drug Administration, or another method or location specified by the Secretary-General of the Food and Drug Administration.

Announced on May 20th, 2024

Somsak Thepsutin

Minister of Public Health

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