Notification of the Ministry of Public Health
Re: Groups of Medical Devices or Medical Devices for Which the Manufacturers and Importers Must Obtain License
B.E. 2563 (2020)

In order to improve the criteria of the groups of medical devices or medical devices for which the manufacturers and importers must obtain license for the efficient control of medical devices in accordance with the country's situation or public health problems and the international standards regarding medical device control, it is appropriate to determine the high-risk medical devices which the manufacturers and importers must obtain license, to ensure adequate safety and consumer protection.

By virtue of the provisions in section 5, paragraph one of the Medical Device Act, B.E. 2551 (2008) and section 6 (1) (a) of the Medical Device Act, B.E. 2551 (2008) as amended by the Medical Device Act (No. 2), B.E. 2562 (2019), the Minister of Public Health, on the recommendation of the Medical Device Committee, issues the notification as follows.

Clause 1. The Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for which the Manufacturers and Importers Must Obtain License, B.E. 2563 (2020) dated 27 April 2020 shall be repealed.

Clause 2. The following groups of in vitro diagnosis medical devices or in vitro diagnosis medical devices that carry high risk to individuals and public health (category IV medical devices) and groups of non-in vitro diagnosis medical devices or non-in vitro diagnosis medical devices that carry high risk (category IV medical devices) shall be medical devices for which the manufacturers and importers must obtain license.

(1) All invasive medical devices through surgery with an intention for transient use.

a. For direct contact with the central nervous system.

b. To diagnose diseases, monitor or treat the defect of the heart or the central blood circulatory system by direct contact with these body parts.

(2) All invasive medical devices through surgery with an intention for short-term usage.

a. For biological effect or for partial or major absorption.

b. For direct contact with the central nervous system.

c. To diagnose diseases, monitor or treat the defect of the heart or the central blood circulatory system by direct contact with these body parts.

(3) All medical devices that are implanted in the body or invade the body by surgery for long-term usage.

a. For direct contact with the heart, the central blood circulatory system, or the central nervous system.

b. For life sustaining or life saving purpose.

c. Active medical devices that are implanted in the body.

d. To give biological effect or for partial or major absorption.

e. To administer drugs.

f. To cause chemical change in the body (except dental medical devices).

g. Implanted breast prosthesis.

(4) Medical devices with medicines (under the medicine law) that are incorporated into the medical devices in order to support the function of the medical devices.

(5) All medical devices that produce or have the following items as their components.

a. Cells, tissues, or derivatives of animals which cannot grow, or

b. Cells, tissues, or derivatives of microorganism or from the genetic recombination, excluding intact-skin medical devices that produce or include non-viable animal tissues.

(6) All medical devices that are used for birth control or to prevent sexually transmitted diseases and are implanted or invade the body in the long term.

(7) In vitro diagnosis medical devices with an intention to detect pathogen of contagious disease or contact lesion of the pathogen that causes contagious disease in blood, blood components, blood derivatives, cells, tissues, or organs in order to conduct an evaluation for giving or transfusing blood or organ transplantation.

(8) in vitro diagnosis medical devices with an intention to detect pathogen or contact lesion of the pathogen that causes contagious disease that results in life-threatening incurable condition with high contagion risk.

Clause 3. The groups of medical devices or medical devices that manufacturers and importers must declare specifications under the Notification of the Ministry of Public Health re: Ophthalmic Viscosurgical Devices, B.E. 2557 (2014) dated 24 November 2014 that are groups of medical devices or medical devices under Clause 2 (5) require license under this Notification.

Clause 4. If the declarer of specifications regarding manufacturing or importing ophthalmic viscosurgical devices under Clause 3, which are the group of medical devices and medical devices that require license under this Notification, wish to continue their business, they must submit applications for license pursuant to the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020) prior to the expiration date of the receipt for the declaration of specifications.

After the submission of the application in first paragraph, the manufacturers or the importers shall continue their business until there is an order rejecting the issuance of license.

If the declarer of specifications does not wish to take action in the first paragraph, they may continue to manufacture or import medical devices until the receipt for the declaration of specifications expires and sells the medical devices in their possession until the products expire or until there is an order to suspend the sale.

If the licensor issues an order rejecting the issuance of license, the medical devices manufactured or imported prior to the effective date of this Notification under their possession can still be sold until the products expire or until there is an order to suspend the sale.

The receipt for the declaration of specifications regarding the manufacturing and the import of ophthalmic viscosurgical devices under the first paragraph that have been issued prior to the effective date of this Notification shall still be valid until the receipt for the declaration of specifications expires or is revoked, as the case may be.

Clause 5. If the registrants for the establishment to manufacture or import medical devices under Clause 2 prior to the effective date of this Notification wish to continue their business, they must submit the application for manufacturing license prior to the expiry date of the manufacturing establishment registration certificate or submit the application for import license prior to the expiry date of the import establishment registration certificate, as the case may be, from the effective date of this Notification onward.

After submitting the application within the timeframe in the first paragraph, the manufacturers and the importers can continue their business until there is an order rejecting the issuance of license. However, the manufacturing establishment registrants must provide the sales evidence or the Thai innovation registration issued by the Budget Bureau, the Prime Minister's Office. The import establishment registrants must provide the medical devices import certificate that is still valid as of the effective date of this Notification for the submission of the application for the license.

For manufacturing or import establishment registrants who submit the application under the first paragraph and the licensor issues the license under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020) prior to the expiration of the license, if the licensees wish to continue their businesses, they must submit applications for renewal using the form in the Notification of the Office of the Food and Drug Administration re: Specification of Forms under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020) issued 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).

If the manufacturing establishment registrants or the parties who receive the medical device import certificates do not wish to continue their businesses, they may continue to manufacture or import the medical devices until the manufacturing establishment certificates or the import certificates expire. The medical devices in their possession can continue to be sold until the products expire or until an order to suspend sale is issued.

If the licensor issues an order rejecting the notification, the manufactured or imported medical devices prior to the effective date of this Notification under their possession can still be sold until the products expire or an order to suspend the sales is issued.

The medical device import certificates are valid until they are canceled or expire.

Clause 6. All applications for declaration of specifications regarding manufacturing or import of medical devices or applications for medical device import certificates submitted prior to the effective date of this Notification and are being considered, if they are for groups of medical devices or medical devices that must be licensed under this Notification, are deemed applications under the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), *mutatis mutandis*.

If the application under the first paragraph is different from the application in the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020), the licensor has the power to request that the applicant make an amendment or submit additional information, documents, or evidence, as necessary, so as to ensure accordance with the Ministerial Regulations on the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License, B.E. 2563 (2020).

Clause 7. If another notification specifically applies to groups of medical devices or medical devices that are listed under Clause 2, and the manufacturer or the importer must specifically obtain permission under that notification, that notification will apply.

Clause 8. The secretary-general of the Food and Drug Administration shall be in charge of and have control over the execution of this Notification. If there is any problem with the classification of the groups of medical devices or medical devices regarding which the manufacturers and the importers must obtain license under this Notification, the secretary-general of the Food and Drug Administration shall have the final decision.

Clause 9. This Notification shall be effective from the date of its publication in the *Government Gazette*.

Issued on 29 December 2020

Anutin Charnvirakul

Minister of Public Health