Notification of the Ministry of Public Health

re: Groups of Medical Devices or Medical Devices that Must Be Registered
by Manufacturers and Importers
B.E. 2563 (2020)

Whereas it is appropriate to amend the criteria for the groups of medical devices or medical devices that must be registered by the manufacturers and importers to ensure efficient medical device control in accordance with the country's situation or public health problems, and to ensure consumer protection

By virtue of the provisions of section 5, paragraph one, of the Medical Device Act, B.E. 2551 (2008), and section 6 (1) (c) of the Medical Device Act, B.E. 2551 (2008), as amended by Medical Device Act No. 2, B.E. 2562 (2019), the minister of public health, upon 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Devices or Medical Devices that Must Be Registered by Manufacturers and the Importers, dated 16 July 2020, shall be repealed.

Clause 2. The following groups of non-in vitro diagnosis medical devices or non-in vitro diagnosis medical devices that carry low risk (category I medical devices) shall be medical devices that must be registered by the manufacturers and the importers:

(1) all non-invasive groups of medical devices or medical devices which have contact with wounded skin and are only designed to close wounds (mechanical barriers) by pressing or by absorbing fluid that is leaking from the wound;

(2) all non-invasive groups of medical devices or medical devices that are used to facilitate the passage of or are for the storage of bodily fluid, bodily tissues, other fluids, or gases, and are intended to provide infusion, administration, and introduction to the body;

(3) all non-invasive groups of medical devices or medical devices that must not have the following characteristics or uses:

a. being in contact with wounded skin and has an intention to be used with laceration wounds which pierce the dermis of the skin, including medical devices with intention to administer the microenvironment of the wound:
b. being in contact with wounded skin and has an intention to be used with laceration wounds which pierce the dermis of the skin, whereby these wounds can be healed by secondary intent;
c. being used to facilitate the passage of or for storage of bodily fluid, bodily tissues, other fluids, or gases and to be connected with the groups of medical devices or medical devices which carry lower-medium risk (category II active medical devices) or higher.
d. being used to facilitate the passage of or for storage of bodily fluid, bodily tissues, other fluids, or gases, and being designed to facilitate the flow of blood, for the storage of other bodily fluids, to facilitate the flow of other bodily fluids, or to store organs, parts of organs, or body tissues, including blood bags;

e. being used to improve blood's biological component or chemical component or those of other bodily fluid or other fluid with an intent to provide infusion; and

F. being used to improve blood's biological component or chemical component or those of other bodily fluid or other fluid and such improvement via filtration, centrifuging, or the exchange of gas or heat;

(4) all invasive groups of medical devices or medical devices that are inserted into the body through body openings (excluding by surgery) for transient use, and which are connected with low-risk groups of medical devices or medical devices (category I medical devices) or are for transient use, and which must not be connected with groups of active medical devices or active medical devices;

(5) all invasive groups of medical devices or medical devices that are inserted into the body through body openings (excluding by surgery) for short-term usage in the oral cavity to throat cavity, ear canal to eardrum, or nasal cavity;

(6) all invasive groups of medical devices or medical devices inserted by surgery for transient use, and which are reusable;

(7) groups of active medical devices or active medical devices used for diagnosis which transmit visible-spectrum or near-infrared light to patient's body only;

(8) groups of active medical devices or active medical devices, which must not have the following characteristics or uses:

a. all groups of active medical devices or active medical devices used in treatment with an intention to administer or exchange energy, including ionizing radiation;
b. all groups of active medical devices or active medical devices with an intention to control or monitor the capacity of groups of active medical devices or active medical devices that are used for treatment and that carry high-medium risk (category III active medical devices) or which are designed to directly affect the capacity of groups of medical devices or medical devices;
c. groups of active medical devices or active medical devices with an intention to transmit energy that is absorbed by human bodies;
d. groups of active medical devices or active medical devices with an intention to make a diagnosis by radiopharmaceuticals;
e. groups of active medical devices or active medical devices with an intention to diagnose or monitor vital physiological processes;
f. groups of active medical devices or active medical devices with an intention to monitor vital physiological parameters in which a change can cause a specific acute danger to the patient;
g. groups of active medical devices for clinical diagnosis to show that the patient is in specific acute danger.
h. groups of active medical devices or medical devices with an intention for ionizing radiation or which are for interventional radiology, including groups of medical devices or medical devices that control or monitor such groups of medical devices or medical devices, or groups of medical devices or medical devices that directly affect the capacity of any such groups of medical devices or medical devices; and
i. all groups of active medical devices or medical devices with an intention to administer or eliminate drugs, bodily fluid, or other substances to or from the body; and

(9) all groups of medical devices or medical devices that produce or contain non-viable animal tissues, which only have contact with intact skin.

Clause 3. Groups of in vitro diagnosis medical devices or in vitro medical devices which carry a low risk to individuals and public health (category I medical devices) as follows must be registered by the manufacturers or importers:

(1) solutions or other substances with specific characteristics intended by the product owners to be used in in vitro diagnosis steps specifically for such diagnosis only;

(2) groups of medical devices or tools intended by the product owners to be used in in vitro diagnosis steps; and

(3) containers for storing specimen.

Clause 4. Groups of medical devices or medical devices designed to be used with animals only must be registered by the manufacturers and the importers.

Clause 5. If an establishment registrant who manufactures or imports medical devices under clause 2, clause 3, or clause 4 wishes to continue their business, they must submit an application for manufacturing registration prior to the expiry date of the manufacturing establishment registration certificate, or submit the application for import registration prior to the expiry date of the import certificate, as the case may be, from the effective date of this Notification onward.

After submitting the application within the timeframe, the manufacturers and the importers can continue their business until an order rejecting the registration is issued. However, a manufacturing establishment registrant must provide the sales evidence or the Thai innovation registration issued by the Bureau of the Budget, the Prime Minister's Office. An import establishment registrant must provide the medical device import certificate that is still valid as of the effective date of this Notification for the submission of the application for registration, as the case may be.

A manufacturing or import establishment registrant which submits an application under paragraph one, for which the licensors issue a registration certificate under the Ministerial Regulation on the Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), must submit an application 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 Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), issued pursuant to the Ministerial Regulation on the Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), prior to the expiration of the registration certificates if they wish to continue their business.

If a manufacturing establishment registrant or a party which receives a medical device import certificate does not wish to continue their business, 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 an order to suspend the sales is issued.

If the licensor issues an order rejecting the application, 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 an order to suspend the sales is issued.

Clause 6. All medical device manufacturing or import report applications or medical device import certificate applications that have been submitted prior to the effective date of this Notification which are under consideration are deemed registration applications under the Ministerial Regulation on the Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), *mutatis mutandis*, if they are for groups of medical devices or medical devices that must be registered under this Notification.

If the application under the first paragraph is different from the application in the Ministerial Regulation on the Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, 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 Registration, or Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020).

Clause 7. 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 must be registered by the manufacturers and the importers under this Notification, the secretary-general of the Food and Drug Administration shall have the final decision.

Clause 8. This Notification shall take effect after thirty days from the date of its publication in the *Government Gazette*.

Issued on 29 December 2020

Anutin Charnvirakul

Minister of Public Health