Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which Manufacturers and Importers Must Declare Specifications (No. 2) B.E. 2563 (2020)

In order to ensure that the grouping of medical devices or the medical devices that manufacturers and the importers must declare specifications is in line with the Notification of the Ministry of Public Health re: Risk Classification for Medical Devices, dated 14 November 2019, and in line with medical device control standards at the ASEAN level and at the international level, groups of medical devices or medical devices should be classified based on the risk of harm to human health, body, or life, or risk with effects on public health.

By virtue of section 5, paragraph one of the Medical Device Act, B.E. 2551 (2008), and section 6 (1) (b) 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, with the recommendation of the Medical Device Committee, issues the following notification.

Clause 1. Groups of in vitro diagnosis medical devices or in vitro diagnosis medical devices which present a medium risk to individuals or a low risk to public health (category II medical devices) and those which present a high risk to individuals or a medium risk to public health (category III medical devices), as follows, shall be groups of medical devices or medical devices that manufacturers and importers must declare specifications:

(1) groups of medical devices or medical devices with intentions to test blood types or tissue types in order to ensure the compatibility of immune response of blood, blood components, cells, tissue, or organs in blood transfusions or organ implants;

(2) groups of medical devices or medical devices with intentions to detect the causes of sexually transmitted diseases or the contact lesion of the causes of sexual transmitted diseases (such as *Chlamydia trachomatis* or *Neisseria gonorrhoeae*);

(3) groups of medical devices or medical devices with intentions to detect pathogens in cerebrospinal fluid or blood, whereby this kind of pathogens carry a risk because it has limitation in terms of culture (such as *Neisseria meningitidis* or *Cryptococcus neoformans*);

(4) groups of medical devices or medical devices with intentions to detect high-risk pathogens, whereby if a mistake occurs, the patient or fetus may die or may become severely disabled (such as the test kit to diagnose *Cytomegalovirus* (CMV), *Chlamydia pneumoniae*, or methycillin-resistant *Staphylococcus aureus*);

(5) groups of medical devices or medical devices with intentions to screen pregnant women for the conditions of the immune systems against the causes of contagious diseases (such as testing the ability of the immune system to protect against rubella or toxoplasmosis);

(6) groups of medical devices or medical devices with intentions to indicate the conditions of infectious disease or immune systems conditions, whereby a mistake would lead to a decision on treatment that could cause a life-threatening situation for the patient (such as testing for enteroviruses, CMV, and *Herpes simplex* virus (HSV) in organ transplant patients);

(7) groups of medical devices or medical devices with intentions to screen patients for a specific therapy or treatment, or to indicate the stage of a disease, or to diagnose cancer (such as giving specific medicines to a person);

(8) groups of medical devices or medical devices for genetic tests in humans (such as for Huntington's disease or cystic fibrosis);

(9) groups of medical devices or medical devices with intentions to monitor the levels of medicine, substances, or biological components, whereby a mistake would lead to a risk that a treatment

would be decided upon which could cause an immediate life-threatening situation to the patient (such as cardiac markers, cyclosporine, or prothrombin time testing);

(10) groups of medical devices or medical devices with intentions to treat patients with life-threatening infectious diseases (such as HCV viral load, HIV viral load, and HIV and HCV geno- and sub-typing);

(11) groups of medical devices or medical devices with intentions to screen congenital anomalies in human fetuses (such as spina bifida or Down syndrome);

(12) groups of medical devices or medical devices for self-testing;

(13) groups of medical devices or medical devices for testing gas in the blood or glucose in the blood, in which the test is conducted near the patient's body;

(14) groups of medical devices or medical devices to be used as controlling factor without any quality or quantity value; and

(15) Groups of in vitro diagnosis medical devices or in vitro diagnosis medical devices purposes, apart from those specified in items (1) to (14), that are not prescribed as category I medical devices or category IV medical devices pursuant to the Notification of the Ministry of Public Health re: Risk Classification for Medical Devices, B.E. 2562 (2019).

Clause 2 The groups of non-in vitro diagnosis medical devices or non-in vitro diagnosis medical devices with lower-medium risk (category II medical devices) and higher-medium risk (category III medical devices), as follows, shall be medical devices that manufacturers and importers must declare specifications:

(1) non-invasive medical devices classified as:
- 1) non-invasive medical devices for laceration wounds which pierce the dermis of the skin, including medical devices designed to manage the microenvironment of a wound;
- 2) non-invasive medical devices for laceration wounds which pierce the dermis of the skin which can be treated by secondary intent;
- 3) non-invasive medical devices that are used as a passageway or used for collecting bodily fluid, tissues, other fluids, or gas, and which:
  - 3.1) are to be connected with an active medical device with medium to high risk;
  - 3.2) facilitate the passageway of blood;
  - 3.3) are to be used for collecting or used as passageway of other bodily fluid;
  - 3.4) are to be used for the storage of organs, parts of organs, or tissues; or
  - 3.5) are to be used as a blood bag without any medicine, blood preservatives, or other components involved; and
- 4) non-invasive medical devices for improving blood's biological component or chemical component or those of other bodily fluid or other fluid, via:
  - 4.1) infusion; or
  - 4.2) treatment involving filtering, centrifuging, or exchange of gas or heat;

(2) invasive medical devices classified as:
- 1) invasive medical devices inserted through body openings (except through surgery), but not designed to be connected to an active medical device, or only designed to be connected to a low-risk medical device, which are:
  - 1.1) to be used along the surface of an eyeball or having a tendency to be absorbed by mucus epithelium;
  - 1.2) for short-term usage; or
  - 1.3) for long-term usage;
- 2) invasive medical devices inserted through body openings (except through surgery), which are designed to be connected to a medium- or high-risk active medical device;
- 3) all invasive medical devices inserted through surgery for transient use, excluding reusable surgical devices, medical devices designed to be in direct contact with the central nervous

system, and medical devices designed to diagnose, monitor, or treat defects in the heart or the central circulatory system by direct contact with these body parts;

4) all invasive medical devices inserted through surgery for short-term usage, excluding medical devices designed to cause biological result or all or major absorption, medical devices designed to be in direct contact with the central nervous system, and medical devices designed to diagnose, monitor, or treat defects in the heart or the central circulatory system by direct contact with these body parts; and

5) all medical devices that are implanted in the body or are implanted in the body by surgery for long-term usage, and which do not carry a high risk.

(3) active medical devices, classified as:

1) all active medical devices for treatment:

1.1) for managing or exchanging energy; or

1.2) for managing or exchanging energy into or out of the body with a dangerous tendency, including radiation that causes ionization, considering the nature, density, and position of the managing or exchanging of energy;

2) all active medical devices designed to control or monitor the capacity of the active medical devices used in treatment with higher-medium risk or designed to directly affect the capacity of those medical devices;

3) active medical devices for diagnosis;

4) active medical devices for diagnosis to transmit energy that is absorbed by human bodies (except medical devices that are used to transmit visible-spectrum or near-infrared light to the patient's body only);

5) active medical devices for diagnosis to create radiopharmaceuticals;

6) active medical devices for diagnosis used to diagnose or monitor vital physiological processes;

7) active medical devices for diagnosis used to track vital physiological parameter for which any change could cause an acute danger to the patients, such as a change to the functioning of the heart, respiration, or the central nervous system;

8) active medical devices for clinical diagnosis to show that the patient is in acute danger;

9) active medical devices designed to release ionizing radiation and to be used in interventional radiology, including medical devices designed to control or monitor any such medical devices or medical devices that directly affect the capacity of any such medical devices;

10) all active medical devices designed to administer or flush out medicine, bodily fluids, or other substances in the body; and

11) all active medical devices designed to administer or flush out medicine, bodily fluids, or other substances in the body when any such medicine, bodily fluid, or other substance could cause a danger, whereby the nature of the substance, pertinent body parts, methods, and channels for the administration or elimination will be taken into consideration; and

(4) other medical devices with specific purposes, as follows:

1) medical devices used to disinfect medical devices or for end-of-process sterilization;

2) medical devices designed to sterilize medical devices before the end of the disinfecting process or before the advanced sterilization process;

3) medical devices designed to sterilize, clean, wash, or moisturize contact lenses; and

4) medical devices used for birth control and to prevent sexually transmitted diseases

Clause 3. Groups of medical devices or medical devices under clause 1 and clauses 2 do not include low-risk groups of medical devices or medical devices (category I medical devices) and high-risk groups of medical devices or medical devices (category IV medical devices), pursuant to the Notification

of the Ministry of Public Health re: Risk Classification for Medical Devices, B.E. 2562 (2019), dated 14 November 2019.

Clause 4. The following groups of medical devices or medical devices that the manufacturers or the importers must obtain a license that are categorized as groups of medical devices or medical devices under clause 1 or clause 2 require declaration of specifications under this Notification:

(1) surgical gloves under Notification of the Ministry of Public Health No. 31, B.E. 2547 (2004) re: Surgical Gloves, dated 10 May 2004;

(2) contact lenses under the Notification of the Ministry of Public Health re: Contact Lenses, dated 31 August 2010;

(3) condoms under the Notification of the Ministry of Public Health re: Condoms, B.E. 2556 (2013), dated 18 September 2013; and

(4) HIV-Related Test Kits under the Notification of the Ministry of Public Health re: HIV-Related Test Kits, dated 2 November 2009, and Notification of the Ministry of Public Heath re: HIV-Related Test Kits No. 2, B.E. 2562 (2019), dated 19 March 2019.

Clause 5. The licensees to manufacture or import surgical gloves under clause 2 (2) and clause 4 (1), condoms under clause 2 (4) 4) and clause 4 (3), contact lenses under clause 2 (2) and clause 4 (2), and test kits related to HIV infection under clause 1 (10) and clause 4 (4), which are groups of medical devices or medical devices of which specifications must be declared under this Notification before the effective date of this Notification, and who wish to continue their business must submit an application to declare specifications under the Ministerial Regulation on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), prior to the expiration date of the license.

After the submission of the application in the first paragraph within the timeframe, the business can be continued until an order is issued rejecting the declaration of specifications.

If a licensee does not wish to take action under the first paragraph, they can continue to manufacture or import medical devices until their license expires. They can continue to sell medical devices in their possession until the products expire or an order to suspend the sales is issued.

If the licensor issues an order rejecting the declaration of specifications, 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.

The licenses to manufacture or import surgical gloves, condoms, contact lenses, and test kits related to HIV infection under the first paragraph that were issued prior to the effective date of these Ministerial Regulations will still be effective until their expiration, a prohibition order is issued, or they are revoked, as the case may be.

Clause 6. Medical device manufacturing or import establishment registrants under clause 1 or clause 2 prior to the effective date of this Notification who wish to continue their businesses shall submit an application for declaration of specifications for manufacturing of medical devices prior to the expiration of the establishment registration certificate or submit an application for declaration of specifications for import of medical devices prior to the expiration of the import certificate, as the case may be, from the effective date of this Notification.

After the submission of the application under the first paragraph within the given timeframe, the registrants can continue their businesses until an order rejecting the declaration is issued. The manufacturing establishment registrants must provide the sales evidence or a Thai innovation registration as issued by the Bureau of the Budget, the Prime Minister's Office. The import establishment registrants must provide a medical device import certificate that is still valid as of the effective date of this Notification as part of the application for declaration of specifications.

Manufacturing or import establishment registrants who submit applications for declaration of specifications under the first paragraph and who have obtained receipt of declaration of specifications under the Ministerial Regulation on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020) 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 Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), issued pursuant to the Ministerial Regulation on Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), prior to the expiration of the receipt for declaration of specifications, if they wish to continue their businesses.

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 an order to suspend the sales is issued.

If the licensor issues an order rejecting the notification, 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.

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

Clause 7. All medical device manufacturing or import applications or medical device import certificate applications that have been 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 require declaration of specifications under this Notification, are deemed application for declaration of specifications under the Ministerial Regulations on Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), *mutatis mutandis*.

If the application under the first paragraph is different from the application in the Ministerial Regulations on Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding 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 Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020).

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 declare specifications pursuant to this Notification, the secretary-general of the Food and Drug Administration shall have the final decision.

Clause 9 If another notification specifically applies to groups of medical devices or medical devices that are listed under this Notification, and the manufacturer or the importer has already specifically declared specifications under that notification, the notification will apply.

Clause 10 This Notification does not apply to the following medical devices:

(1) teeth whitening products, pursuant to the Notification of the Ministry of Public Health re: Determination that Teeth Whitening Products are Medical Devices, B.E. 2561 (2018), dated 27 August 2018;

(2) products containing alcohol used as sanitizers for humans, animals, and medical devices, pursuant to the Notification of the Ministry of Public Health re: Products Containing Alcohol Used as Sanitizers for Humans, Animals, and Medical Devices, B.E. 2562 (2019), dated 9 August 2019;

(3) hemodialysis concentrate products, pursuant to the Notification of the Ministry of Public Health re: Hemodialysis Concentrate Products, dated 3 October 2017; and

(4) contact lens care products, pursuant to the Notification of the Ministry of Public Health re: Contact Lens Care Products, B.E. 2562 (2019), dated 3 April 2019.

Clause 11. This Notification shall take effect from the date of its publication in the *Government Gazette*.

Issued on 29 December 2020
Anutin Charnvirakul
Minister of Public Health