NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: CLASSES OF MEDICAL DEVICES OR MEDICAL DEVICES OF WHICH MANUFACTURERS OR IMPORTERS ARE REQUIRED TO DECLARE SPECIFICATIONS (NO. 2), B.E. 2563 (2020)*

In order to ensure that the classification of classes of medical devices or medical devices of which manufacturers or importers are required to declare specifications is in compliance with the Notification of the Ministry of Public Health Re: Risk Classification of Medical Devices, B.E. 2562 (2019) dated the 14th day of November B.E. 2562 (2019) and consistent with the control of medical devices at the ASEAN region and international levels, it is expedient to classify classes of medical devices or medical devices according to the level of their risks of danger to the health, body or life of human or impacts on public health.

By virtue of the provisions of section 5 paragraph one of the Medical Devices Act, B.E. 2551 (2008) and section 6 (1) (b) of the Medical Devices Act, B.E. 2551 (2008) as amended by the Medical Devices Act (No. 2), B.E. 2562 (2019), the Minister of Public Health, upon recommendation of the Board of Medical Devices, hereby issues the Notification as follows.

Clause 1. The following classes of in vitro diagnostic medical devices or in vitro diagnostic medical devices with a moderate individual risk or a low public health risk (type 2 medical devices) and those with a high individual risk or a moderate public health (type 3 medical devices) shall be medical devices of which manufacturers or importers are required to declare specifications:

(1) classes of medical devices or medical devices intended for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs for blood transfusion or transplantation;

(2) classes of medical devices or medical devices intended for use in detecting the presence of or exposure to a sexually transmissible agent (e.g. Chlamydia trachomatis, Neisseria gonorrhoeae);

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(3) classes of medical devices or medical devices intended for use in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation (e.g. Neisseria meningitidis or Cryptococcus neoformans);

(4) classes of medical devices or medical devices intended for use in detecting the presence of an infectious agent where there is a high risk that an erroneous result would cause death or severe disability to the patient or fetus (e.g. diagnostic assay for Cytomegalovirus (CMV), Chlamydia pneumoniae, Methycillin Resistant Staphylococcus aureus);

(5) classes of medical devices or medical devices intended for use in pre-natal screening of pregnant women in order to determine their immune status towards transmissible agents (e.g. immune status tests for Rubella or Toxoplasmosis);

(6) classes of medical devices or medical devices intended for use in determining infectious disease status or immune status where there is a risk that an erroneous result will lead to a therapy decision resulting in a life-threatening situation for the patient (e.g. Enteroviruses, CMV and Herpes simplex virus (HSV) in transplant patients);

(7) classes of medical devices or medical devices intended for use in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer (e.g. personalized medicine);

(8) classes of medical devices or medical devices intended for use in human genetic testing (e.g. Huntington's Disease, Cystic Fibrosis);

(9) classes of medical devices or medical devices intended for use to monitor levels of medicinal drugs, substances or biological components when there is a risk that an erroneous result will lead to a therapy decision resulting in an immediate life-threatening situation for the patient (e.g. Cardiac markers, cyclosporin, prothrombin time testing);

(10) classes of medical devices or medical devices intended for use in the treatment of patients suffering from a life-threatening infectious disease (e.g. HCV viral load, HIV Viral Load and HIV and HCV geno - and subtyping);

(11) classes of medical devices or medical devices intended for use in screening for congenital disorders in the fetus (e.g. Spina Bifida or Down Syndrome);

(12) classes of medical devices or medical devices intended for use for self-testing;

(13) classes of medical devices or medical devices intended for use for blood gases and blood glucose determinations for near-patient testing;

(14) classes of medical devices or medical devices intended for use as controls without a quantitative or qualitative assigned value;

(15) classes of in vitro diagnostic medical devices or in vitro diagnostic medical devices other than those specified in (1) to (14) in respect of which there is no rule to classify

them as type 1 medical devices or type 4 medical devices under the Notification of the Ministry of Public Health Re: Risk Classification of Medical Devices, B.E. 2562 (2019).

Clause 2. The following classes of non-in vitro diagnostic medical devices with a low-moderate risk (type 2 medical devices) and a moderate-high risk (type 3 medical devices) shall be medical devices of which manufacturers or importers are required to declare specifications:

(1) non-invasive medical devices as follows:

1) non-invasive medical devices intended to be used with wounds which have breached the dermis, including medical devices intended to manage the microenvironment of a wound;

2) non-invasive medical devices intended to be used with wounds which have breached the dermis and can heal by secondary intent;

3) non-invasive medical devices intended for channeling or storing body liquids, body tissues, other liquids or gases as follows:

3.1) those connected to an active medical device with a moderate to high risk;

3.2) those used for channeling of blood;

3.3) those used for storing or channeling of other body liquids;

3.4) those used for storing organs, parts of organs or body tissues;

3.5) blood bags that do not incorporate medicinal drugs, anti-coagulants or other compounds;

4) non-invasive medical devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids as follows:

4.1) those for infusion into the body;

4.2) treatment consisting of filtration, centrifuging or exchanges of gas or of heat;

(2) invasive medical devices as follows:

1) invasive medical devices with respect to body orifices (other than those which are surgically invasive) which are not intended for connection to an active medical device or intended for connection to a medical device with a low risk only as follows:

1.1) those intended for use on the external surface of any eyeball or are liable to be absorbed by the mucous membrane;

1.2) those intended for short-term use;

1.3) those intended for long-term use;

2) invasive medical devices with respect to body orifices (other than those which are surgically invasive) which are intended to be connected to an active medical device with a moderate risk or a high risk;

3) all surgically invasive medical devices intended for transient use, excluding reusable surgical instruments, medical devices intended for use in direct contact with the central nervous system and medical devices intended for diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with such parts of the body;

4) all surgically invasive medical devices intended for short-term use, excluding medical devices intended to have a biological effect or be wholly or mainly absorbed, medical devices intended to be in direct contact with the central nervous system, medical devices intended for diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with such parts of the body;

5) all implantable medical devices and long-term surgically invasive medical devices that are not medical devices with a high risk;

(3) active medical devices as follows:

1) all active therapeutic devices:

1.1) those intended to administer or exchange energy;

1.2) those intended to administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of administration or exchange of the energy;

2) all active medical devices intended to control or monitor the performance of active therapeutic devices with a moderate-high risk, or intended directly to influence the performance of such medical devices;

3) active devices intended for diagnosis;

4) active devices intended for diagnosis to supply energy which will be absorbed by the human body (except for medical devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum);

5) active devices intended for diagnosis to image in vivo distribution of radiopharmaceuticals; or

6) active devices intended for diagnosis to allow direct diagnosis or monitoring of vital physiological processes;

7) active devices intended for diagnosis to monitor vital physiological parameters, where the nature of variations could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system;

8) active devices intended for diagnosis to determine in clinical situations where the patient is in immediate danger;

9) active medical devices intended to emit ionizing radiation and intended for diagnostic or interventional radiology, including medical devices which control or monitor such medical devices, or medical devices which directly influence their performance;

10) all active medical devices intended to administer and/or remove medicinal drugs, body liquids or other substances to or from the body;

11) all active medical devices intended to administer and/or remove medicinal drugs, body liquids or other substances to or from the body where the administration or removal is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration or removal;

(4) other medical devices intended for specific cases as follows:

1) medical devices used for sterilizing medical devices, or disinfecting as the end point of processing;

2) medical devices intended for disinfecting medical devices prior to end point sterilization or higher-level disinfection;

3) medical devices intended for disinfecting, cleaning, rinsing or hydrating contact lenses;

4) medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases.

Clause 3. The classes of medical devices or medical devices under clause 1 and clause 2 do not include classes of medical devices or medical devices with a low risk (type 1 medical devices) and with a high risk (type 4 medical devices) under the Notification of the Ministry of Public Health Re: Risk Classification of Medical Devices, B.E. 2562 (2019) dated the 14th day of November B.E. 2562 (2019).

Clause 4. The following classes of medical devices or medical devices for which manufacturers or importers are required to obtain a license and that are specifically classified as classes of medical devices or medical devices under clause 1 or clause 2 shall be subject to the requirement of declaration of specifications under this Notification:

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

(2) contact lenses under the Notification of the Ministry of Public Health Re: Contact Lenses dated the 31st day of August B.E. 2553 (2010);

(3) condoms under the Notification of the Ministry of Public Health Re: Condoms dated the 18th day of September B.E. 2556 (2013);

(4) test kits related to HIV infection under the Notification of the Ministry of Public Health Re: Test Kits Related to HIV Infection dated the 2nd day of November B.E. 2552 (2009) and the Notification of the Ministry of Public Health Re: Test Kits Related to HIV Infection (No. 2) B.E. 2562 (2019) dated the 19th day of March B.E. 2562 (2019).

Clause 5. A licensee with a license 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 2 (2) and clause 4 (2) and test kits related to HIV infection under clause 1 (10) and clause 4 (4) classified as classes of medical devices or medical devices subject to the requirement of declaration of specifications under this Notification prior to the date on which this Notification comes into force, who wishes to continue operating the business, shall submit an application to declare specifications under the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Importation of Medical Devices, B.E. 2563 (2020) before the date of expiration of the license.

Upon submission of the application within the period under paragraph one, the operation may be continued until an order refusing to accept the declaration of specifications is given.

In the case where the licensee does not wish to proceed in accordance with paragraph one, the licensee may continue to manufacture or import the medical devices until the expiration of the license. The medical device products remaining in the possession may continue to be sold until the products expire or an order is given to suspend the sale.

In the case where the licensor gives an order refusing to accept the declaration of specifications, the medical devices that are manufactured or imported prior to the date on which this Notification comes into force and remain in the possession may continue to be sold until the products expire or an order is given to suspend the sale.

The license to manufacture or import surgical gloves, condoms, contact lenses and test kits related to HIV infection under paragraph one that is issued prior to the date this Ministry Notification comes into force shall remain to be valid until the license expires, or an order refusing the license is given, or the license is revoked, as the case may be.

Clause 6. An establishment registrant manufacturing or importing a medical device under clause 1 or clause 2 prior to the date on which this Notification comes into force, who wishes to continue the operation, shall submit an application to declare

manufacturing specifications before the date of expiration of the manufacturing establishment registration certificate, or submit an application to declare import specifications before the date of expiration of the import establishment registration certificate, as the case may be. This shall apply as from the date on which this Notification comes into force.

Upon submission of the application within the period under paragraph one, the operation may be continued until an order refusing to accept the declaration of specifications is given. The manufacturing establishment registrant must produce evidence of sale or of listing on the Thai Innovation List issued by the Bureau of the Budget, Office of the Prime Minister. The import establishment registrant must produce a medical device import certificate which remains valid on the date on which this Notification comes into force in support of the application to declare specifications.

With respect to a medical device manufacturing or import establishment registrant who submits an application to declare specifications under paragraph one and to whom the licensor issues a specification declaration receipt under the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020) prior to the expiration of the specification declaration receipt, if the manufacturing or import specification declarer wishes to continue the operation, such person shall submit an application for renewal in the form under the Notification of the Food and Drug Administration Re: Specification of Forms under the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020) issued under the provisions of the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020).

In the case where a manufacturing establishment registrant or a recipient of a medical device import certificate does not wish to continue the operation, such person may continue to manufacture or import the medical devices until the expiration of the manufacturing establishment registration certificate or the medical device import certificate. The medical device products remaining in the possession may continue to be sold until the products expire or an order is given to suspend the sale.

In the case where the licensor gives an order refusing to accept the declaration of specifications, the medical devices that are manufactured or imported prior to the date on which this Notification comes into force and remain in the possession may continue to be sold until the products expire or an order is given to suspend the sale.

The medical device import certificate shall remain to be valid until the certificate expires or is cancelled.

Clause 7. All applications for a license to manufacture or import medical devices or all applications for a medical device import certificate that were submitted before this Notification comes into force and remain under the consideration, if classified as classes of medical devices or medical devices subject to the requirement of declaration of specifications under this Notification, shall be deemed applications for declaration of specifications under the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020) *mutatis mutandis*.

In the case where the application under paragraph one contain particulars which are different from the application under the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020), the licensor shall have the power to require the applicant for the declaration of specifications to make an amendment or submit additional information, documents or evidence as may be necessary for the compliance with the Ministerial Regulation on Declaration of Specifications and Issuance of Specification Declaration Receipts for Manufacturing or Import of Medical Devices, B.E. 2563 (2020).

Clause 8. The Secretary-General of the Food and Drug Administration shall have charge and control of the execution of this Notification. In the case where there is a problem as to the classification of classes of medical devices or medical devices of which manufacturers or importers are required to declare specifications under this Notification, the Secretary-General of the Food and Drug Administration shall have the power to make a decision thereon.

Clause 9. In the case where there is a Notification specifically prescribing classes of medical devices or medical devices under this Notification of which manufacturers or importers are required to declare specifications, such Notification shall be complied with.

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

(1) teeth whitening products under the Notification of the Ministry of Public Health Re: Prescription of Teeth Whitening Products as Medical Devices, B.E. 2561 (2018) dated the 27th day of August B.E. 2561 (2018);

(2) alcohol-based disinfectant products for human, animals and medical devices under the Notification of the Ministry of Public Health Re: Alcohol-based Disinfectant

Products for Human, Animals and Medical Devices, B.E. 2562 (2019) dated the 9th day of August B.E. 2562 (2019);

(3) concentrate for haemodialysis under the Notification of the Ministry of Public Health Re: Concentrate for Haemodialysis dated the 3rd day of October B.E. 2560 (2017);

(4) contact lens care products under the Notification of the Ministry of Public Health Re: Contact Lens Care Products, B.E. 2562 (2019) dated the 3rd day of April B.E. 2562 (2019).

Clause 11. This Notification shall come into force as from the day of its publication in the Government Gazette.

Announced on the 29th day of December B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health