NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: CLASSES OF MEDICAL DEVICES OR MEDICAL DEVICES FOR WHICH MANUFACTURERS OR IMPORTERS ARE REQUIRED TO OBTAIN A LICENSE, B.E. 2563 (2020)*

In order to ensure that the control of medical devices is efficient, suitable to public health situations and problems of the country and consistent with the control of medical devices at the international level, it is expedient to prescribe classes of medical devices or medical devices with high risks of danger from their use as medical devices for which manufacturers or importers are required to obtain a license with a view to ensuring safety and appropriate consumer protection.

By virtue of the provisions of section 5 paragraph one and section 6 (1) (a) 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 medical devices shall be medical devices for which manufacturers or importers are required to obtain a license:

(1) all surgically invasive medical devices intended for transient use—

a. in direct contact with the central nervous system;

b. 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;

(2) all surgically invasive medical devices intended for short-term use—

a. to have a biological effect or be wholly or mainly absorbed;

b. in direct contact with the central nervous system;

c. 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;

(3) all implantable medical devices and surgically invasive medical devices intended for long-term use—

a. in direct contact with the heart, central circulatory system or central nervous system;

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b. for life supporting or life sustaining;

c. to be active implantable medical device;

d. to have a biological effect or be wholly or mainly absorbed;

e. for administration of medicinal drugs;

f. for undergoing chemical change in the body, except for medical devices placed in the teeth;

g. which are breast implants;

(4) medical devices incorporating, as an integral part thereof, a medicinal drug under the law on drugs which is liable to act on the human body with action ancillary to that of the medical devices;

(5) all medical devices manufactured from or incorporating the following:

a. cells, tissues or derivatives of animals which are non-viable; or

b. cells, tissues or derivatives of microorganisms or from recombination of genes;

However, these exclude medical devices manufactured from or incorporating non-viable animal tissues or derivatives that come into contact with skin only;

(6) all medical devices used for contraception or prevention of the transmission of sexually transmitted infectious diseases that are implantable or long-term invasive devices;

(7) in vitro diagnostic medical devices intended for detecting the presence of or exposure to a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation;

(8) in vitro diagnostic medical devices intended for use to detect the presence of or exposure to a transmissible agent that causes a life-threatening, incurable disease with a high risk of propagation.

Clause 2. The list of medical devices in the classes of medical devices under clause 1 shall be in accordance with the list annexed to this Notification.

Clause 3. In cases where there is a Notification specifically prescribe classes of medical devices or medical devices for which manufacturers or importers are required to obtain a license, such Notification shall be complied with.

Clause 4. This Notification shall come into force as from the day of its publication in the Government Gazette.

Announced on the 27th day of April B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

List of Medical Devices
Annexed to the Notification of the Ministry of Public Health Re: Classes of Medical Devices or Medical Devices
For Which Manufacturers or Importers Are Required to Obtain a License, B.E. 2563 (2020)

Item	Class of Medical Devices or Medical Devices	Rules, Procedures and Conditions	Remark
1	Test kits related to HIV infection	They shall be in accordance with the Notification of the Public Health Re: Test Kits Related to HIV Infection dated the 2nd day of November B.E. 2552 (2009).	Under clause 1 (8) of this Notification
2	Test kits related to self-screening of HIV infection	They shall be in accordance with the Notification of the Public Health Re: Test Kits Related to Self-screening of HIV Infection, B.E. 2562 (2019) dated the 19th day March B.E. 2562 (2019).	Under clause 1 (8) of this Notification
3	Injection-type hyaluronic acid for correction of skin defects	They shall be in accordance with the Notification of the Public Health Re: Injection-type Hyaluronic Acid for Correction of Skin Defects, B.E. 2562 (2019) dated the 9th day of August B.E. 2562 (2019)	Under clause 1 (4) of this Notification
4	Silicone breast implants	They shall be in accordance with the Notification of the Public Health Re: Silicone Breast Implants, B.E. 2562 (2019) dated the 7th day of November B.E. 2562 (2019)	Under clause 1 (3) ฐ. of this Notification
5	Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection	Test kits and reagents related to diagnosis of SARS-CoV-2 (virus causing COVID-19) infection means reagents, reagent products and kit components, including relevant calibrators or control materials, whether used alone or in a combination, to conduct a test, a confirmatory test or a quantitative test on a specimen derived the	Under clause 1 (8) of this Notification

Item	Class of Medical Devices or Medical Devices	Rules, Procedures and Conditions	Remark
		human body to diagnose the infection of SARS-CoV-2 (virus causing COVID-19). They may be classified by their test into 3 types: (1) the type that tests for genetic materials through the real time RT-PCR method or other method; (2) the type that tests for antibodies; (3) the type that tests for antigens. They may be classified by their use into 2 types: (1) test kits and reagents required to be used in combination with an analytical device; (2) test kits and reagents not required to be used in combination with an analytical device.	