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

In order to ensure that the classification of classes of medical devices or medical devices in respect of which manufacturers or importers are required to make a notification 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 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 and section 6 (1) (c) 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 non-in vitro diagnostic medical devices or non-in vitro diagnostic medical devices with a low risk (type 1 medical devices) shall be medical devices in respect of which manufacturers or importers are required to make a notification:

(1) all classes of non-invasive medical devices or non-invasive medical devices which are in contact with wounded skin and intended to be used as a mechanical barrier for compression or for absorption of exudates leaked from the wound only;

(2) all classes of non-invasive medical devices or non-invasive medical devices used for channeling or storing body liquids, body tissues, other liquids or gases for the purpose of infusion, administration or introduction into the body;

(3) all classes of non-invasive medical devices or non-invasive medical devices which do not have the characteristics or application as follows:

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a. being in contact with wounded skin and intended to be used with wounds which have breached the dermis, including medical devices intended to manage the microenvironment of a wound;

b. being in contact with wounded skin and intended to be used with wounds which have breached the dermis and can only heal by secondary intent;

c. being used for channeling or storing body liquids, body tissues, other liquids or gases and are connected to classes of medical devices or medical devices with a low-moderate risk (type 2 medical device) or a higher type;

d. being used for channeling or storing body liquids, body tissues, other liquids or gases and intended for use of channeling blood, storing or channeling other body liquids, or storing organs, parts of organs or body tissues, including blood bags;

e. being used for modifying the biological or chemical composition of blood, body liquids or other liquids and intended for infusion into the body;

f. being used for the modification of the biological or chemical composition of blood, body liquids or other liquids which consists of filtration, centrifuging or exchanges of gas or of heat;

(4) all classes of invasive medical devices or invasive medical devices with respect to body orifices (other than those which are surgically invasive) which are intended for transient use and for connection with classes of medical devices or medical devices with a low risk (type 1 medical devices) only, or are intended for transient use and not intended for connection to classes of active medical devices or active medical devices;

(5) all classes of invasive medical devices or invasive medical devices with respect to body orifices (other than those which are surgically invasive) which are intended for short-term use and for use on the external surface of an eyeball, or are liable to be absorbed by the mucous membrane;

(6) classes of surgically invasive medical devices or surgically invasive medical devices which are intended for transient use and are reusable surgical instruments;

(7) classes of active devices or active devices intended for diagnosis which are used solely to illuminate the patient's body with light in the visible or near infra-red spectrum;

(8) classes of active medical devices or active medical devices which do not have the characteristics or application as follows:

a. all classes of active therapeutic devices or active therapeutic devices intended to administer or exchange energy, including ionizing radiation;

b. all classes of active medical devices or active medical devices intended to control or monitor the performance of active therapeutic devices which are classes of medical devices or medical devices with a moderate-high risk (type 3 active medical devices),

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or intended directly to influence the performance of such classes of medical devices or medical devices;

c. classes of active devices or active devices intended for diagnosis by supplying energy which will be absorbed by the human body;

d. classes of active medical devices or active devices intended for diagnosis by imaging in vivo distribution of radiopharmaceuticals;

e. classes of active medical devices or active devices intended for diagnosis by allowing direct diagnosis or monitoring of vital physiological processes;

f. classes of active medical devices or active devices intended for diagnosis for monitoring of vital physiological parameters, where the nature of variations could specifically result in immediate danger to the patient;

g. classes of active medical devices or active devices intended for diagnosis for diagnosing in clinical situations where the patient is particularly in immediate danger;

h. classes of active medical devices or active medical devices intended to emit ionizing radiation and intended for diagnostic or interventional radiology, including classes of medical devices or medical devices which control or monitor such classes of medical devices or medical devices, or those which directly influence their performance;

i. all classes of active medical devices or active medical devices intended to administer or remove medicinal drugs, body liquids or other substances to or from the body;

(9) all classes of medical devices or medical devices manufactured from or incorporating non-viable animal tissues or their derivatives that come in contact with intact skin only, provided that they are manufactured from or incorporate the following:

a. animal cells, tissues or derivatives thereof which are non-viable; or

b. cells, tissues or derivatives of microbial or recombinant origin.

Clause 2. The following classes of in vitro diagnostic medical devices or in vitro diagnostic medical devices with low individual and public health risks (type 1 medical devices) shall be medical devices in respect of which manufacturers or importers are required to make a notification:

(1) reagents or other substances that possess specific characteristics intended by the product owner to be used for in vitro diagnostic procedures related to a specific examination;

(2) classes of medical devices or medical devices intended by the product owner specifically to be used for in vitro diagnostic procedures;

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(3) specimen receptacles.

Clause 3. The Secretary-General of the Food and Drug Administration shall have charge and control of the execution of this Notification. In cases where there is a problem as to the classification of classes of medical devices or medical devices which are subject to the notification under this Notification, the Secretary-General of the Food and Drug Administration shall have the power to make a decision thereon.

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

Announced on the 16th day of July B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

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