

NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: RULES, PROCEDURES AND CONDITIONS ON DISPLAY OF LABELS
AND MEDICAL DEVICE PACKAGE INSERTS,
B.E. 2563 (2020)*

In the interest of protecting consumers so that they could receive necessary information pertaining to the use and storage of medical devices which display labels and medical device package inserts in a correct manner for safety reasons;

By virtue of the provisions of section 5 paragraph one of the Medical Devices Act, B.E. 2551 (2008) and section 44 paragraph two 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 hereby issues the Notification as follows.

Clause 1. In this Notification:

“home use medical device” means a medical device intended to be used by lay users at a place which, by nature or circumstances, is not a medical establishment, such as residence, or a medical device ordered by medical personnel to be used for patients or sick animals outside of a medical establishment, and shall include a medical device intended to be used both inside and outside of a medical establishment;

“professional use medical device” means a medical device which is not intended to be used by lay persons, but is intended to be used only by a medical and public health professional or under the supervision of a medical and public health professional.

Clause 2. An establishment registrant, a licensee, a specification declarer or a notifier who manufactures or imports a medical device shall provide a label or a medical device package insert, as the case may be, which is clearly visible in accordance with clause 3 or clause 4. The statements shown therein must not be represented in a false or exaggerated manner, or not contain overstatement as to the properties or cause fundamental misunderstanding.

* Published in the Government Gazette, Vol. 137, Special Issue, Part 260d, page 13, dated 5th November B.E. 2563 (2020)

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Clause 3. A label of a medical device that requires licensing, declaration of specifications or notification shall be displayed in conformity with the following.

(1) A home use medical device must be accompanied by a label which is in Thai language and clearly readable.

(2) A professional use medical device must be accompanied by a label which is in Thai or English language and clearly readable.

A label of a medical device under (1) or (2) may also include other languages, but the meaning of statements in such other language must not be contrary to or inconsistent with the statements in Thai or English language.

(3) The label must be displayed at a conspicuous place on the medical device or a container of the medical device and be clearly readable. The label must at least contain the following details:

- (a) name of the product;
- (b) necessary details relating to the medical device, such as main components, operation principles, category and type;
- (c) intended uses or indications;
- (d) number, quantity contained or quantity that can be contained, as the case may be;
- (e) directions, except for a medical device of which usage is already apparent;
- (f) name and location of the manufacturing facility or import facility, as the case may be, provided that in cases of an importer, the name of the manufacturing facility, city and country of manufacturing shall also be displayed, but if the name of the facility and city of the manufacturer are not displayed, the name of the product owner, city and country of the product owner and country of the manufacturer shall instead be displayed;
- (g) reference number of the license, specification declaration receipt or notification receipt;
- (h) name, address and telephone number, or contact information in cases of requesting additional information or making complaints;
- (i) number or alphabet identifying the batch number or lot number, or serial number;
- (j) month and year or year and month of manufacturing or expiry which shall be displayed in a four-digit number, provided that in the case where the medical device has a shelf life, the month and year or year and month of expiry shall also be displayed;
- (k) storage instructions;

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(l) warnings, contraindications or precautions for safe usage of the medical device (if any).

If the statements in (c), (e), (h), (k) and (l) cannot be displayed on the label, they shall be displayed in the medical device package insert instead.

A label of a home use medical device under (i) may be displayed in English language or as abbreviations in English language.

A label of a professional use medical device under (i) and (j) may be displayed in English language or as abbreviations in English language.

In cases of the display of a label of a professional use medical device, if abbreviations in English language or symbols are used in lieu of a statement, their meanings shall also be clarified in Thai language or English language on the label or in the medical device package insert.

Clause 4. A package insert of a home use medical device shall display statements in Thai language, and may include other languages but the meaning of the statements in such other languages must not be contrary to or inconsistent with statements in Thai language. The package insert shall at least contain the following details:

- (1) name of the product;
- (2) necessary details relating to the medical device, such as main components, operation principles, category and type;
- (3) intended uses;
- (4) number, quantity contained or quantity that can be contained, as the case may be;
- (5) name and location of the manufacturing facility or import facility, as the case may be, provided that in cases of an importer, the name of the manufacturing facility, city and country of manufacturing shall also be displayed, but if the name of the facility and city of the manufacturer are not displayed, the name of the product owner, city and country of the product owner and country of the manufacturer shall instead be displayed;
- (6) indications, directions and instructions for use;
- (7) storage instructions;
- (8) warnings, contraindications or precautions for safe usage of the medical device (if any);
- (9) month and year of issuance or latest revision of the medical device package insert, or up-to-date control code of the document.

In the case where the statements in (5) or (7) have already been displayed on the label, the details need not be displayed in the medical device package insert.

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In the case where the statements in (1) to (8) have already been displayed on the label in a complete manner, it shall be deemed to have been exempted from the preparation of a medical device package insert.

A professional use medical device must at least be accompanied by a medical device package insert which is in English language and clearly readable.

Clause 5. A medical device package insert under clause 4 may be represented in the form of either a paper or any other object on which meanings are made appeared through statements related to the medical device, which is inserted in or made as part of the container or packaging of such medical device, and shall also include a instruction manual of such medical device.

Any other object under paragraph one shall include the representation of a medical device package insert in an electronic form, such as CD-ROM, QR Code and website to which lay users and medical and public health professionals can easily access.

Clause 6. The following medical devices shall be medical devices granted exemption from displaying a label and a medical device package insert under clause 3 and clause 4:

(1) surgical instruments and equipment designed or manufactured to be reusable;

(2) medical devices specified by the Notification of the Minister to not be under the requirement of displaying labels and medical device package inserts.

The medical device granted exemption under paragraph one must at least display a label in Thai or English language as follows:

(a) name of the product;

(b) name and location of the manufacturing facility or import facility, as the case may be, provided that in cases of an importer, the name of the manufacturing facility, city and country of manufacturing shall also be displayed, but if the name of the facility and city of the manufacturer are not displayed, the name of the product owner, city and country of the product owner and country of the manufacturer shall instead be displayed;

(c) number or alphabet identifying the batch number or lot number, or serial number;

(d) month and year or year and month of manufacturing or expiry which shall be displayed in a four-digit number, provided that in the case where the medical device has a shelf life, the month and year or year and month of expiry shall also be displayed.

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A label of a medical device under (c) and (d) may be displayed as abbreviations in English language.

Clause 7. A licensee, a specification declarer or a notifier who imports a medical device shall, when carrying out import at a medical device inspection checkpoint, display a label with statements in Thai or English language that at least contains the details under clause 6 paragraph two and paragraph three, with an exception of the display of the name and location of the import facility, for inspection by the competent official. The licensee, specification declarer or notifier shall prepare labels and medical device package inserts under clause 3 and clause 4, as the case may be, in a correct and complete manner before the sale, provided that this shall not exceed one hundred and eighty days from the date of import clearance by the competent official at the medical device inspection checkpoint.

Clause 8. In the case where there is a question as to the consideration or decision under this Notification, the Secretary-General shall have to power to make a decision, and the decision shall be deemed final.

Clause 9. This Notification shall not apply to the following cases:

- (1) medical devices of which the display of labels and medical device package inserts is specifically prescribed by a Notification;
- (2) medical devices of which manufacturing or importation is granted exemption under section 27 of the Medical Devices Act, B.E. 2551 (2008) as amended;
- (3) medical devices manufactured or imported for the purpose of export out of the Kingdom.

Clause 10. This Notification shall come into force after the expiration of three hundred and sixty days from the date of its publication in the Government Gazette.

Announced on the 22nd day of September B.E. 2563 (2020)

Anutin Charnvirakul
Minister of Public Health

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