

**MINISTERIAL REGULATION**  
**PRESCRIBING RULES, PROCEDURES AND CONDITIONS ON REGISTRATION OF**  
**MEDICAL DEVICE MANUFACTURING ESTABLISHMENTS,**  
**B.E. 2552 (2009)\***

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By virtue of the provisions of section 5, section 15 paragraph two, section 30 paragraph two, section 31 paragraph two and section 32 paragraph two of the Medical Devices Act, B.E. 2551 (2008) which contains certain provisions in relation to the restriction of rights and liberties of a person, in respect of which section 29 in conjunction with section 33, section 41, section 43 and section 45 of the Constitution of the Kingdom of Thailand, so permit by virtue of law, the Minister of Public Health hereby issues the Ministerial Regulation as follows.

**Clause 1.** Any person who wishes to manufacture a medical device shall submit an application for registration of a medical device manufacturing establishment to the licensor in a form prescribed by the Secretary-General with approval of the Board and published in the Government Gazette together with the documents or evidence specified in clause 2.

The application for registration of a medical device manufacturing establishment located in Bangkok Metropolis shall be submitted at the Food and Drug Administration. For other provinces, it may also be submitted at the provincial public health office.

**Clause 2.** An applicant under clause 1 must attach the following documents or evidence in support of the application for registration of a medical device manufacturing establishment:

(1) a map showing the location of the manufacturing facility and storage facility of medical devices as well as structures situated in the vicinity thereof;

(2) a layout plan of structures within the area of the manufacturing facility and storage facility of medical devices at the correct scale which shows the following particulars:

(a) a front-view plan, a side-view plan, a floor plan and a cross-section plan of the building used for the manufacture and storage of medical devices;

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\* Published in the Government Gazette, Vol. 126, Part 93a, page 4, dated 11<sup>th</sup> December B.E. 2552 (2009)

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(b) partition of rooms and areas used for the manufacture and storage of medical devices;

(c) particulars concerning systems of wastewater disposal, waste and garbage disposal and air control systems;

(3) other documents or evidence as specified in the application form.

**Clause 3.** A medical device manufacturing facility must be suitably separated and situated in a suitable and hygienic area not adjacent to a filthy or unwholesome place or a source of filth which may possibly contaminate raw materials or medical devices already manufactured. The structure of a medical device manufacturing facility must be constructed with strong and durable materials that can be easily cleaned, and must have necessary wastewater drainage, waste disposal, cleaning, air ventilation and security systems.

A medical device manufacturing facility, tools and equipment used for the manufacture, storage and control or preservation of quality of medical devices under section 16 (8) must be in compliance with the description and available in the quantity prescribed by the Minister in the Notification published in the Government Gazette.

**Clause 4.** A medical device manufacturing establishment registration certificate shall be in the form prescribed by the Secretary-General with approval of the Board and published in the Government Gazette.

**Clause 5.** An establishment registrant who wishes to renew a medical device manufacturing establishment registration certificate shall submit an application to the licensor no later than ninety days prior to the date of expiration of the medical device manufacturing establishment registration certificate in the form prescribed by the Secretary-General with approval of the Board and published in the Government Gazette together with the documents or evidence specified in such application form.

The permission to renew a medical device manufacturing establishment registration certificate under paragraph one may be made by means of an endorsement or issuance of a new medical device manufacturing establishment registration certificate.

**Clause 6.** An establishment registrant who wishes to relocate or change a manufacturing facility or a storage facility of medical devices already registered as medical device manufacturing establishment shall submit an application to the licensor in the form prescribed by the Secretary-General with approval of the Board and published in the

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Government Gazette together with the documents or evidence specified in such application form.

The permission to relocate or change a manufacturing facility or a storage facility of medical devices already registered as medical device manufacturing establishment under paragraph one shall be shown in the addendum to the medical device manufacturing establishment registration certificate.

An establishment registrant who wishes to temporarily relocate or change a manufacturing facility or a storage facility of medical devices already registered as medical device manufacturing establishment due to urgent necessity shall submit a written notice to the licensor within five days from the date of the relocation or change of such place. It shall be deemed that the relocated or changed facility is a facility registered as medical device manufacturing establishment. The registrant shall submit an application under paragraph one within ninety days from the date of notice of the relocation or change of such place.

**Clause 7.** An establishment registrant who wishes to vary any particular in a medical device manufacturing establishment registration certificate shall, only in the following cases, submit an application to the licensor in the form prescribed by the Secretary-General with approval of the Board and published in the Government Gazette together with the documents or evidence specified in such application form:

- (1) a change of name of the establishment registrant in case of a change of name of the juristic person without a change of status of the juristic person;
- (2) a change of establishment registrant in case of death of the establishment registrant under section 39;
- (3) a change of business operator in case of a juristic person;
- (4) a change of manufacture controller under section 6 (7);
- (5) a change of first name or surname of the establishment registrant, business operator or manufacture controller;
- (6) a change of name, place number, street name, sub-district, district or province of the manufacturing facility or storage facility of medical devices;
- (7) a change of scope of manufactured medical devices.

The permission to vary a particular under paragraph one shall be shown in the addendum to the medical device manufacturing establishment registration certificate.

**Clause 8.** An establishment registrant whose medical device manufacturing establishment registration certificate is lost, destroyed or damaged shall submit an application for a replacement of the medical device manufacturing establishment

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registration certificate to the licensor in the form prescribed by the Secretary-General with approval of the Board and published in the Government Gazette together with the documents or evidence specified in such application form.

The issuance of a replacement of a medical device manufacturing establishment registration certificate shall be made by means of issuance of a new medical device manufacturing establishment registration certificate marked with the word “REPLACEMENT” on the front, and the date, month and year of the issuance of the replacement shall be indicated along with the signature of the licensor or a person entrusted thereby.

**Clause 9.** All applications for medical device manufacturing establishment registration submitted to the licensor prior to the date on which this Ministerial Regulation comes into force shall be deemed as applications for medical device manufacturing establishment registration submitted under this Ministerial Regulation. The licensor may request the applicant for medical device manufacturing establishment registration to proceed or submit additional documents or evidence as deemed appropriate.

Given on the 19<sup>th</sup> day of November B.E. 2552 (2009)

Vittaya Kaewparadai  
Minister of Public Health

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Remark: The grounds for the promulgation of this Ministerial Regulation are as follows. Whereas section 15 paragraph two, section 30 paragraph two, section 31 paragraph two and section 32 paragraph two of the Medical Devices Act, B.E. 2551 (2008) provide that the application for registration and registration of an establishment, application for renewal of establishment registration certificate, submission of application and permission for an establishment registrant to relocate or change a manufacturing facility or a storage facility of medical devices and application for a replacement of an establishment registration certificate shall be in accordance with the rules, procedures and conditions prescribed in Ministerial Regulation, it is therefore necessary to issue this Ministerial Regulation.

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