Unofficial Translation[*]

MEDICAL DEVICES ACT,
B.E. 2551 (2008)

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BHUMIBOL ADULYADEJ, REX.

Given on the 26th Day of February B.E. 2551.

Being the 63rd Year of the Present Reign.

His Majesty King Bhumibol Adulyadej is graciously pleased to proclaim that:

Whereas it is expedient to revise the law on medical devices;

Whereas this Act contains certain provisions in relation to the restriction of rights and liberties of persons, 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 permits by virtue of provisions of law;

Be it, therefore, enacted by the King, by and with the advice and consent of the National Assembly, as follows.

Section 1. This Act is called the "Medical Devices Act, B.E. 2551 (2008)".

Section 2.[1] This Act shall come into force as from the day following the date of its publication in the Government Gazette.

Section 3. The Medical Devices Act, B.E. 2531 (1988) shall be repealed.

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[*] Translated by Associate Professor Dr. Pinai Nanakorn under contract for the Office of the Council of State of Thailand's Law for ASEAN project. – Tentative Version – subject to final authorisation by the Office of the Council of State.

[1] Published in Government Gazette, Vol. 125, Part 43a, dated 5th March B.E. 2551 (2008).

Section 4. In this Act:

"medical device"[2] means:

(1) a device, an appliance, a mechanical tool, an object inserted into the body, a solution used for performing a test inside or outside a laboratory, a product, software or any other object specifically intended by the manufacturer or owner to be used, for any one or more of the following purposes, on human-beings or animals, whether independently from, in conjunction with or as an accessory of any other article;

(a) conducting a diagnosis, the prevention, a follow-up, a therapy, the alleviation or a treatment of a disease;

(b) conducting a diagnosis, a follow-up, a therapy, the alleviation or a treatment of an injury;

(c) performing the examination, replacement, correction, modification, support, backing or upkeeping in relation to anatomy or a physiological process of the body;

(d) performing life support or rescue;

(e) conducting birth control or reproductive assistance;

(f) providing assistance in response to, or providing compensation for, infirmity or disability;

(g) providing information from the examination of body specimens for a medical purpose or for a diagnosis;

(h) performing disinfection or sterilisation of medical devices;

(2) supplementary equipment for use in conjunction with a medical device under (1);

(3) a device, appliance, mechanical tool, product or any other object prescribed in the Notification of the Minister as a medical device;

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[2] In section 4, the definition of "medical device" is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

provided that the achievement of the purposes of the articles mentioned under (1) occurring in the human or animal body must not principally result from a pharmacological or immunological process or a metabolic reaction;

"supplementary equipment"[3] means an article, appliance or product specifically intended by the manufacturer or owner to be used in conjunction with a medical device for facilitating or causing such medical device to be usable for the intended purpose thereof;

"manufacture" means an act of making, assembling, inventing, divisional re-packaging, combinational re-packaging, improving, transforming, modifying or sterilising;

"sell" means an act of distributing, supplying, giving, exchanging, lending, granting a lease, granting a lease on a hire-purchase basis or transferring rights or possession to another person, for the purpose of trade, and shall also include an act of having in possession for sale;

"import" means an act of bringing or ordering into the Kingdom;

"export" means an act of bringing or sending out of the Kingdom;

"label" means any statement displayed on a medical device or the container or packaging thereof;

"medical device documentation" means paper or any other object capable of presenting a meaning through any statement relating to a medical device, which is inserted or enclosed in the container or packaging of such medical device and shall also include a manual for using such medical device;

"statement" includes an act of causing an appearance through a letter, figure, artificial mark, image, cinematographic movie, light, sound or mark or any act enabling persons in general to comprehend the meaning;

"advertising" means an act, by whatever method, done with a view to causing members of the public to see, hear or know a statement, for the purpose of trade, and shall also include an act of sale promotion;

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[3] In section 4, the definition of "supplementary equipment" is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

"sale promotion" means an act of giving information or soliciting or any act by any means with a view to securing a sale;

"medical establishment" means a medical establishment under the law on medical establishments and an animal medical establishment under the law on animal medical establishments and shall also include a medical establishment and an animal medical establishment of a State agency;

"medical and public health practitioner" means a medical practitioner, a dental practitioner, a first-class veterinary practitioner, a physiotherapy practitioner, a medical technology practitioner or any other medical and public health practitioner as prescribed in the Notification of the Minister;

"permission grantee" means a person to whom a licence is granted under this Act and, in the case where a juristic person is granted a licence, shall also include a person appointed or entrusted by the juristic person to operate the business;

"specification declarer" means a person to whom a specification declaration certificate is granted under this Act and, in the case where a juristic person is granted a specification declaration certificate, shall also include a person appointed or entrusted by the juristic person to operate the business;

"notifier"[4] means a person to whom a notification certificate is granted under this Act and, in the case where a juristic person is granted a notification certificate, shall also include a person appointed or entrusted by the juristic person to operate the business;

"establishment registrant" means a person to whom an establishment registration certificate is granted under this Act and, in the case where a juristic person is granted an establishment registration certificate, shall also include a person appointed or entrusted by the juristic person to operate the business;

"permission grantor" means the Secretary-General of the Food and Drug Administration or the person entrusted by the Secretary-General of the Food and Drug Administration;

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[4] In section 4, the definition of "notifier" is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

"Commission" means the Medical Devices Commission;

"member" means a member of the Medical Devices Commission;

"competent official" means a person appointed by the Minister to perform activities under this Act;

"State agency" means the central administration, provincial administration, local administration, a State enterprise, a public organisation and any other agency of the State;

"Secretary-General" means the Secretary-General of the Food and Drug Administration;

"Minister" means the Minister having charge and control of the execution of this Act.

Section 5. The Minister of Public Health shall have charge and control of the execution of this Act and shall have the power to appoint competent officials, issue Ministerial Regulations prescribing fees not exceeding the rates annexed hereto and exempting fees, issue Notifications and prescribe other matters in the execution of this Act.

Such Ministerial Regulations and Notifications shall come into force upon their publication in the Government Gazette.

Section 6. For the purposes of controlling medical devices and protecting safety of consumers, the Minister, upon recommendation of the Commission, shall have the power to issue Notifications prescribing:

(1)[5] classes of medical devices or medical devices, being classified by reference to levels of risks of danger to health, physical conditions or lives of human-beings or animals or impacts on public health and also rules, procedures and conditions for the manufacture or import of such medical devices, for the purpose of laying down measures for controlling classes of medical devices or medical as follows;

(a) classes of medical devices or medical devices in respect of which manufacturers or importers are required to be granted permission;

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[5] Section 6 (1) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(b) classes of medical devices or medical devices in respect of which manufacturers or importers are required to make the declaration of specifications;

(c) classes of medical devices or medical devices in respect of which manufacturers or importers are required to make the notification;

(2)[6] (repealed);

(3)[7] classes of medical devices or medical devices in respect of which sellers are required to be granted permission and also rules, procedures and conditions for the sale of medical devices;

(4) standards of medical devices required to be complied with by manufacturers, importers or sellers;

(5) quality standards of the manufacture, import or sale of medical devices;

(6) standards of containers and the use thereof and requirements as to articles prohibited from being used as containers of medical devices, which are required to be complied with by manufacturers, importers or sellers;

(7) medical devices in respect of which controllers are required to be provided for controlling the manufacture, import or sale, and also the qualifications, number and duties of controllers;

(8) medical devices in respect of which technological appraisal is required to ensure that the use of such medical devices is appropriate for and consistent with public health problems as well as economic and social circumstances of the country;

(9) medical devices permitted to be sold only to consumers upon a prescription by a medical and public health practitioner, and also rules, procedures and conditions for the sale thereof;

(10) medical devices permitted to be sold only to medical establishments or medical and public health practitioners and also rules, procedures and conditions for the sale thereof;

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[6] Section 6 (2) is repealed by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[7] Section 6 (3) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(11) medical devices which are prohibited from being manufactured, imported or sold;

(12) medical devices in respect of which the operation of the business of direct sale or direct marketing under the law on direct sale and direct marketing is prohibited;

(13) medical devices which are subject to the requirement that the usage life, warnings, use-prohibition statements and use cautions be displayed in labels or medical device documentation, and also rules, procedures and conditions for such display;

(14) medical devices in respect of which a register of patient users thereof is required to be provided, and also rules, procedures and conditions for the provision of such register of patient users thereof;

(15) rules, procedures and conditions for the use of medical devices in relation to clinical research;

(16) rules and procedures for transportation, storage, destruction or elimination of medical devices;

(17)[8] any place in the Kingdom as a check-point for imported medical devices;

(18) medical devices exempted from compliance with certain control measures under this Act and measures to which the exemption relates;

(19)[9] maximum rates of costs and costs to be collected from applicants in Part I, Process for Medical Device Permission, of Chapter II, Registration of Establishments, Application for Permission and the Granting of Permission, Specification Notification and Notification;

(20)[10] maximum rates for listing fees and listing fees to be collected from domestic and foreign specialists, specialists' organisations, State agencies or private organisations;

(21)[11] costs of the appraisal of technical documents, analytical tests, the inspection of establishments or the examination of medical devices for the purposes of

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[8] Section 6 (17) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[9] Section 6 (19) is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[10] Section 6 (20) is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

conducting the monitoring, examination or surveillance intended to control the manufacture, import and sale of medical devices;

(22)[12] rules, procedures and conditions for the receipt and disbursement of money acquired from collection of payments in the process for medical device permission or the monitoring, examination or surveillance intended to control the manufacture, import and sale of medical devices.

CHAPTER I
MEDICAL DEVICES COMMISSION

Section 7. There shall be a commission called the "Medical Devices Commission" consisting of the Permanent-Secretary for Public Health as Chairperson, the Director-General of the Department of Medical Services, Director-General of the Department of Disease Control, Director-General of the Department of Livestock Development, Director-General of the Department of Medical Sciences, Director-General of the Department of Health Service Support, Secretary-General of the Consumer Protection Board, Secretary-General of the Food and Drug Administration, a representative of the Office of the Council of State and a representative of the Customs Department, as members, and not less than nine but not more than eleven qualified persons appointed by the Minister as members, provided that such number shall be constituted by the appointment of one medical practitioner, one nursing and midwifery practitioner, one dental practitioner, one first-class veterinary practitioner, one medical technology practitioner, one physiotherapy practitioner, one representative of an association or foundation having the objectives relating to the promotion or support of the operation of medical establishments, one representative of an association or business operators having the object in connection with the manufacture, import or sale of medical devices and one representative of an association or foundation having the object relating to consumer protection.

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[11] Section 6 (21) is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[12] Section 6 (22) is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

The Deputy Secretary-General as entrusted by the Secretary-General shall be a member and secretary and the Director of the Medical Device Control Division of the Office of the Food and Drug Administration shall be a member and assistant secretary.

The appointment of qualified members shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister.[13]

Section 8. A qualified member shall hold office for a term of two years.

In the case where a qualified member vacates office before the expiration of the term, the Minister may appoint another person as a replacing qualified member and the appointed person shall hold office in accordance with the term of the replaced member.

In the case where the Minister appoints an additional qualified member during the term of office of members already appointed, the person appointed as an additional qualified member shall be in office for the remaining term of the qualified members already appointed.

At the expiration of the term under paragraph one, if qualified members have not yet been appointed, the qualified members who vacate office at the expiration of the term shall remain in office for continuing the work until newly appointed qualified members take office.

A qualified member who vacates office at the expiration of the term may be re-appointed but may not serve for more than two consecutive terms.

Section 9. In addition to the vacation of office upon the expiration of the term, a qualified member vacates office upon:

(1) death;

(2) resignation;

(3) being removed by the Minister on the ground of neglect of duties, misbehaviour or lack of competence;

(4) being a bankrupt;

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[13] Section 7 paragraph three is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(5) being an incompetent person or a quasi-incompetent person;

(6) having been sentenced to imprisonment by a final judgment, except for an offence committed through negligence or a petty offence.

Section 10. At a meeting of the Commission, the presence of not less than one half of the total number of members is required to constitute a quorum.

At a meeting of the Commission, if the Chairperson is not present or is unable to perform the duty, members present at the meeting shall elect one member to preside over the meeting.

A decision of a meeting shall be by a majority of votes. In casting votes, each member shall have one vote. In the case of an equality of votes, the person presiding over the meeting shall have an additional vote as a casting vote.

Section 11.[14] The Commission shall have the duties and powers as follows:

(1) to give the Minister advice or opinions on policies and measures in connection with the control of medical devices to ensure compliance with this Act;

(2) to give the Minister advice on issuance of Notifications under this Act;

(3) to give approval to the Secretary-General in the issuance of Notifications under this Act;

(4) to give approval to the suspension and revocation of establishment registration certificates, licences or specifications declaration certificates;

(5) to perform any other activities as provided in this Act or as entrusted by the Minister.

Section 12. The Commission shall have the power to appoint sub-committees for performing any acts as entrusted by the Commission and the provisions of section 10 shall apply to a meeting of a sub-committee *mutatis mutandis*.

[14] Section 11 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

In appointing sub-committees in the execution of Part I, Process for Medical Device Permission, of Chapter II, Registration of Establishments, Application for Permission and the Granting of Permission, Specification Notification and Notification, there shall be a representative of the Office of the Public Sector Development Commission, a representative of an association or foundation having the object relating to consumer protection and a representative of an association or business operators having the object in connection with the manufacture, import or sale of medical devices, as members. In this regard, the rules for the appointment of qualified members as specified in section 7 paragraph three shall also apply *mutatis mutandis*. In the sub-committee in charge of considering and prescribing fees for listing and costs, there shall also be a representative of the Ministry of Finance as an additional member.[15]

Section 13. In the performance of duties under this Act, the Commission and a sub-committee shall have the power to issue orders in writing instructing any person to give statements or furnish relevant documents or evidence or any articles for assisting consideration.

Section 14. In the performance of duties under this Act, members of the Commission and a sub-committee shall be officials under the Penal Code.

CHAPTER II
REGISTRATION OF ESTABLISHMENTS, APPLICATION FOR PERMISSION AND THE GRANTING OF PERMISSION, SPECIFICATION NOTIFICATION AND NOTIFICATION[16]

Section 15. Any person who intends to manufacture or import medical devices shall carry out registration of an establishment with the permission grantor.

[15] Section 12 paragraph two is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[16] The title of Chapter II, Registration of Establishments, Application for Permission and the Granting of Permission, Specification Notification and Notification, is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

The application for registration and the approval of the application for registration of an establishment under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 16. The permission grantor may issue an establishment registration certificate, for the manufacture or import of medical devices, to the applicant for the establishment registration when it is apparent that the applicant for the establishment:

(1) is the owner of the business in respect of an establishment registration certificate is sought;

(2) is of not lower than twenty years of age;

(3) has a residence in Thailand;

(4) is not a bankrupt;

(5) has never been sentenced to imprisonment by a final judgment for an offence which is provided by law to be constituted by an element of a dishonest act or for an offence under this Act, unless the applicant has been discharged from the penalty for more than two years prior to the date of the application for registration;

(6) is not a person of unsound mind or an incompetent person or a quasi-incompetent person;

(7) does not have diseases as prescribed in the Notification of the Minister;

(8) has places of manufacture or places of import of medical devices and equipment used for the manufacture, storage and control or preservation of the quality of medical devices, in accordance with such descriptions and number as prescribed in the Notification of the Minister;

(9) does not use the name, in the operation of commercial business, which is identical or similar to any name used in the operation of commercial business of the establishment registrant who is under suspension of an establishment registration certificate or revocation of an establishment registration certificate, when less than one year has elapsed therefrom;

(10) is not a person who is under suspension of an establishment registration certificate under this Act;

(11) has never had an establishment registration certificate revoked under this Act except that more than two years have elapsed since the revocation thereof prior to the date of the application for registration of an establishment.

In the case where a juristic person is an applicant for registration of an establishment, its manager or representative in charge of the operation of the business shall have the qualifications under (2) and (3) and be under no prohibitions under (4), (5), (6), (7), (10) or (11).

Section 17.[17] Any establishment registrant who intends to manufacture or import medical devices under section 6 (1) (a) shall submit an application for permission and may manufacture or import such medical devices when the permission grantor has issued a licence therefor.

The application for permission and the issuance of a licence under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

The permission grantee under paragraph one shall also comply with the rules, procedures and conditions for the manufacture or import of medical devices as prescribed in the Notification of the Minister under section 6 (1) (a).

Section 18[18] Any establishment registrant who manufactures or imports medical devices as prescribed in the Notification under section 6 (1) (a) on the date on which such Notification comes into force and intends to continue the operations shall submit an application for permission within the period of time indicated in such Notification. Upon submission of such application within the time limit, operations may be continued until an order is given for refusal to grant permission.

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[17] Section 17 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[18] Section 18 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

The provisions of section 17 paragraph two and paragraph three shall apply *mutatis mutandis*.

Section 19[19] Any establishment registrant who intends to manufacture or import medical devices under section 6 (1) (b) or (c) shall submit an application for the declaration of specifications or for the notification, as the case may be, and may manufacture or import such medical devices when the permission grantor has issued a specification declaration certificate or a notification certificate.

The declaration of specifications, the issuance of a specification declaration certificate, the notification and the issuance of a notification certificate under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

The specification declarer or the notifier under paragraph one shall also comply with the rules, procedures and conditions for the manufacture or import of medical devices as prescribed in the Notification of the Minister under section 6 (1) (b) or (c).

Section 20[20] Any establishment registrant who manufactures or imports medical devices as prescribed in the Notification under section 6 (1) (b) or (c) on the date on which such Notification comes into force and intends to continue the operations shall submit an application for the declaration of specifications or for the notification within the period of time indicated in such Notification. Upon submission of such application within the time limit, operations may be continued until an order is given for refusal to accept the declaration of specifications or for refusal to accept the notification.

The provisions of section 19 paragraph two and paragraph three shall apply *mutatis mutandis*.

Section 21. Upon the Notification prescribing medical devices under section 6 (8), a manufacturer, importer, seller or possessor, who has such medical devices in possession on the date on which the Notification comes into force, shall make the notification of the

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[19] Section 19 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[20] Section 20 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

possession thereof to the permission grantor within sixty days as from the date on which such Notification comes into force.

In the case where medical devices under paragraph one are subsequently intended to be relocated from one place to another, the possessor of such medical devices shall notify it to the permission grantor prior to the relocation. In this regard, in the case of necessity for safety in the use of such medical devices, the permission grantor shall provide an inspection of readiness of medical devices, places and personnel. Costs incurred in such inspection of readiness, if any, shall be collected from the possessor of the medical devices.

The notification of the possession under paragraph one, the relocation, the inspection of readiness and costs for the operation under paragraph two shall be in accordance with the rules, procedure and conditions prescribed by the Secretary-General, with the approval of the Commission, and published in the Government Gazette.

Section 22. Any establishment registrant who intends to manufacture or import medical devices under section 6 (8) shall submit to the permission grantor an application for the appraisal of their efficiency, quality, standards and safety for use and also the appraisal of impacts as well as economic and social worthiness to ensure that the use of the medical devices is in an appropriate, comprehensive and fair manner, and may carry out the manufacture or import when the permission grantor has issued an appraisal certificate, provided that in the case of medical devices in respect of which the manufacturer or importer is required to be granted permission or to make the declaration of specifications, the manufacture or import may be carried out when the permission grantor has issued a licence or a specification declaration certificate under section 17 or section 19, as the case may be.

The submission of an application for the appraisal, the appraisal and the issuance or a certificate of appraisal of medical devices under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General with the approval of the Commission and published in the Government Gazette.

The Minister, with the recommendation of the Commission, has the power to issue a Notification requiring specialists, specialists' organisations, State agencies or other agencies in the country or in foreign countries to carry out the appraisal of medical devices

under paragraph one and prescribing rates and methods of payment of, and exemption from, costs of the appraisal of such medical devices.

Costs incurred in the appraisal of medical devices under paragraph three shall be collected from the person intending to carry out the manufacture or import thereof.

The provisions of section 21 paragraph two and paragraph three shall also apply to the case where medical devices which pass the appraisal under paragraph one are subsequently relocated from one place to another.

Section 23. The provisions of section 21 and section 22 shall also apply to State agencies and the Thai Red Cross Society *mutatis mutandis*.

Section 24. Any person who intends to sell medical devices under section 6 (3) shall submit an application for permission and may sell such medical devices when the permission grantor has issued a licence therefor.

The application for permission and the issuance of a licence under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

The permission grantee under paragraph one shall also comply with the rules, procedures and conditions for the sale of medical devices as prescribed in the Notification of the Minister under section 6 (3).

The manufacturer or importer under section 17 or section 19 shall be deemed to be the permission grantee for the sale of medical devices under paragraph one manufactured or imported by such manufacturer or importer without being required to submit an application for sale permission, provided that the rules, procedures and conditions as prescribed in the Notification of the Minister under section 6 (3) shall be complied with.

Section 25.[21] Any person who sells medical devices as prescribed in the Notification under section 6 (3) on the date on which such Notification comes into force and intends to continue the operations shall submit an application for permission within the period

[21] Section 25 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

of time indicated in such Notification. Upon submission of such application within the time limit, operations may be continued until an order is given for refusal to grant permission.

The provisions of section 24 paragraph two, paragraph three and paragraph four shall apply *mutatis mutandis*.

Section 26. The permission grantor may grant a licence for the sale of medical devices to an applicant for permission when it appears that the applicant

(1) is the owner of the business in respect of a licence for sale is sought;

(2) possesses qualifications and is under no prohibitions under section 16 (2), (3), (4), (5), (6) and (7);

(3) does not use the name, in the operation of commercial business, which is identical or similar to any name used in the operation of commercial business of the establishment registrant or the permission grantee who is under suspension of an establishment registration certificate or a licence or under revocation of an establishment registration certificate or a licence, when less than one year has elapsed therefrom;

(4) is not a person who is under suspension of a licence under this Act;

(5) has never had a licence revoked under this Act except that more than two years have elapsed since the revocation thereof prior to the date of submission of the application for permission;

(6) has the sale quality system under section 6 (5);

(7) has sale controllers in the case of medical devices under section 6 (7).

In the case where a juristic person is an applicant for permission, its manager or representative in charge of the operation of the business shall have the qualifications and be under no prohibitions under section 16 (2), (3) (4), (5), (6) and (7) and shall be under no prohibitions under (4) and (5) as well.

Section 27. The provisions of section 15, section 17, section 19 and section 24 shall not apply to:

(1) the manufacture, import or sale of medical devices by State agencies in the discharge of duties in connection with the prevention, diagnosis or treatment of diseases or the rehabilitation and the Thai Red Cross Society;

(2) the manufacture of medical devices specifically for the purpose of sterilisation in medical establishments under the law on medical establishments;

(3) the manufacture or sale of medical devices manufactured by medical and public health practitioners for their particularly individual patients or animals;

(4)[22] the sale of medical devices, in respect of which a licence, a specification declaration certificate or a notification certificate has been granted, by medical establishments or medical and public health practitioners for their particularly individual patients or animals;

(5) the manufacture or import of medical devices in the quantity meeting the necessity for personal use, for use as samples, for an exhibition or for use in studies, research, analysis or tests of the quality and standards;

(6)[23] the import of medical devices for particularly individual patients or animals;

(7) the manufacture of medical devices as samples for export;

(8) the manufacture or import of medical devices in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister with the recommendation of the Commission.

Any person exempted from the application under (1), (2), (3), (4), (5), (6) and (7) shall comply with the rules, procedures and conditions prescribed in the Notification of the Minister with the recommendation of the Commission.

The Secretary-General, with the approval of the Commission, shall have the power to prescribe, by publication in the Government Gazette, rates and methods of payment of, exemption from and persons responsible for, costs of the appraisal of technical documents, the inspection of an establishment and the inspection or analytical tests of medical devices.

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[22] Section 27 (4) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[23] Section 27 (6) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 28.[24] An establishment registration certificate, a licence, a specification declaration certificate or a notification certificate shall also provide protection in favour of employees and representatives of the establishment registrant, the permission grantee, the specification declarer and the notifier.

It shall be deemed that an act of employees or representatives enjoying the protection under paragraph one is also an act of the establishment registrant, the permission grantee, the specification declarer or the notifier unless the establishment registrant, the permission grantee, the specification declarer or the notifier proves that such act is beyond his knowledge or control.

Section 29. An establishment registration certificate under section 15, a licence under section 17 and a specification declaration certificate under section 19 shall be valid until 31st December of the fifth year as from the year of issuance thereof.

A licence for the sale under section 24 shall be valid until 31st December of the year of issuance thereof.

A notification certificate under section 19 shall be valid for five years as from the date shown therein.[25]

Section 30. In the case where the establishment registrant, the permission grantee or the specification declarer intends to apply for renewal of the establishment registration certificate, the licence or the specification declaration certificate, an application therefor shall be submitted prior to the date of its expiry. Upon submission of an application and payment of the fee for renewal at the time of the submission thereof, the operation of business may be continued until the permission grantor issues an order refusing to grant permission for the renewal of such establishment registration certificate, the licence or the specification declaration certificate.

[24] Section 28 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[25] Section 29 paragraph three is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

The application for renewal of an establishment registration certificate, a licence or a specification declaration certificate and the granting of permission for renewal shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

The establishment registrant, the permission grantee or the specification declarer whose establishment registration certificate, licence or specification declaration certificate has expired for a period not exceeding one month may submit an application for renewal and relaxation upon presentation of reasons for failure to submit an application for renewal within the time limit and upon payment of the renewal fee, provided that such application for the relaxation does not constitute a ground for being absolved from liability under section 91.

No application for renewal of an establishment registration certificate, a licence or a specification declaration certificate shall be made after the lapse of a period of one month as from the date of its expiry.

In the case where the permission grantor issues an order for the refusal to grant permission for renewal of an establishment registration certificate, a licence or a specification declaration certificate, the renewal fee shall be *pro rata* returned to the applicant for the renewal. In this regard, the calculation shall be made on a monthly basis as from the date of the order for the refusal to grant permission up to the date of the expiry of the establishment registration certificate, the licence or the specification declaration certificate for which renewal is sought, except that, in the case where an appeal is made against the order for the refusal to grant permission for renewal of the establishment registration certificate, the licence or the specification declaration certificate and the Minister has issued an order permitting the applicant for the renewal thereof to operate the business for the time being, the calculation shall be made, if the Minister orders dismissal of the appeal, as from the date of the order for the dismissal thereof. A fraction of one month, where it reaches fifteen days, shall be counted as one month.

Section 30/1.[26] In the case where the notifier intends to apply for renewal of the notification certificate, an application therefor shall be submitted prior to the date of its expiry. Upon submission of an application and payment of the fee for renewal at the time of the

[26] Section 30/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

submission thereof, the operation of business may be continued until the permission grantor issues an order refusing to grant permission for the renewal of such notification certificate.

The application for renewal of a notification certificate and the granting of permission for renewal thereof shall be in accordance with the rules, procedures and conditions prescribed by the permission grantor.

The notifier whose notification certificate has expired for a period not exceeding one month may submit an application for renewal and relaxation upon presentation of reasons for failure to submit an application for renewal within the time limit and upon payment of the renewal fee, provided that such application for the relaxation does not constitute a ground for being absolved from liability under section 91.

No application for renewal of a notification certificate shall be made after the lapse of a period of one month as from the date of its expiry.

In the case where the permission grantor issues an order for the refusal to grant permission for renewal of a notification certificate, the renewal fee shall be *pro rata* returned to the applicant for the renewal. In this regard, the calculation shall be made on a monthly basis as from the date of the order for the refusal to grant permission up to the date of the expiry of the notification certificate for which renewal is sought, except that, in the case where an appeal is made against the order for the refusal to grant permission for renewal of the notification certificate and the Minister has issued an order permitting the applicant for the renewal thereof to operate the business for the time being, the calculation shall be made, if the Minister orders dismissal of the appeal, as from the date of the order for the dismissal thereof. A fraction of one month, where it reaches fifteen days, shall be counted as one month.

Section 31. In the case where the establishment registrant, the permission grantee or the specification declarer intends to vary particulars in the establishment registration certificate, the licence or the specification declaration certificate or other relevant particulars, an application therefor shall be submitted to the permission grantor except that it is the case of a temporary relocation or change of a place on account of urgent necessity under which application for permission is impracticable.

The submission of an application, the granting of permission and the temporary relocation or change of a place on account of urgent necessity under which application for permission is impracticable shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 31/1.[27] In the case where the information entered in the notification has any change, the notifier shall notify it to the permission grantor.

The notification of the information under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the permission grantor.

Section 32. In the case where an establishment registration certificate, a licence, a specification declaration certificate, an appraisal certificate under section 22 or a certificate is lost, destroyed or damaged, the establishment registrant, the permission grantee or the specification declarer shall submit an application for a substitute document within fifteen days as from the date of the knowledge of the loss, destruction or damage.

The application for a substitute document under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 33.[28] (repealed)

Section 34. For the purpose of export, the manufacturer may manufacture for export medical devices which have qualities, standards, labels or other details as required by the buyer but shall comply with the rules, procedures and conditions prescribed by the Commission and published in the Government Gazette.

No person shall sell medical devices under paragraph one in the Kingdom.

Section 35. In the case where there exist requirements of a foreign country or international agreements concerning standards, efficiency or safety or rules of a foreign country or international rules in connection with the import of medical devices of such country, the Office of the Food and Drug Administration may enter into an agreement, with foreign agencies,

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[27] Section 31/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[28] Section 33 is repealed by the Medical Devices Act (No. 2), B.E. 2562 (2019).

on the recognition of the inspection or certification of medical devices or medical device establishments of such foreign agencies in accordance with the rules and conditions prescribed by the Commission, whether the foreign agencies are State agencies or private agencies.

In giving the recognition of the inspection or certification by foreign agencies under paragraph one, the Secretary-General, with the approval of the Commission, shall have the power to publish a list of foreign agencies and the scope of the inspection or certification of medical devices or medical device establishments of the foreign agencies to which the recognition is given.

PART I
PROCESS FOR MEDICAL DEVICE PERMISSION[29]

Section 35/1.[30] The process for medical device permission in this Part shall mean the consideration of an application, the examination of accuracy of documents, the appraisal of technical documents, analytical tests, the inspection of an establishment or the examination for the purpose of issuing a certificate, a registration certificate, a licence, a specification declaration certificate, a notification certificate or an appraisal certificate and any consideration in connection with medical devices.

The process for medical device permission under paragraph one shall be conducted in a manner that importance shall also be attached to the promotion of the domestic manufacture of medical devices.

Section 35/2.[31] In the process for medical device permission, apart from officials of the Office of the Food and Drug Administration and officials of agencies attached to the Ministry of Public Health who are entrusted to perform activities in the discharge of duties and powers of the Office of the Food and Drug Administration, there shall be specialists, specialists'

[29] Part I, Process for Medical Device Permission, consisting of section 35/1 to section 35/7, is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[30] Section 35/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[31] Section 35/2 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

organisations, State agencies or private agencies in the country or from foreign countries for performing duties in connection with the appraisal of technical documents, analytical tests, inspection of establishments or examination in order to facilitate expediency and efficiency of the process for medical device permission by the Central Administration and the Provincial Administration. In this regard, such persons, agencies or organisations must be listed by the Office of the Food and Drug Administration.

The rules, procedures and conditions for the process for medical device permission under paragraph one shall be as prescribed by the Secretary-General, with the approval of the Commission, and published in the Government Gazette.

Costs to be collected from applicants in the process for medical device permission under paragraph one shall be as prescribed in the Notification of the Minister with the recommendation of the Commission. In this regard, costs to be collected shall not exceed the maximum rate of costs under section 35/4 (2), provided that costs may be exempted in whole or in part.

Section 35/3.[32] The Secretary-General, with the approval of the Commission, shall have the power to issue the Notification, by publication in the Government Gazette, prescribing rules, procedures and conditions for the acquisition of specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries under section 35/2.

The Notification under paragraph one shall prescribe qualifications, standards and work operation of specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries. In the case where there is a due reason and necessity, the rules, procedures and conditions for the acquisition of such persons, agencies or organisations may be exempted in whole or in part.

A listing fee to be collected from specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries under paragraph one shall be as prescribed in the Notification of the Minister with the recommendation of the

[32] Section 35/3 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Commission. The listing fee to be collected shall not exceed the maximum rate of the listing fee under section 35/4 (1), provided that the listing fee may be exempted in whole or in part.

Section 35/4.[33] The Minister, with the recommendation of the Commission, shall have the power to issue Notifications prescribing the following:

(1) the maximum rate of the listing fee to be collected from specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries;

(2) the maximum rate of costs to be collected from applicants in the process for medical device permission.

The maximum rate of the listing fee and the maximum rate of costs under (1) and (2) shall come into force upon approval by the Council of Ministers.

Section 35/5.[34] Costs to be collected under section 35/2 paragraph three and section 35/6 paragraph three and the listing fee to be collected under section 35/3 paragraph three shall be the money of the Office of the Food and Drug Administration or the agency entrusted to perform activities in the discharge of the duties and powers of the Office of the Food and Drug Administration, which has made the collection, as the case may be, without being required to be remitted to the Treasury as the State revenue, and shall be expended for the following purposes:

(1) funding remuneration of persons, organisations or agencies under section 35/2;

(2) funding expenses incurred in the operation of wok in pursuit of action plans or projects which are beneficial to the public, for the purpose of consumer protection in relation to medical devices;

(3) funding expenses incurred in the development of potential of agencies and officials, with a view to developing work systems relating to the process for medical device permission and enhancing efficiency of operations in the process for medical device permission;

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[33] Section 35/4 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[34] Section 35/5 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(4) funding other relevant and necessary expenses in connection with operations intended to enhance efficiency in the process for medical device permission, as prescribed in the Notification of the Minister.

Section 35/6.[35] In performing the monitoring, inspection or surveillance for the purpose of controlling the manufacture, import and sale of medical devices in respect of which a licence, a specification declaration certificate, a notification certificate or an appraisal certificate has been granted, as the case may be, the provisions of section 35/2 paragraph one and paragraph two shall apply *mutatis mutandis* when there is a reasonable cause to suspect that any medical device may be standard deficient or unsafe for use.

Costs incurred in the appraisal of technical documents, analytical tests, inspection of establishments or inspection of medical devices under paragraph one shall be borne by the applicant, the establishment registrant, the permission grantee, the specification declarer, the notifier, the manufacturer, importer or seller of medical devices, as the case may be.

The costs under paragraph two shall be as prescribed in the Notification of the Minister with the recommendation of the Commission. In this regard, costs to be collected shall not exceed the maximum rate of costs under section 35/4 (2), provided that costs may be exempted in whole or in part.

Section 35/7.[36] The receipt of money under section 35/2 paragraph three, section 35/3 paragraph three and section 35/6 paragraph three and the disbursement of money under section 35/5 shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister with recommendation of the Commission and with the approval by the Ministry of Finance.

CHAPTER III
CESSATION OF BUSINESS AND TRANSFER OF BUSINESS

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[35] Section 35/6 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[36] Section 35/7 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 36.[37] Any establishment registrant under section 15, permission grantee under section 17 or section 24 or specification declarer or notifier under section 19 who ceases the business in respect of which the establishment registration has been effected, the permission has been granted or the specification declaration or the notification has been made under this Act shall give the written notification of the cessation of the business and furnish the establishment registration certificate, the licence or the specification declaration certificate, as the case may be, to the permission grantor within thirty days as from the date of the cessation of the business and it shall be deemed that the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate expires as from the date of the cessation of such business.

In giving the notification of the cessation of the business of the permission grantee or the specification declarer under paragraph one, an indication shall be made of the number of remaining medical devices and places of storage of such medical devices, in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

In the case where any establishment registrant ceases the business in respect of which the establishment registration has been effected without giving the notification of the cessation of the business to which the licence, the specification declaration certificate or the notification certificate relates, it shall be deemed that the licence, the specification declaration certificate or the notification certificate also expires.

In the case where any establishment registrant under section 15, any permission grantee under section 17 or section 24, any specification declarer or notifier under section 19 ceases the business without giving the notification under paragraph one, it shall be deemed that the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate expires as from the date of the cessation of the business.

Section 37. Any establishment registrant under section 15, any permission grantee under section 17 or section 24 or any specification declarer under section 19, who fails to renew the establishment registration certificate, the licence or the specification declaration

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[37] Section 36 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

certificate or who receives the permission grantor's refusal to grant permission for renewal of the establishment registration certificate, the licence or the specification declaration certificate, as the case may be, shall notify the permission grantor of the number of remaining medical devices and places of storage of such medical devices within thirty days as from the expiry date or the date of the permission grantor's refusal to grant permission for renewal of the establishment registration certificate, the licence or the specification declaration certificate.

The notification under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

Section 38. The permission grantee, being granted permission for the sale of medical devices under section 24, who has given the notification of the cessation of the business, whose licence expires or who receives the permission grantor's refusal to grant permission for renewal of the licence, as the case may be, may sell his remaining medical devices to other permission grantees or persons deemed appropriate by the permission grantor within sixty days as from the date of the cessation of the business, the date of expiry of the licence or the date of the permission grantor's refusal to grant permission for renewal of the licence, provided that the permission grantor may grant extension of such period of time as he may deem appropriate.

If, at the expiration of the time limit under paragraph one, there remain medical devices in respect of which the seller is required to be granted permission under section 24, the permission grantee shall not sell such medical devices and the permission grantee shall notify the permission grantor of the number of such medical devices and places of storage thereof within fifteen days as from the date of the expiration of the time limit under paragraph one.

The notification under paragraph two shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

Section 39. In the case where the establishment registrant, the permission grantee, the specification declarer or the notifier dies and his heir or the person who obtains consent from the heir makes a declaration of an intention to continue the operation of such

business to the permission grantor within ninety days as from the date of death of the establishment registrant, the permission grantee, the specification declarer or the notifier, the person making the declaration of such intention may, when the permission grantor considers after the examination that such person has the qualifications under section 16 or section 26, as the case may be, continue the operation of the business until the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate expires, and it shall be deemed that the person making the declaration of the intention is the establishment registrant, the permission grantee, the specification declarer or the notifier under this Act as from the date of death of the establishment registrant, the permission grantee, the specification declarer or the notifier.[38]

The declaration of an intention and the examination shall be in accordance with the rules, procedures and conditions prescribed by the Commission and published in the Government Gazette.

The provisions of section 38 paragraph two and paragraph three shall apply *mutatis mutandis* to the case where the heir who possesses such medical devices or the administrator of the estate fails to make a declaration of an intention to operate the business under paragraph one.

CHAPTER IV
DUTIES OF ESTABLISHMENT REGISTRANTS, PERMISSION GRANTEES, SPECIFICATION DECLARERS, NOTIFIERS AND SELLERS[39]

Section 40.[40] An establishment registrant, a permission grantee, a specification declarer or a notifier shall not manufacture, import, sell or store medical devices outside of places indicated in the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate except that it is the case of:

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[38] Section 39 paragraph one is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[39] The title of Chapter IV, Duties of Establishment Registrants, Permission Grantees, Specification Declarers, Notifiers and Sellers, is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[40] Section 40 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(1) a temporary storage upon permission from the permission grantor, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister with the recommendation of the Commission;

(2) a sale directly to medical and public health practitioners;

(3) an assembly for the installation of medical devices in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister with the recommendation of the Commission.

Section 41.[41] An establishment registrant, a permission grantee, a specification declarer or a notifier shall perform the following:

(1) exercising control and supervision of the operation of business in connection with the manufacture, import or sale of medical devices to ensure compliance with quality standards for the manufacture, import or sale of medical devices under section 6 (5);

(2) providing controllers of the manufacture, import or sale of medical devices under section 6 (7) and exercising control and supervision of such persons to ensure their full performance of duties under section 6 (7);

(3) preparing records of the manufacture, import or sale of medical devices for the purpose of inspection by competent officials and preparing a report to the permission grantor, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister;

(4) preparing a report of irregular functionality of medical devices or undesirable incidences occurring to consumers and reporting to the permission grantor remedial action, in the interest of safety of use of such medical devices, whether such irregular functionality or incidences shall have occurred in the country or outside the country, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister;

(5) providing complaint channels, complaint records and complaint handling mechanisms in connection medical devices manufactured, imported or sold, for the purpose of

[41] Section 41 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

inspection by competent officials, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister;

(6) providing signboards indicating places of manufacture, places of import, places of sale or places of storage of medical devices at an open point at such places as specified in the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate, as the case may be, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister;

(7) providing boards displaying names and qualifications of controllers in the case of medical devices under section 6 (7) at an open point at places of manufacture, places of import or places of sale, in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister;

(8) displaying the establishment registration certificate or the licence for sale of medical devices at an open and conspicuous point at the place specified in the establishment registration certificate or the licence for sale;

(9) providing technical documents in confirmation that his medical devices meet the qualities, standards, efficiency and safety, for the purpose of examination or submission to competent officials upon request, in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

Section 42. A manufacturer, importer or seller of medical devices under section 6 (14) or a medical establishment operator in a medical establishment where such medical devices are used shall provide a register of patients for whom such medical devices are used.

The provision of a register of patients for whom medical devices are used under paragraph one shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister under section 6 (14).

Section 43. A seller of medical devices under section 6 (9) or (10) shall sell such medical devices only to consumers having prescriptions by medical and public health practitioners or only to medical establishments or medical and public health practitioners.

The seller under paragraph one shall comply with the rules, procedures and conditions prescribed in the Notification of the Minister under section 6 (9) or (10).

CHAPTER V
LABELS AND MEDICAL DEVICE DOCUMENTATION

Section 44.[42] An establishment registrant, a permission grantee, a specification declarer or a notifier who manufactures or imports medical devices shall provide labels and medical device documentation without representation of any false or exaggerative statement.

The display of labels and medical device documentation shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister.

A seller of medical devices shall ensure the presence of labels or labels as well as medical device documentation, as the case may be, as provided by the establishment registrant, the permission grantee, the specification declarer or the notifier under paragraph one.

Section 45. Subject to section 44, an establishment registrant, a permission grantee, a specification declarer or a notifier who manufactures or imports medical devices under section 6 (13) shall display the usage life, warnings, use-prohibition statements or use cautions in labels or medical device documentation.[43]

The display of the usage life, warnings, use-prohibition statements or use cautions in labels or medical device documentation shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister under section 6 (13).

CHAPTER VI
MEDICAL DEVICE CONTROL

[42] Section 44 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[43] Section 45 paragraph one is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 46. No person shall manufacture, import or sell the following medical devices:

(1) counterfeit medical devices;

(2) medical devices of a deficient standard;

(3) medical devices of a deteriorating quality;

(4) medical devices unsafe for use;

(5)[44] medical devices manufactured or imported at variance with the stipulations indicated in the permission, the specification declaration or the notification;

(6)[45] medical devices in respect of which the licence or the specification declaration certificate is revoked under section 70 or the notification certificate is cancelled under section 70/1.

Section 46/1.[46] No person shall sell medical devices for which no licence, specification declaration certificate or notification certificate is granted.

Section 47. A counterfeit medical device means a medical device of the following descriptions:

(1) a medical device which is fake or an imitation in whole or in part;

(2) a medical device which is misleading as to its name, components, quality, quantity, month and year of manufacture, month and year of expiry, the name of its manufacturer, the place of its manufacture, the name of its importer or its quality certification mark or trademark;

(3)[47] a medical device which is falsely represented to be the one for which permission has been granted or the specification declaration or notification has been made.

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[44] Section 46 (5) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[45] Section 46 (6) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[46] Section 46/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[47] Section 47 (3) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 48. A medical device of a deficient standard means:

(1)[48] a medical device of which the quality or standard fails to meet the stipulations indicated in the permission, the specification declaration or the notification;

(2) a medical device of which the standard fails to be in accordance with section 6 (4) or of which the container standard fails to be in accordance with section 6 (6) unless it is a medical device permitted to be manufactured for export under section 34.

Section 49. A medical device of a deteriorating quality means a medical device which turns to be a medical device of a deficient standard or a medical device of which the displayed usage life expires.

Section 50. A medical device which is unsafe for use means a medical device of the following descriptions:

(1) a medical device which is capable of single use and has been used;

(2) a medical device which is manufactured or stored unhygienically;

(3) a medical device which is contaminated by foreign materials or materials likely to be harmful to health;

(4) a medical device which contains degradable substances and is likely to be so toxic as to be harmful to users;

(5) a medical device which is of unreliable usefulness;

(6) a medical device which is designed or manufactured in a manner likely to cause harm to users if it is put into use;

(7) a medical device in respect of which a display of a label or documentation fails to be in accordance with section 44 or section 45 and may thereby cause harm to users.

Section 51. Upon the Notification under section 6 (15), a manufacturer, importer, sponsor of research and researcher of medical devices requiring clinical research shall comply with the rules, procedures and conditions prescribed in such Notification.

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[48] Section 48 (1) is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 52. Upon the Notification under section 6 (16), a manufacturer, importer, seller, possessor or person carrying out the destruction or elimination of medical devices shall comply with the rules and procedures prescribed in such Notification.

Section 53.[49] Upon the Notification under section 6 (17), the import of medical devices shall undergo an inspection by the competent official at a medical device checkpoint.

Section 54. In the interest of the protection of health and safety of consumers, when there is a cause justifying the suspicion that any medical device fails to meet the required quality, standard or efficiency, is unsafe for use or likely to be harmful to health or has a change in the standard, the Secretary-General shall have the power to order the manufacturer or importer of the medical device to furnish documents or evidence for proving the quality, standard or efficiency and safety.

When the proceeding under paragraph one is in progress, the Secretary-General shall have the power to order temporary suspension of the manufacture, import or sale until it can be proved that such medical device meets the required quality, standard or efficiency and safety.

Section 55.[50] In the interest of the protection of health and safety of consumers, when it is apparent that any medical device has the quality, standard or efficiency at variance with the stipulations indicated in the permission, the specification declaration or the notification, is unsafe for use or likely to be harmful to health or has a change in the standard, the Secretary-General shall have the power as follows:

(1) to issue an order in writing instructing the permission grantee, the specification declarer and the notifier to correct particulars indicated in the permission, the specification declaration or the notification;

(2) to issue an order in writing instructing the manufacturer, importer or seller of the medical device, or the possessor thereof for use, to rectify or improve the medical device so manufactured, imported, sold or possessed;

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[49] Section 53 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[50] Section 55 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(3) to issue an order in writing instructing the manufacturer, importer or seller of the medical device to discontinue the manufacture, import or sale thereof or take other relevant action as determined by the Commission;

(4) to publish results of the examination or analysis of the medical device and publish the acts violating or failing to comply with the requirements in (2) or (3) for public information expeditiously and, in the case where the Secretary-General deems it appropriate, notify them to persons concerned;

(5) to recall the medical device from the manufacturer, importer, seller or possessor or order the manufacturer, importer or seller to recall the medical device manufactured, imported or sold by him from the market within the time specified by the Secretary-General and, if it is found that such medical device is the medical device under section 46, order that the same be destroyed or handled as is reasonable in a particular case, provided that the manufacturer, importer, seller or possessor shall be responsible for costs incurred therein.

CHAPTER VII
ADVERTISEMENT

Section 56. No person shall advertise medical devices under section 6 (11) or medical devices under section 46.

Section 57. Subject to section 56, advertisement of medical devices shall be made upon obtaining a licence from the permission grantor. An advertisement licence shall be valid for a period not exceeding three years as from the date of issuance thereof.

The application for permission, the granting of a licence and the period of validity of a licence under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the permission grantor. In this regard, the permission grantor may also prescribe specific conditions for advertisement and restrict the use of advertisement media.

The provisions of section 33 shall also apply to the consideration as regards the issuance of an advertisement licence or the consideration as regards the approval of a change, correction or revision of particulars in an advertisement licence *mutatis mutandis*.

In carrying out advertisement of medical devices directly towards medical and public health practitioners, the Minister, with the recommendation of the Commission, shall have the power to issue the Notification prescribing medical devices as well as rules, procedures and conditions for advertisement in respect of which the requirement as to the application for permission is exempted.[51]

Section 58. In the case where an advertisement licence is lost, destroyed or damaged, the permission grantee, having been granted permission for advertisement, shall submit an application for a substitute document within fifteen days as from the date of the knowledge of the loss, destruction or damage.

The application for a substitute document for the advertisement licence shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General and published in the Government Gazette.

Section 59. Advertisement of medical devices shall:

(1) not make any false or exaggerative indication of the usefulness, quality, quantity, standard, components or origin of medical devices;

(2) not make any representation or commendation of the usefulness of medical devices by any particular person;

(3) not provide any prize obtainable by any aleatory means;

(4) not make any representation, in relation to their usefulness, of their claimed ability to prevent, cure, alleviate or treat diseases or symptoms of diseases, in respect of which advertisement is prohibited as prescribed in the Notification of the Minister;

(5) not display any statement causing fundamental misunderstanding as to medical devices.

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[51] Section 57 paragraph four is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 60. In the case where the permission grantor considers that any advertisement violates section 57 or section 59, the permission grantor shall have the power to issue any of the orders directing the following:

(1) the correction of statements or means of the advertisement;

(2) the prohibition of the use of certain statements or means as envisioned in the advertisement;

(3) the suspension of such advertisement.

In an order under paragraph one, the permission grantor may also order that correct information be published for a dissemination purpose.

CHAPTER VIII
COMPETENT OFFICIALS

Section 61. In the performance of duties, a competent official has the powers as follows:

(1) to enter a place of manufacture, import or sale or a place of storage of medical devices during working hours of such place for inspection or control in the execution of this Act;

(2) to take medical devices, in a reasonable quantity, as samples for inspection or analysis;

(3) to seize or attach medical devices as well as any device, appliance or object suspected of being the subject-matter of an offence or likely to be connected with the commission of an offence and also containers, packaging, labels, medical device documentation and documents pertinent to such medical devices;

(4) to enter any place or vehicle for inspection or control in the execution of this Act in the case where there is a reasonable cause to suspect that an offence under this Act is committed;

(5) to summon, in writing, any person to give statements or furnish necessary documents and evidence to assist the consideration of the competent official.

Section 62. In the performance of duties, a competent official shall present a competent official identification card to persons concerned.

Competent official identification cards shall be in accordance with the form prescribed in the Notification of the Minister.

Section 63.[52] A permission grantee, a specification declarer, a notifier and persons having duties in connection with the manufacture, import, sale and storage of medical devices shall assist competent officials in the course of the performance of duties under section 61 and section 66 paragraph two.

Section 64. Articles seized or attached under section 61 (3) shall vest in the Ministry of Public Health when it is apparent that:

(1) there appears no apparent owner or no person identifies oneself as the owner or possessor within ninety days as from the date of the seizure or attachment;

(2) in the case where no legal action is taken, the owner or possessor fails to make a request for a return thereof within ninety days as from the date of receipt of the notification of the order that no legal action is taken;

(3) in the case where a legal action is taken, the Public Prosecutor has a final non-prosecution order or the Court does not render judgment for confiscation and the owner or possessor fails to make a request for a return thereof within ninety days as from the date of the knowledge of the final non-prosecution order or the date of the final judgment of the Court, as the case may be.

Section 65. In the case where the article seized or attached under section 61 (3) is perishable or is the one of which the determined usage life is nearing expiry or its storage involves a risk of damage or storage expenses in excess of its value, the Office of the Food and Drug Administration may make arrangements for its sale by auction before the case becomes final or before such article vests in the Ministry of Public Health. Net proceeds of the sale thereof as remaining from the deduction of all expenses and encumbrances shall be seized in lieu of such article and deposited with a State-owned bank.

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[52] Section 63 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 66. In the performance of activities under this Act, competent officials shall be officials under the Penal Code.

In the case where there is a reasonable cause, the Secretary-General may order competent officials to conduct inquiries jointly with inquiry officials in accordance with the Rule prescribed by the Ministry of Public Health with the approval of the Bureau of the Royal Thai Police. For this purpose, such competent officials shall have the status as inquiry officials under the Criminal Procedure Code.

CHAPTER IX
SUSPENSION AND REVOCATION OF ESTABLISHMENT REGISTRATION CERTIFICATES, LICENCES OR SPECIFICATION DECLARATION CERTIFICATES OR CANCELLATION OF NOTIFICATION CERTIFICATES[53]

Section 67. In the case where any establishment registrant, permission grantee or specification declarer violates or fails to comply with this Act or a Ministerial Regulation or Notification issued under this Act, the permission grantor with the approval of the Commission has the power to order suspension of the establishment registration certificate, the licence or the specification declaration certificate for a period not exceeding one hundred twenty days, but in the case where an action is instituted before the Court against the establishment registrant, the permission grantee or the specification declarer for the commission of an offence under this Act, the permission grantor may, with the approval of the Commission, order suspension of the establishment registration certificate, the licence or the specification declaration certificate until a final judgment is rendered.

The establishment registrant, permission grantee or specification declarer whose establishment registration certificate, licence or specification declaration certificate is suspended shall not operate the business to which the suspension relates.

[53] The title of Chapter IX, Suspension and Revocation of Establishment Registration Certificates, Licences or Specification Declaration Certificates or Cancellation of Notification Certificates, is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 68. The permission grantor has the power to order cancellation of the order for suspension of an establishment registration certificate, a licence or a specification declaration certificate before the specified time when it appears that the establishment registrant, the permission grantee or the specification declarer has already complied with this Act or the Ministerial Regulation or Notification issued under this Act. In this regard, the permission grantor shall report the cancellation of such order to the Commission for information.

Section 69. The permission grantor, with the approval of the Commission, has the power to order revocation of an establishment registration certificate, a licence or a specification declaration certificate when it appears that:

(1) the establishment registrant lacks qualifications or is under prohibitions or fails to comply with section 16, as the case may be;

(2) the permission grantee lacks qualifications or is under prohibitions or fails to comply with section 26, as the case may be;

(3) the establishment registrant, permission grantee or specification declarer is convicted, by a final judgment, of having violated this Act;

(4) the establishment registrant, permission grantee or specification declarer violates the order for suspension of the establishment registration certificate, the licence or the specification declaration certificate.

Section 70. In the interest of the protection of health and safety of consumers, the permission grantor, with the approval of the Commission, has the power to order revocation of a licence or a specification declaration certificate if thereafter there appears any of the following events:

(1) medical devices are of such a deficient standard as to be incapable of rectification, medical devices are unsafe for use or medical devices are counterfeit;

(2) the permission grantee or the specification declarer has changed the purpose of use or usefulness of medical devices into drugs, psychotropic substances, narcotics, hazardous substances or cosmetics without permission;

(3) medical devices do not possess such usefulness as indicated in the permission or the specification declaration, as revealed by reliable technical documents.

Section 70/1.[54] In the interest of the protection of health and safety of consumers, the permission grantor has the power to cancel a notification certificate if thereafter there appears any of the following events:

(1) information as regards medical devices in respect of which the notification has been made does not corresponds to the true fact;

(2) medical devices in respect of which the notification has been made are counterfeit medical devices or medical devices which are unsafe for use;

(3) the notifier has changed the purpose of use or usefulness of medical devices into drugs, psychotropic substances, narcotics, hazardous substances or cosmetics without permission;

(4) medical devices in respect of which the notification has been made do not possess such usefulness as indicated in the notification, as revealed by reliable technical documents.

Section 71.[55] In the case where the permission grantor requires that medical devices in respect of which permission has been granted or the specification declaration or notification has been made be changed into drugs, psychotropic substances, narcotics, hazardous substances or cosmetics, the permission grantee, the specification declarer or the notifier shall take action in accordance with the rules, procedures, conditions and period of time prescribed by the Secretary-General and published in the Government Gazette.

In the case where no action has been taken under paragraph one within the period of time prescribed by the Secretary-General, the licence, the specification declaration certificate or the notification certificate shall expire.

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[54] Section 70/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[55] Section 71 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 72.[56] An order for suspension or revocation of an establishment registration certificate, a licence or a specification declaration certificate and an order for cancellation of a notification certificate shall be made in writing and notified to the establishment registrant, the permission grantee, the specification declarer or the notifier, as the case may be, and in the case where the establishment registrant, the permission grantee, the specification declarer or the notifier is not found or the establishment registrant, the permission grantee, the specification declarer or the notifier refuses to accept such order, the order shall be posted at an open and conspicuous location at the place indicated in the establishment registration certificate, the licence, the specification declaration certificate or the notification certificate and it shall be deemed that the establishment registrant, the permission grantee, the specification declarer or the notifier has the knowledge of such order as from the date on which the order is posted.

The order for suspension or revocation of the establishment registration certificate, the licence or the specification declaration certificate and the order for cancellation of the notification certificate may also be published in a newspaper or by any other method.

Section 73.[57] Subject to section 46, the person whose establishment registration certificate, licence or specification declaration certificate has been revoked or the person whose notification certificate has been cancelled may sell his remaining medical devices to other establishment registrants, permission grantees, specification declarers or notifiers or persons deemed appropriate by the permission grantor within one hundred eighty days as from the date of the knowledge of the order for revocation of the establishment registration certificate, the licence or the specification declaration certificate or the order for cancellation of the notification certificate or the date of the knowledge of the decision of the Minister, unless the permission grantor grants extension of such time limit.

[56] Section 72 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[57] Section 73 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

CHAPTER X
APPEAL

Section 74.[58] In the case where the permission grantor refuses to issue an establishment registration certificate, a licence, a specification declaration certificate or a notification certificate or refuses to issue an appraisal certificate under section 22 or refuses to grant permission for renewal of an establishment registration certificate, a licence, a specification declaration certificate or a notification certificate, the applicant has the right to make an appeal in writing against such order to the Minister within thirty days as from the date of receipt of the written notification of the refusal to issue an establishment registration certificate, a licence, a specification declaration certificate or a notification certificate or the refusal to issue an appraisal certificate under section 22 or the refusal to grant permission for renewal of an establishment registration certificate, a licence, a specification declaration certificate or a notification certificate, as the case may be.

The decision of the Minister shall be final.

In the case where the permission grantor refuses to grant permission for renewal of an establishment registration certificate, a licence, a specification declaration certificate or a notification certificate, the Minister has the power to, upon the appellant's application, issue an order permitting the operation of business for the time being before the Minister gives a decision upon the appeal under paragraph two.

Section 75.[59] The establishment registrant, the permission grantee or the specification declarer whose establishment registration certificate, licence or specification declaration certificate has been suspended or revoked or the notifier whose notification certificate has been cancelled has the right to make an appeal in writing to the Minister within thirty days as from the date of the knowledge of the order.

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[58] Section 74 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[59] Section 75 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

The appeal under paragraph one does not stay the execution of the order for suspension or revocation of the establishment registration certificate, the licence or the specification declaration certificate or the order for cancellation of the notification certificate.

The decision of the Minister shall be final.

Section 76. In considering an appeal under section 74 and section 75, the Minister shall complete the consideration of the appeal within one hundred twenty days as from the date of receipt thereof. If there is a necessary cause preventing the completion of the consideration within such period of time, a notification shall be given to the appellant in writing before the expiration of such period of time. In this regard, the period of time for the consideration of the appeal shall be extended for a period not exceeding one hundred twenty days as from the date of the expiration of such period.

CHAPTER XI
CIVIL LIABILITY

Section 77. A manufacturer, importer or seller of medical devices shall be liable for injury arising from the use of medical devices unless it can be proved that the injury has resulted from *force majeure* or has not resulted from any defect in such medical devices or resulted from the injured person's own fault.

Section 78. Any person who uses a medical device, or causes it to be used, on another person and thereby causes injury to life, the body or health shall be liable to such other person's injury as caused by the use of such medical device, unless it can be proved that he has exercised due care in accordance with the technical standard concerned or such injury resulted from *force majeure* or resulted from the injured person's own fault.

The provisions of paragraph one shall also apply to mental injury in consequence of the injured person's physical or health injury.

Section 79. A claim of damages arising from medical devices or the use of medical devices under this Chapter shall be barred by prescription upon the lapse of three

years as from the day on which the injured person knew of the injury and knew of the person bound to pay damages, provided that the claim shall be made not later than ten years as from the date of the occurrence of the injury arising from such medical devices or the use thereof.

Section 80. The person liable under section 77 or section 78, who has paid damages to the injured person, has the right of recourse against the person contributing to the injury, provided that the right of recourse shall be exercised within three years as from the date of his payment of damages. But, the person exercising the right of recourse is entitled to the recourse only to the extent exceeding his own liability.

CHAPTER XII
PENALTIES

Section 81. Any controller of the manufacture, import or sale of medical devices who fails to perform the duties prescribed in the Notification under section 6 (7) shall be liable to a fine not exceeding ten thousand Baht.

Section 82. Any person who violates the Notification issued under section 6 (11) shall be liable to imprisonment for a term not exceeding five years or to a fine not exceeding five hundred thousand Baht or to both.

Section 83. Any person who violates the Notification issued under section 6 (12) shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Section 84. Any person who fails to comply with an order of the Commission or a sub-committee under section 13 shall be liable to imprisonment for a term not exceeding one month or to a fine not exceeding ten thousand Baht or to both.

Section 85. Any person who manufactures or imports medical devices without registration of an establishment under section 15 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 86.[60] Any person who manufactures or imports medical devices under section 6 (1) (a) without being granted a licence under section 17 paragraph one or section 18 paragraph one, as the case may be, shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Any permission grantee, being granted permission for the manufacture or import of medical devices under section 6 (1) (a), who fails to comply with section 17 paragraph three or section 18 paragraph two shall be liable to a fine not exceeding one hundred fifty thousand Baht.

Section 87.[61] Any person who manufactures or imports medical devices under section 6 (1) (b) without being granted a specification declaration certificate under section 19 paragraph one or section 20 paragraph one, as the case may be, shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Any person who manufactures or imports medical devices under section 6 (1) (c) without being granted a notification certificate under section 19 paragraph one or section 20 paragraph one, as the case may be, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any specification declarer who fails to comply with section 19 paragraph three or section 20 paragraph two shall be liable to a fine not exceeding one hundred thousand Baht.

Any notifier who fails to comply with section 19 paragraph three or section 20 paragraph two shall be liable to a fine not exceeding fifty thousand Baht.

Section 88. Any manufacturer, importer, seller or possessor of medical devices under section 6 (8) who fails to comply with section 21 or section 22 paragraph five, as the case may be, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 89. Any person who sells medical devices without being granted a licence under section 24 paragraph one or section 25 paragraph one, as the case may be, shall

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[60] Section 86 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[61] Section 87 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Any permission grantee, being granted permission for the sale of medical devices, who fails to comply with section 24 paragraph three or section 25 paragraph two shall be liable to a fine not exceeding one hundred fifty thousand Baht.

Section 90. Any person, being granted exemption under section 27 (2), (3), (4), (5), (6) or (7), who fails to comply with the rules, procedures and condition prescribed in the Notification of the Minister under section 27 paragraph two or any person, being granted exemption under section 27 (8), who fails to comply with the rules, procedures and condition prescribed in the Notification of the Minister under section 27 (8) shall be liable to a fine not exceeding one hundred thousand Baht.

Section 91.[62] Any permission grantee or specification declarer who manufactures, imports or sells medical devices after the licence or the specification declaration certificate expires but has submitted an application for renewal of the licence or the specification declaration certificate within the time prescribed under section 30 paragraph three shall be liable to a daily fine at the rate of one thousand Baht a day throughout the period in which failure to submit an application for renewal of the licence or the specification declaration certificate occurs.

Any establishment registrant or notifier who manufactures, imports or sells medical devices after the establishment registration certificate or the notification certificate expires but has submitted an application for renewal of the establishment registration certificate within the time prescribed under section 30 paragraph three or has submitted an application for renewal of the notification certificate within the time prescribed under section 30/1 paragraph three shall be liable to a daily fine at the rate of five hundred Baht a day throughout the period in which failure to submit an application for renewal of the establishment registration certificate or the notification certificate occurs.

[62] Section 91 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 92.[63] Any permission grantee or specification declarer who fails to comply with section 31 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any establishment registrant who fails to comply with section 31 shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Section 92/1.[64] Any notifier who fails to comply with section 31/1 paragraph one shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Section 93.[65] Any permission grantee or specification declarer who fails to comply with section 32 paragraph one shall be liable to a fine not exceeding ten thousand Baht.

Any establishment registrant who fails to comply with section 32 paragraph one shall be liable to a fine not exceeding five thousand Baht.

Section 94. Any manufacturer of medical devices for export who fails to comply with section 34 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any person who violates section 34 paragraph two shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Section 95.[66] Any permission grantee under section 17 or section 24 or specification declarer under section 19 who ceases the business without complying with section 36 paragraph one shall be liable to a fine not exceeding ten thousand Baht.

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[63] Section 92 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[64] Section 92/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[65] Section 93 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[66] Section 95 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Any establishment registrant under section 15 or notifier under section 19 who ceases the business without complying with section 36 paragraph one shall be liable to a fine not exceeding five thousand Baht.

Section 96.[67] Any permission grantee under section 17 or section 24 or specification declarer under section 19 who, when his licence or specification declaration certificate expires or the permission grantor has refused to grant permission for renewal of the licence or the specification declaration, fails to give the notification under section 37 paragraph one shall be liable to a fine not exceeding ten thousand Baht.

Any establishment registrant under section 15 who, when his establishment registration certificate expires or the permission grantor has refused to grant permission for renewal of the establishment registration certificate, fails to give the notification under section 37 paragraph one shall be liable to a fine not exceeding five thousand Baht.

Section 97. Any permission grantee, being granted permission for the sale of medical devices under section 24, who fails to give the notification under section 38 paragraph two when he has given the notification of the cessation of the business, the licence expires or the permission grantor has refused to grant permission for renewal of the licence shall be liable to a fine not exceeding ten thousand Baht.

Any permission grantee, being granted permission for the sale of medical devices under section 24, who sells medical devices after the time limit under section 38 paragraph one when he has given the notification of the cessation of the business, the licence expires or the permission grantor has refused to grant permission for renewal of the licence shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Section 98. Any heir or possessor of medical devices or administrator of the estate under section 39 who fails to give the notification under section 38 paragraph two shall be liable to a fine not exceeding ten thousand Baht.

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[67] Section 96 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 99.[68] Any permission grantee or specification declarer who violates section 40 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any establishment registrant or notifier who violates section 40 shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Section 100.[69] Any permission grantee or specification declarer who fails to comply with section 41 (1), (2), (3), (4) or (9) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any permission grantee or specification declarer who prepares a record or report under section 41 (3), prepares a report under section 41 (4), prepares a complaint record under section 41 (5) or provides technical documents under section 41 (9), in a manner containing falsity, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any permission grantee or specification declarer who fails to comply with section 41 (5) shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Any permission grantee or specification declarer who fails to comply with section 41 (6), (7) or (8), as the case may be, shall be liable to a fine not exceeding one hundred thousand Baht.

Section 100/1.[70] Any establishment registrant or notifier who fails to comply with section 41 (1), (2), (3), (4) or (9) shall be liable to imprisonment for a term not exceeding six month or to a fine not exceeding fifty thousand Baht or to both.

Any establishment registrant or notifier who prepares a record or report under section 41 (3), prepares a report under section 41 (4), prepares a complaint record under section 41

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[68] Section 99 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[69] Section 100 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[70] Section 100/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(5) or provides technical documents under section 41 (9), in a manner containing falsity, shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Any establishment registrant or notifier who fails to comply with section 41 (5) shall be liable to imprisonment for a term not exceeding three months or to a fine not exceeding thirty thousand Baht or to both.

Any establishment registrant or notifier who fails to comply with section 41 (6), (7) or (8), as the case may be, shall be liable to a fine not exceeding fifty thousand Baht.

Section 101. Any manufacturer, importer or seller of medical devices under section 6 (14) or a medical establishment operator in a medical establishment where such medical devices are used who fails to comply with section 42 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any person under paragraph one who fails to comply with section 42 paragraph two shall be liable to a fine not exceeding fifty thousand Baht.

Section 102. Any seller of medical devices under section 6 (9) or (10) who fails to comply with section 43 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any person under paragraph one who fails to comply with section 43 paragraph two shall be liable to a fine not exceeding fifty thousand Baht.

Section 103.[71] Any permission grantee or specification declarer who manufactures or imports medical devices without complying with section 44 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any establishment registrant or notifier who manufactures or imports medical devices without complying with section 44 paragraph one shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

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[71] Section 103 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Any person under paragraph one who fails to comply with section 44 paragraph two shall be liable to a fine not exceeding one hundred thousand Baht.

Any person under paragraph two who fails to comply with section 44 paragraph two shall be liable to a fine not exceeding fifty thousand Baht.

Any seller of medical devices who fails to comply with section 44 paragraph three shall be liable to a fine not exceeding fifty thousand Baht.

Section 104.[72] Any permission grantee or specification declarer who manufactures or imports medical devices under section 6 (13) without complying with section 45 paragraph one shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any establishment registrant or notifier who manufactures or imports medical devices under section 6 (13) without complying with section 45 paragraph one shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Any person under paragraph one who fails to comply with section 45 paragraph two shall be liable to a fine not exceeding one hundred thousand Baht.

Any person under paragraph two who fails to comply with section 45 paragraph two shall be liable to a fine not exceeding fifty thousand Baht.

Section 105. Any person who manufactures or imports counterfeit medical devices in violation of section 46 (1) shall be liable to imprisonment for a term not exceeding ten years or to a fine not exceeding one million Baht or to both.

Any person who sells counterfeit medical devices in violation of section 46 (1) shall be liable to imprisonment for a term not exceeding five years or to a fine not exceeding five hundred thousand Baht or to both.

[72] Section 104 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 106.[73] Any person who manufactures or imports medical devices, in respect of which a licence has been granted under section 6 (1) (a) or a specification declaration certificate has been granted under section 6 (1) (b), being medical devices of a deficient standard in violation of section 46 (2), shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Any person who manufactures or imports medical devices, in respect of which a notification certificate has been granted under section 6 (1) (c), being medical devices of a deficient standard in violation of section 46 (2), shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any person who sells medical devices of a deficient standard in violation of section 46 (2) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 107. Any person who manufactures or imports medical devices of a deteriorating quality in violation of section 46 (3) shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Any person who sells medical devices of a deteriorating quality in violation of section 46 (3) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 108. Any person who manufactures or imports medical devices unsafe for use in violation of section 46 (4) shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Any person who sells medical devices unsafe for use in violation of section 46 (4) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 109.[74] Any person who manufactures or imports medical devices manufactured or imported at variance with the stipulations indicated in the permission, the

[73] Section 106 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[74] Section 109 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

specification declaration or the notification in violation of section 46 (5) shall be liable to a fine not exceeding two hundred thousand Baht.

Any person who sells medical devices manufactured or imported at variance with the stipulations indicated in the permission, the specification declaration or the notification in violation of section 46 (5) shall be liable to a fine not exceeding one hundred thousand Baht.

Section 109/1.[75] Any person who sells medical devices for which no licence or no specification declaration certificate is granted, in violation of section 46/1, shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Any person who sells medical devices for which no notification certificate is granted, in violation of section 46/1, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 110. Any person who manufactures or imports medical devices for which the licence or the specification declaration certificate is revoked, in violation of section 46 (6), shall be liable to imprisonment for a term not exceeding five years or to a fine not exceeding five hundred thousand Baht or to both.

Any person who sells medical devices for which the licence or the specification declaration certificate is revoked, in violation of section 46 (6), shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any person who manufactures or imports medical devices for which the notification certificate is cancelled, in violation of section 46 (6), shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.[76]

[75] Section 109/1 is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[76] Section 110 paragraph three is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Any person who sells medical devices for which the notification certificate is cancelled, in violation of section 46 (6), shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.[77]

Section 111. Any manufacturer, importer, sponsor of research or researcher of medical devices requiring clinical research who fails to comply with section 51 shall be liable to a fine not exceeding five hundred thousand Baht.

Section 112. Any manufacturer, importer, seller, possessor or person carrying out the destruction or elimination of medical devices who fails to comply with section 52 shall be liable to a fine not exceeding five hundred thousand Baht.

Section 113.[78] Any importer of medical devices who fails to comply with section 53 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 114. Any manufacturer, importer or seller of medical devices who fails to comply with an order of the Secretary-General under section 54 paragraph two or section 55 (2), (3) or (5) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any permission grantee or specification declarer who fails to comply with an order of the Secretary-General under section 55 (1) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Any notifier who fails to comply with an order of the Secretary-General under section 55 (1) shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.[79]

Section 115. Any person who advertises medical devices under section 6 (11) or medical devices under section 46 (1), (2), (3), (4) or (6) in violation of section 56 shall be liable to

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[77] Section 110 paragraph four is added by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[78] Section 113 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[79] Section 114 paragraph three is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both.

Any person who advertises medical devices under section 46 (5) in violation of section 56 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 116. Any person who advertises medical devices without being granted a licence under section 57 paragraph one shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand Baht or to both.

Section 117. Any person who advertises medical devices in violation of section 59 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 118. Any advertiser who fails to comply with an order of the permission grantor under section 60 shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand Baht or to both and also to a daily fine at the rate of one thousand Baht a day until due compliance is carried out.

Section 119.[80] Any person who fails to appear for giving statements or fails to furnish necessary documents or evidence under section 61 (5) without any due reason shall be liable to a fine not exceeding ten thousand Baht.

Section 120.[81] Any permission grantee, specification declarer, notifier or person having the duty in connection with the manufacture, import, sale or storage of medical devices who fails to assist the competent official under section 63 shall be liable to imprisonment for a term not exceeding one month or to a fine not exceeding ten thousand Baht or to both.

[80] Section 119 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[81] Section 120 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 121.[82] Any permission grantee or specification declarer who violates section 67 paragraph two shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand Baht or to both.

Any establishment registrant who violates section 67 paragraph two shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand Baht or to both.

Section 122.[83] In the case where the offender is a juristic person, if the commission of the offence by such juristic person has resulted from the instruction or an action of a director or a manager or any person responsible for the operation of such juristic person or in the case where such person has the duty to give instructions or take action and refrains from giving instructions or taking action, thereby leading to the commission of the offence by such juristic person, such person shall also be liable to the penalty as provided for such offence.

Section 123. Any offence under this Act which is punishable only by a fine or is an offence punishable by imprisonment for a term not exceeding one year may be settled by the Secretary-General or the person entrusted by the Secretary-General in accordance with the rules prescribed by the Commission and, when the alleged offender has made payment of the fine in such amount as required for the settlement within thirty days as from the date of the settlement, the case shall be deemed to have been extinguished under the Criminal Procedure Code.[84]

In the case where the inquiry official finds that any person has committed an offence under paragraph one and such person consents to have the settlement, the inquiry official shall refer the matter to the Secretary-General or the person entrusted by the Secretary-General within seven days as from the date of such person's declaration of the consent thereto.

TRANSITORY PROVISIONS

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[82] Section 121 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[83] Section 122 is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

[84] Section 123 paragraph one is amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

Section 124. A manufacturer or importer of medical devices under the Medical Devices Act, B.E. 2531 (1988) prior to the date on which this Act comes into force shall submit an application for registration of an establishment in accordance with the provisions of this Act within ninety days as from the date on which this Act comes into force and may continue the operation of such business until such person receives the notification of the permission grantor's refusal to issue an establishment registration certificate. In this regard, the permission grantor shall complete his consideration within one hundred twenty days as from the date of receipt of the application. If such period of time is exceeded, it shall be deemed that the applicant is an establishment registrant under this Act.

Upon the action having been carried out under paragraph one, licences for the manufacture or import issued under the Medical Devices Act, B.E. 2531 (1988) prior to the date on which this Act comes into force shall remain valid until their expiry.

Section 125. Licences for the sale of medical devices issued under the Medical Devices Act, B.E. 2531 (1988) prior to the date on which this Act comes into force shall remain valid until their expiry.

Section 126. Specification declarations under the Medical Devices Act, B.E. 2531 (1988) prior to the date on which this Act comes into force shall remain valid for another two years as from the date on which this Act comes into force, except that in the case where the medical device in respect of which the specification declaration has been made is prescribed by the Notification as a medical device for which application for permission is required under section 6 (1), the specification declarer shall take action in accordance with section 18.

Section 127. Any advertisement of medical devices approved by the Secretary-General of the Food and Drug Administration prior to the date on which this Act comes into force shall remain valid for a period of time prescribed by the Secretary-General of the Food and Drug Administration.

Section 128. Applications for permission and specification declaration as submitted or made under the Medical Devices Act, B.E. 2531 (1988) and pending the consideration shall be deemed to be applications for permission or applications for specification

declaration under this Act *mutatis mutandis*. Amendment to the applications for permission or applications for specification declaration, if any, shall be in accordance with this Act.

Section 129. Ministerial Regulations or Notifications issued under the Medical Devices Act, B.E. 2531 (1988) as in force prior to the date on which this Act comes into force shall continue to be in force insofar as they are not contrary to or inconsistent with the provisions of this Act until Ministerial Regulations or Notifications to be issued under this Act come into force.

The issuance of Ministerial Regulations or Notifications under paragraph one shall be completed within two years as from the date on which this Act comes into force. If their completion cannot be achieved, the Minister shall report the reasons therefor to the Council of Ministers.

Countersigned by:

General Surayud chulanont
Prime Minister

RATES OF FEES[85]

(1) Manufacturing Establishment Registration Certificates	10,000 Baht each
(2) Importing Establishment Registration Certificates	20,000 Baht each
(3) Licences for Manufacturing Medical Devices	100,000 Baht each
(4) Licences for Importing Medical Devices	200,000 Baht each
(5) Licences for Selling Medical Devices	10,000 Baht each
(6) Licences for Advertising Medical Devices	10,000 Baht each
(7) Specification Declaration Certificates for Medical Device Manufacture	50,000 Baht each
(8) Specification Declaration Certificates for Medical Device Import	100,000 Baht each
(9) Notification Certificates for Medical Device Manufacture	5,000 Baht each
(10) Notification Certificates for Medical Device Import	10,000 Baht each
(11) Certificates	5,000 Baht each
(12) Medical Device Appraisal Certificates under Section 22	2,000 Baht each
(13) Substitutes for Establishment Registration Certificates, Substitutes for Licences, Substitutes for Specification Declaration Certificates, Substitutes for Medical Device Appraisal Certificates under Section 22 and Substitutes for Certificates	500 Baht each
(14) Applications for Establishment Registration	100 Baht each
(15) Applications for Permission	1,000 Baht each
(16) Applications for Specification Declaration	1,000 Baht each
(17) Applications for Notification	1,000 Baht each
(18) Applications for Relocation or Change of Places of Manufacture, Import or Sale or Places of Storage of Medical Devices	1,000 Baht each
(19) Applications for Correction or Variation of Particulars in Establishment Registration Certificates	100 Baht each
(20) Applications for Correction or Variation of Particulars in Licences or Other Particulars to Which Permission Relates	1,000 Baht each

[85] Rates of Fees are amended by the Medical Devices Act (No. 2), B.E. 2562 (2019).

(21) Applications for Correction or Variation of Particulars in Specification Declaration Certificates or Other Particulars to Which Specification Declaration Relates — 500 Baht each

(22) Renewal of Establishment Registration Certificates:

Subject to the fee equal to that charged for each copy of establishment registration certificates of respective classes

(23) Renewal of Licences: Subject to the fee equal to that charged for each copy of licences of respective classes

(24) Renewal of Specification Declaration Certificates: Subject to the fee equal to that charged for each copy of specification declaration certificates of respective classes

(25) Renewal of Notification Certificates for Medical Device Manufacture — 2,500 Baht each

(26) Renewal of Notification Certificates for Medical Device Import — 5,000 Baht each

(27) Other Applications — 1,000 Baht each

In issuing Ministerial Regulations prescribing fees, different rates of fees may be prescribed, having regard to categories, classes and types of medical devices, the size and business of operators and types of correction and variation.