

Translation

Medical Device Act B.E. 2551 (2008)¹

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 device;

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 permit by virtue of law;

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

Section 1. This Act is called the “Medical Device Act B.E. 2551 (2008)”.

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

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 The Medical Device Act B.E. 2531 (1988) shall be repealed.

Section 4. In this Act:
“Medical device” means:

¹ This translation has been prepared by the Legal Research Institute Foundation (LRIF) for information purposes only. Whilst LRIF has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

(1) an instrument, tool, mechanical device or object that is used for insertion into a human or animal body, fluid for laboratory examination, product, software or any other object specifically intended by the manufacturer for one of the following uses, either solely or as a constituent or accessory of any other object:

(a) therapy practice, medical practice, nursing and midwifery practice, dental practice, medical technology practice, physiotherapy and veterinary practices under the laws governing the respective professions or other medical or public health practices as prescribed by Notification of the Minister;

(b) diagnosis, prevention, monitoring, treatment, relief or cure of human or animal disease;

(c) diagnosis, monitoring, treatment or cure of human or animal injury;

(d) inspection, replacement, remedy, alteration, support, sustainment or aid pertaining to the human or animal anatomy or body process;

(e) human or animal life support or aid;

(f) contraception or promotion of fertility of a human or animal;

(g) assistance or compensation for a disability or handicap of a human or animal;

(h) generation of data from the examination of specimen extracted from a human or animal body for medical or diagnostic purposes;

(i) disinfection or sterilization of a medical device;

(2) an equipment or constituent of an instrument, tool, mechanical device product or object under (1);

(3) other instrument, tool, mechanical device product or object as prescribed by Notification of the Minister.

The accomplishment of purposes of the articles stated in (1) which occurs within a human or animal body must not be the result of a pharmacological, immunological or metabolic process.

“Manufacture” means to make, assemble, invent, pack in portions or as a whole, improve, convert, modify or sterilize.

“Sell” means to dispose, distribute, issue, exchange, lend, lease, lease on hire purchase or transfer of right or possession to another person for commercial purposes and includes possession for sale.

“Import” means to bring or order into the Kingdom.

“Export” means to bring or send out of the Kingdom.

“Label” means any text displayed on a medical device, container or packaging of a medical device.

“Medical device documentation” means paper or other object which discloses a meaning by means of a statement pertaining to the medical device inserted or enclosed in the container or packaging of such medical device and shall also include the instruction manual of such medical device.

“Statement” includes the display of a letter, picture, marking, design, illustration, video, light, sound, mark or any act which enables persons generally to understand a meaning.

“Advertisement” means an act by any means which exposes the public to sight, sound or acknowledgement of a statement for commercial purposes and shall also include a sales promotion.

“Sales promotion” means the communication of information, persuasion or an act, by any means, to promote sales.

“Medical centre” means medical centre under the law on medical centre and veterinary centre under the law on veterinary centre and shall also include medical centres and veterinary centres run by state agencies.

“Medical and public health practitioner” means a medical practitioner, dental practitioner, first class veterinary practitioner, physiotherapy practitioner, medical technology practitioner or other medical and public health practitioner prescribed by Notification of the Minister.

“Licensee” means a licensee under this Act; in the case where the licensee is a juristic person, it shall also include a person appointed or designated by the juristic person to administer operations.

“Specifications provider” means the recipient of a specifications declaration receipt under this Act; in the case where a juristic person is the recipient of a specifications declaration receipt, it shall also include a person appointed or designated by the juristic person to administer operations.

“Establishment registrant” means the recipient of a registration certificate for an establishment under this Act; in the case where the recipient of a registration certificate for an establishment is a juristic person, it shall also include a person appointed or designated by the juristic person to administer operations.

“Licensor” means the Secretary-General of the Food and Drug Administration or a person designated by the Secretary-General of the Food and Drug Administration.

“Board” means the Medical Device Board.

“Member” means a Member of the Medical Device Board.

“Competent official” means a person appointed by the Minister to execute this Act.

“State agency” means the central administration, regional administration, local administration, state enterprise, public organization and other state agencies.

“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 to prescribe fees not exceeding the rates attached to this Act, provide fee exemptions, issue Notifications and determine other operations for the execution of this Act.

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

Section 6. For the benefit of controlling medical devices and safeguarding consumer safety, the Minister, by the advice of the Board, shall have the power to prescribe the following by Notification:

(1) medical devices for which a manufacturer or importer must obtain a licence, as well as the rules, procedures and conditions for the manufacture and import of medical devices;

(2) medical devices of which a manufacturer or importer must declare specifications, as well as the rules, procedures and conditions for the manufacture or import of medical devices;

(3) medical devices for which a vendor must obtain a licence, as well as the rules, procedures and conditions for selling medical devices;

(4) standards of medical devices that must be complied with by a manufacturer, importer or vendor;

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

(6) standards of containers and use of containers, as well as materials prohibited from use as containers of medical devices that must be complied with by manufacturers, importers and vendors;

(7) medical devices which require designation of a controller for manufacture, import or sale, as well as the qualifications, number and duties of the controller;

(8) medical devices which require a technological assessment in order to ensure that the use of such medical devices are suitable and corresponds to the health problems of the public and the economic and social conditions of the country;

(9) medical devices which must be sold only to a consumer having a prescription issued by a medical and public health practitioner, as well as the rules, procedures and conditions for selling medical devices;

(10) medical devices which must be sold only to medical centres or medical and public health practitioners, as well as the rules, procedures and conditions for selling medical devices;

(11) medical devices of which manufacture, import or sale are prohibited;

(12) medical devices of which direct sales or direct marketing under the law on direct sales and marketing are prohibited;

(13) medical devices which must display data on shelf lives, warnings, prohibitions or use cautions on the labels or medical device documentation, as well as the rules, procedures and conditions for such display;

(14) medical devices which must be accompanied by a register of patients using such medical devices, as well as rules, procedures and conditions for the registration of patients using such medical devices;

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

(16) rules and procedures for the transport, safekeeping and destruction or disintegration of medical devices;

(17) designation of a place within the Kingdom as a checkpoint for the inspection of imported or exported medical devices;

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

CHAPTER I BOARD OF MEDICAL DEVICES

Section 7. There shall be a Board called the “Board of Medical Devices” comprising the Permanent Secretary of the Ministry of 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 and not fewer than nine but not

more than eleven Qualified Members appointed by the Minister as Members. Amongst the Qualified Members appointed, there must be one medical practitioner, one nursery and midwifery practitioner, one dental practitioner, one first class veterinary practitioner, one medical technology practitioner, one physical therapy practitioner, one representative of an association or foundation having an objective relating to the promotion or support of medical centre operations, one representative of an association or operator having the objective of manufacturing, import or sale of medical devices, and one representative of an association or foundation having an objective relating to consumer protection.

A Deputy Secretary-General designated by the Secretary-General shall be a Member and Secretary, and the Director of the Medical Device Control Division, Food and Drug Administration, shall be a Member and Assistant Secretary.

Section 8. A Qualified Member shall hold office for a term of two years.

In the case where a Qualified Member vacates office prior to the expiry of term, the Minister may appoint another person to become a replacement Member and the appointed person shall remain in office for the remaining term of the replaced Member.

In the case where the Minister appoints an additional Qualified Member during the term of the existing appointed Members, the additionally appointed Qualified Member shall hold office for a period equivalent to the remaining term of the existing Qualified Members.

Upon the completion of the term under paragraph one, if new Qualified Members have not yet been appointed, the Qualified Members retiring at the completion of term shall remain in office until newly appointed Qualified Members takes office.

A Qualified Member retiring at the completion of term may be reappointed but shall not hold office for more than two consecutive terms.

Section 9. In addition to retirement at the completion of term, a Qualified Member retires from office upon:

- (1) death;
- (2) resignation;
- (3) removal by the Minister due to defective performance of duties, misconduct or ineptitude;
- (4) being a bankrupt;
- (5) being an incompetent or quasi-incompetent person;
- (6) being sentenced by a final judgment to a term of imprisonment, except for a sentence imposed for an offence committed negligently or a minor offence.

Section 10. A meeting of the Board must be attended by not less than one-half of the total number of Members in order to constitute a quorum.

In a meeting of the Board, if the Chairman is not present or is unable to perform duties, the Members present at the meeting shall elect one among themselves to be the presiding officer.

A decision of the meeting shall be passed by a majority vote. Each Member shall have one vote. In the case of an equality of votes, the presiding officer shall cast an additional vote as a casting vote.

Section 11. The Board shall have the following powers and duties:

(1) to give recommendations or opinions to the Minister on policies and measures concerning the control of medical devices so as to ensure compliance with this Act;

(2) to give recommendations to the Minister on the issuance of Notifications under section 6;

(3) to give approvals for the suspension and revocation of an establishment registration certificate, licence or specifications declaration receipt;

(4) to perform other tasks as provided under this Act or as assigned by the Minister.

Section 12. The Board shall have the power to appoint subcommittees to perform tasks assigned by the Board and the provisions of section 10 shall *mutatis mutandis* apply to the meeting of subcommittees.

Section 13. In the performance of functions under this Act, the Board and subcommittee shall have the power to issue a summons for any person to testify or produce relevant documents and evidence or other items for use in the consideration.

Section 14. In the performance of functions under this Act, Members and subcommittee members shall be officers under the Penal Code.

CHAPTER II
REGISTRATION OF ESTABLISHMENTS, LICENCE APPLICATIONS AND LICENSING
AND SPECIFICATIONS DECLARATION

Section 15. Any person who wishes to manufacture or import a medical device shall register his/her establishment with the licensor.

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

Section 16. The Licensor shall issue a certificate of registration for a medical device manufacturing or import establishment to an applicant for establishment registration when it appears that the applicant for establishment registration:

(1) is the owner of the undertaking for which an establishment registration certificate is sought;

(2) has attained not less than twenty years of age;

(3) has residence in Thailand;

(4) is not a bankrupt;

(5) has never been sentenced to a term of imprisonment by a final judgment for an offence which the law stipulates dishonesty as an element of the offence, or an offence under this Act, except where a period of more than two years has lapsed since the sentence expiry on the day prior to registration application;

(6) is not insane, incompetent or quasi-incompetent;

(7) is not afflicted with a disease prescribed by Notification of the Minister;

(8) has a place for the manufacture or import of medical devices and equipments for the manufacture, storage and control or quality preservation of medical devices having the description and being present in the quantities prescribed by Notification of the Minister;

(9) does not use a trade name which is identical or similar to a trade name of an establishment registrant whose establishment registration certificate is suspended or where less than one year has lapsed since the revocation of such person's establishment registration certificate or licence;

(10) is not a person whose establishment registration certificate is suspended under this Act;

(11) has never had an establishment registration certificate revoked under this Act, except where a period of more than two years has lapsed since the revocation of the establishment registration certificate to the date of establishment registration application.

In the case where the establishment registration applicant is a juristic person, the manager or representative of the juristic person who administers the operations must have the qualifications under (2) and (3) and must not have the disqualifications under (4), (5), (6), (7), (10) or (11).

Section 17. An establishment registrant who wishes to manufacture or import a medical device under section 6(1) shall submit a licence application, and the manufacture or import of medical device may be carried out only upon the issuance of a license by the licensor.

A licence application and licensing under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by Ministerial Regulation.

A licensee under paragraph one shall also comply with the rules, procedures and conditions of manufacture or import of medical devices as prescribed by Notification of the Minister under section 6(1).

Section 18. An establishment registrant who manufactures or imports a medical device stated in a Notification under section 6(1) on the effective date of such Notification and wishes to continue with the operations must submit a licence application within thirty days as from the effective date of the Notification. Upon the submission of such an application within the prescribed period, the operations may be continued until an order to reject a licence is issued.

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

Section 19. An establishment registrant who wishes to manufacture or import a medical device under section 6(2) shall submit an application to declare specifications, and the manufacture or import of the medical device may be carried out only upon issuance of a specifications declaration receipt by the licensor.

A declaration of specifications and issuance of specifications declaration receipt under paragraph one shall be in accordance with rules, procedures and conditions prescribed by Ministerial Regulation.

A specifications provider under paragraph one must also comply with the rules, procedures and conditions of manufacture and import of medical devices as prescribed by Notification of the Minister under section 6(2).

Section 20. An establishment registrant who manufactures or imports a medical device stated in a Notification under section 6(2) on the effective date of such Notification and wishes to continue with the operations must submit an application to declare specifications within thirty days as from the effective date of the Notification. Upon the submission of such an application within the prescribed period, the operations may be continued until an order to reject the declaration of specifications is issued.

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

Section 21. Upon the issuance of a Notification on medical devices under section 6(8), the manufacturers, importers, vendors or possessors having possession of such medical devices on the effective date of the Notification shall declare possession of such medical devices to the licensor within sixty days as from the effective date of such Notification.

In the case where a medical device under paragraph one is to be relocated from one premises to another, the possessor of such medical device shall notify the licensor prior to the relocation. In any event, where necessary for the safe use of such medical device, the licensor shall carry out an inspection of the readiness of the medical device, premises and personnel. Any expenses incurred for such readiness inspection shall be collected from the possessor of the medical device.

A declaration of possession under paragraph one, relocation and readiness inspection, as well as the expenses for proceedings under paragraph two, shall be in accordance with rules, procedures and conditions prescribed by the Secretary-General with the approval of the Board as published in the Government Gazette.

Section 22. An establishment registrant who wishes to manufacture or import a medical device under section 6(8) shall submit an application to the licensor for an assessment of the medical device's efficiency, quality, standard and user safety, including an assessment of its economic and social impact and worthiness, so as to ensure the suitable, comprehensive reach and fair use of the medical device. Manufacture and import may only be carried out upon the issuance of an assessment certificate by the licensor, provided that in the case of a medical device where the manufacturer or importer must obtain a license or declare specifications, the manufacture or import may only be carried out upon the licensor's issuance of a license or specifications declaration receipt under section 17 or section 19, as the case may be.

An assessment application, assessment and issuance of a medical device assessment certificate under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General with the approval of the Board as published in the Government Gazette.

The Minister, by the advice of the Board, shall have the power to designate by Notification experts, expert entities, state agencies or other agencies, either domestic or overseas, as assessors of medical devices under paragraph one, as well as the rate, payment procedures and exemptions from expenses arising from the assessment of such medical devices.

The expenses arising from the assessment of a medical device under paragraph three shall be collected from the person wishing to manufacture or import such medical device.

The provisions of section 21 paragraph two and paragraph three shall also apply to a case where an assessed medical device under paragraph one is to be subsequently relocated from one premises 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 wishes to sell a medical device under section 6(3) shall submit a licence application. The sale of such medical device may be carried out only upon the issuance of a licence by the licensor.

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

A licensee under paragraph one must also comply with the rules, procedures and conditions governing the sale of medical devices as prescribed by Notification of the Minister under section 6(3).

A manufacturer or importer under section 17 or section 19 shall be regarded as a licensed vendor of medical devices under paragraph one manufactured by oneself or may import without having to submit a sales licence application, but must comply with the rules, procedures and conditions prescribed by Notification of the Minister under section 6(3).

Section 25. Any person who sells a medical device stated in a Notification under section 6(3) on the effective date of such Notification and wishes to continue operations must submit a licence application within thirty days as from the effective date of

the Notification. Upon the submission of such an application within the prescribed period, the operations may continue until an order to reject a licence is issued.

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

Section 26. A licensor may issue a licence to sell medical devices to a licence applicant when it appears that the licence applicant:

- (1) is the owner of the undertaking seeking to obtain a sales licence;
- (2) has the qualifications and does not have the disqualifications under section 16(2), (3), (4), (5), (6) and (7);
- (3) does not use a trade name which is identical or similar to a trade name of an establishment registrant or licensee whose establishment registration certificate or licence is suspended or where less than one year has lapsed since the revocation of such person's establishment registration certificate or licence;
- (4) is not a person whose licence is suspended under this Act;
- (5) has never had a licence revoked under this Act, except where a period of more than two years has lapsed since the revocation of the licence to the date of establishment registration application;
- (6) has a sales quality system under section 6(5);
- (7) has a sales controller in the case of a medical device under section 6(7).

In the case where the licence applicant is a juristic person, the manager or representative of the juristic person administering the operations must have the qualifications and not have the disqualifications under section 16(2), (3), (4), (5), (6) and (7) and must also not have the disqualifications under (4) and (5).

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 functions pertaining to disease prevention, diagnosis and treatment, or rehabilitation, and the Thai Red Cross Society;
- (2) the manufacture of a medical device only for sterilization in a medical centre under the law on medical centres;
- (3) the manufacture and sale of a medical device which has been manufactured by a medical and public health practitioner for a particular patient or animal;
- (4) the sale of a medical device, for which a medical centre or medical and public health practitioner has obtained a licence or specifications declaration receipt, for a particular patient or animal;

(5) the manufacture or import of medical devices in an amount necessary for personal use, use as a sample, exhibition or use in a study, research, analysis or quality and standard test;

(6) the import of a medical device which is an accessory or constituent for the manufacture of a medical device or the import of a medical device for a particular patient or animal;

(7) the manufacture of a medical device for use as an export sample;

(8) the manufacture or import of a medical device in accordance with the rules, procedures and conditions prescribed by Notification of the Minister upon the advice of the Board.

An exempted person under (1), (2), (3), (4), (5), (6) and (7) must comply with the rules, procedures and conditions prescribed by Notification of the Minister upon the advice of the Board.

The Secretary-General, by the approval of the Board, shall have the power to publish in the Government Gazette the prescription of rates, payment procedures, exemptions and the persons responsible for expenses incurred in the assessment of technical documentation, inspection of premises and the inspection or analysis of medical devices.

Section 28. An establishment registration certificate, licence or specifications declaration receipt shall also cover the employees and agents of the establishment registrant, licensee and specifications provider.

The action of an employee or agent covered under paragraph one shall also be deemed to be the action of the establishment registrant, licensee or specifications provider unless the establishment registrant, licensee or specifications provider can prove that acquiring knowledge or control of such an action is not possible.

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

A sales licence under section 24 shall remain valid until the 31st December of the year of licence issuance.

Section 30. In the case where an establishment registrant, licensee or specifications provider wishes to renew an establishment registration certificate, licence or specifications declaration receipt, an application shall be submitted before the expiry of the

establishment registration certificate, licence or specifications declaration receipt. After the submission of the application and payment of renewal fee therewith, the operations may continue until the renewal of establishment registration, licence or specifications declaration receipt is rejected by the licensor.

An application to renew an establishment registration certificate, licence or specifications declaration receipt and the grant of renewal shall be in accordance with the rules, procedures and conditions prescribed by Ministerial Regulation.

An establishment registrant, licensee or specifications provider whose establishment registration certificate, licence or specifications declaration receipt has expired for not more than one month may submit an application for renewal and dispensation, which shall indicate the reasons for not submitting renewal application within the time limit, along with the payment of the renewal fee. Nevertheless, the application for dispensation shall not constitute an excuse from liability under section 91.

An application for renewal of establishment registration certificate, licence or specifications declaration receipt may not be submitted after the lapse of more than one month as from the expiry date of the establishment registration certificate, licence or specifications declaration receipt.

In the case where the licensor rejects the renewal of an establishment registration certificate, licence or specifications declaration receipt, the renewal fee shall be returned to the renewal applicant in the proportion calculated on a monthly basis as from the day of rejection order to the expiry date of the establishment registration certificate, licence or specifications declaration receipt for which a renewal was requested, except in the case of an appeal against the order rejecting the renewal of the establishment registration certificate, licence or specifications declaration receipt and the Minister orders the provisional continuation of operations of the applicant for renewal of establishment registration certificate, licence or specifications declaration receipt, if the Minister dismisses the appeal, the proportion shall be calculated from the day of appeal dismissal order. A fraction of one month amounting to fifteen days shall be regarded as one month.

Section 31. In the case where an establishment registrant, licensee or a specifications provider wishes to change or amend an item in the establishment registration certificate, licence, specifications declaration receipt or other related items, an application shall be submitted to the licensor, except for a temporary relocation or change of premises due to a necessary and urgent cause which renders the submission of an application impracticable.

An application, authorization and temporary relocation or change of premises due to a necessary and urgent cause which renders the submission of an application

impracticable shall be in accordance with the rules, procedures and conditions prescribed by Ministerial Regulation.

Section 32. In the case where an establishment registration certificate, licence, specifications declaration receipt, assessment certificate under section 22 or certificate is lost, destroyed or damaged, the establishment registrant, licensee or specifications provider shall submit an application for a replacement within fifteen days as from the day of knowledge of the loss, destruction or damage.

An application for a replacement under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by Ministerial Regulation.

Section 33. The Secretary-General, by the approval of the Board, shall have the power to publish in the Government Gazette the designation of experts, expert entities, state agencies or other agencies, either domestic or overseas, as well as the rates and payment procedures for expenses arising from the assessment of technical documents, inspection of establishments, inspection or analysis of medical devices as part of the consideration on the following matters:

(1) considerations for the issuance of an establishment registration certificate, licence, specifications declaration receipt or certificate;

(2) considerations for the authorization of a change, amendment, modification of medical device or item in the establishment registration certificate, licence, specifications declaration receipt or other related items.

The applicant shall be responsible for expenses arising from proceedings under paragraph one.

Section 34. For the benefit of exports, a manufacturer may manufacture medical devices for export having the qualities, standards or other details stipulated by the purchaser provided that the rules, procedures and conditions prescribed by Notification of the Board as published in the Government Gazette are complied with.

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

Section 35. In the case where there is a foreign regulation or international agreement pertaining to the standard, efficiency, safety or foreign or international rules governing the import of medical devices for such country, the Food and Drug Administration may enter into an agreement with the foreign agency in relation to the recognition of inspections or certifications of medical devices or medical device establishments conducted

by such foreign agency in accordance with the rules and conditions prescribed by the Board, regardless of whether the foreign agency is a state or private agency.

In regard to the recognition of inspections or certifications conducted by a foreign agency under paragraph one, the Secretary-General, by the approval of the Board, shall have the power to publish the list of recognized foreign agencies and scope of inspections or certifications of medical devices or medical device establishments conducted by such foreign agencies.

CHAPTER III

CESSATION AND TRANSFER OF OPEATIONS

Section 36. Any establishment registrant under section 15, licensee under section 17 or section 24 or a specifications provider under section 19 who ceases an operation that is registered, licensed or specifications have been declared under this Act shall serve a notice of cessation in writing along with the establishment registration certificate, licence or specifications declaration receipt, as the case may be, to the licensor within thirty days as from the day of operation cessation. The establishment registration certificate, licence or specifications declaration receipt shall be deemed to expire as from the day of such operation cessation.

A notice of cessation under paragraph one shall specify the amount of medical devices remaining and the storage place of such medical devices in accordance with the rules, procedures and conditions prescribed by Notification of the Secretary-General as published in the Government Gazette.

In the case where an establishment registrant who ceases an operation for which an establishment has been registered fails to serve a notice of cessation of the operation that has been issued with a licence or specifications declaration receipt, the licence or specifications declaration receipt shall also be deemed to expire.

In the case where an establishment registrant under section 15, licensee under section 17 or section 24 or specifications provider under section 19 ceases an operation without serving a notice under paragraph one, the establishment registration certificate, licence or specifications declaration receipt shall be deemed to expire as from the day of operation cessation.

Section 37. Any establishment registrant under section 15, licensee under section 17 or section 24 or specifications provider under section 19 who does not renew an

establishment registration certificate, licence or specifications declaration receipt or the renewal of whose establishment registration certificate, licence or specifications declaration receipt is rejected by the licensor, as the case may be, must notify the licensor of the quantities of remaining medical devices and storage place of such medical devices within thirty days as from the expiry date or day of rejection of the renewal of establishment registration certificate, licence or specifications declaration receipt.

A notice under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by Notification of the Secretary-General as published in the Government Gazette.

Section 38. A licensed vendor of medical devices under section 24 who has served a notice of cessation, whose licence has expired or whose licence renewal is rejected by the licensor, as the case may be, may sell the remaining medical devices to other licensees or other persons deemed appropriate by the licensor within sixty days as from the day of operation cessation, licence expiry date or day of licence renewal rejection by the licensor, provided that the licensor may extend such time limit as deemed appropriate.

Upon the expiry of the prescribed period under paragraph one and there remain medical devices for which a vendor must obtain a licence under section 24, the licensee shall not sell such medical devices and the licensee shall notify the licensor of the quantities of medical devices and storage place of such medical devices within fifteen days as from the expiry date of the time limit under paragraph one.

A notice under paragraph two shall be in accordance with the rules, procedures and conditions prescribed by Notification of the Secretary-General as published in the Government Gazette.

Section 39. In the case where an establishment registrant, licensee or specifications provider dies and an heir or person authorized by the heir expresses to the licensor an intent to continue with the operations within ninety days as from the death of the establishment registrant, licensee or specifications provider, if the licensor is satisfied upon examination that such person has the qualifications under section 16 or section 26, as the case may be, the expresser of intent shall continue with the operations until the expiry of the establishment registration certificate, licence or specifications declaration receipt and the expresser of intent shall be deemed to be the establishment registrant, licensee or specifications provider under this Act as from death of the establishment registrant, licensee or specifications provider.

An expression of intent and examination shall be in accordance with the rules, procedures and conditions prescribed by Notification of the Board as published in the Government Gazette.

The provisions of section 38 paragraph two and paragraph three shall apply *mutatis mutandis* to the case where an heir in possession of such medical devices or an administrator or executor does not express an intent to continue with the operations under paragraph one.

CHAPTER IV
DUTIES OF ESTABLISHMENT REGISTRANTS, LICENSEES,
SPECIFICATIONS PROVIDERS AND VENDORS

Section 40. An establishment registrant, licensee or specifications provider shall not manufacture, import, sell or store medical devices in a place other than as specified in the establishment registration certificate, licence or specifications declaration receipt, except for:

- (1) temporary storage permitted by the licensor in accordance with rules, procedures and conditions prescribed by Notification of the Minister by the advice of the Board;
- (2) direct sale to a medical and public health practitioner;
- (3) assembly for the installation of medical devices in accordance with the rules, procedures and conditions prescribed by Notification of the Minister by the advice of the Board.

Section 41. An establishment registrant, licensee or specifications provider shall perform the following acts:

- (1) control and supervise operations pertaining to the manufacture, import and sale of medical devices to conform with the quality system for manufacture, import or sale of medical devices under section 6(5);
- (2) provide a controller of manufacture, import or sale of medical devices under section 6(7) and to supervise such person's total compliance with section 6(7);
- (3) keep records of manufacture, import or sale of medical devices to be made available for inspection by a competent official and reporting to the licensor in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(4) report abnormal functioning of a medical device or undesired result occurring to a consumer as well as report steps taken to remedy such results to the licensor, regardless of whether the result occurred in the country or outside of the country, in accordance with rules, procedures and conditions prescribed by Notification of the Minister;

(5) provide a signboard indicating the place of manufacture, place of import, place of sale or place of storage of medical devices to be displayed in a conspicuous location at such place as specified in the establishment registration certificate, licence or specifications declaration receipt, as the case may be, in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(6) provide a notice displaying the name and qualifications of the controller in the case of a medical device under section 6(7) to be displayed in a conspicuous location at the place of manufacture, place of import or place of sale in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(7) display the establishment registration certificate, licence or specifications declaration receipt in a conspicuous and noticeable location at the place specified in the establishment registration certificate, licence or specifications declaration receipt;

(8) provide technical documentation confirming that one's medical device meets the required quality, standard, efficiency and safety to be examined or submitted to an official upon request in accordance with the rules, procedures and conditions prescribed by the Secretary-General by a Notification published in the Government Gazette.

Section 42. A manufacturer, importer or vendor of a medical device under section 6(14) or an operator of a medical centre which uses such medical device shall provide for a register of patients using such medical device.

The provision of a register of patients using a medical device under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by a Notification of the Minister under section 6(14).

Section 43. A vendor of a medical device under section 6(9) or (10) shall sell such medical device only to a person having a prescription issued by a medical and public health practitioner or only to a medical centre or medical and public health practitioner.

A vendor under paragraph one shall comply with the rules, procedures and conditions prescribed by a Notification of the Minister under 6(9) or (10).

CHAPTER V
LABELING AND MEDICAL DEVICE DOCUMENTATION

Section 44. An establishment registrant, licensee or specifications provider who manufactures or imports medical devices shall provide for labels and medical device documentation which shall must not contain false or exaggerated messages.

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

A vendor of medical device shall ensure that there is a label or medical device documentation, as the case may be, provided by the establishment registrant, licensee or specifications provider under paragraph one.

Section 45. Subject to section 44, an establishment registrant, licensee or specifications provider who manufactures or imports a medical device under section 6(13) shall display the shelf life, warning, prohibited uses or cautions on the label of medical device documentation.

The display of shelf life, warning, prohibited uses or cautions on the label or medical device documentation shall be in accordance with the rules, procedures and conditions prescribed by a Notification of the Minister under section 6(13).

CHAPTER VI
CONTROL OF MEDICAL DEVICES

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

- (1) counterfeit medical device;
- (2) medical device not in conformity with standards;
- (3) deteriorated medical device;
- (4) medical device not safe for use;
- (5) medical device manufactured or imported not in conformity with a licence or declared specifications;
- (6) medical device pertaining to which a licence or specifications declaration receipt has been revoked under section 70.

Section 47. Counterfeit medical device means a medical device having the following characteristics:

- (1) medical device which is a forgery or imitation in whole or in part;
- (2) medical device which is misleading in regard to its name, constituent, quality, quantity, month and date of manufacture, name of manufacturer, place of manufacture, name of importer or quality certification mark or trademark;
- (3) medical device which is falsely represented as being licensed or whose specifications has been declared.

Section 48. Medical device which fails to meet standards means:

- (1) medical device having a quality or standard that is not in conformity a licence or declared specifications;
- (2) medical device having a standard that is not in conformity with section 6(4) or whose packaging standard is not in conformity with section 6(6), except for a medical device under licence for the manufacture of exports under section 34.

Section 49. Deteriorated medical device means a medical device that has degenerated into a medical device which fails to meet standards or a medical device whose displayed shelf life has expired.

Section 50. Medical device not safe for use means a medical device having the following characteristics:

- (1) single-use medical device which has already been used;
- (2) medical device manufactured or stored under unhygienic conditions;
- (3) medical device contaminated by a foreign matter or material which is likely to be hazardous to health;
- (4) medical device which consists of a degradable substance and may produce a toxin that is harmful to the user;
- (5) medical device which has unreliable benefits;
- (6) medical device designed or manufactured in such a way that may be harmful to a user;
- (7) medical device displaying a label or documentation which is not in accordance with section 44 or section 45 and may thereby cause harm to the user.

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

Section 52. Upon a Notification under section 6(16), a manufacturer, importer, vendor, possessor or person destroying or disintegrating a medical device shall comply with the rules and procedures prescribed in such Notification.

Section 53. Upon a Notification under section 6(17), an import or export of medical device must undergo an inspection by a competent official at the medical device checkpoint.

Section 54. For the benefit of safeguarding the health and safety of consumers, when there is a cause for suspicion that a medical device does not meet the required quality, standard or efficiency, is unsafe for use, is potentially harmful to health, or there is a change of standard, the Secretary-General shall have the power to order the manufacturer or importer of medical device to submit documents or evidence as proof of quality, standard or efficiency and safety.

During the proceedings under paragraph one, the Secretary-General shall have the power to order the temporary suspension of manufacture, import or sale until the quality, standard or efficiency and safety of the medical device has been proven.

Section 55. For the benefit of safeguarding the health and safety of consumers, when it appears that the quality or standard or efficiency of medical device is not in conformity with a licence or declared specifications, is unsafe for use, is potentially harmful to health, or there is a change of standard, the Secretary-General shall have the following powers:

(1) issue a written order to instruct a licensee or specifications provider to amend an item licensed or stipulated in the declared specifications;

(2) issue a written order to instruct a manufacturer, importer, vendor of a medical device, or person having possession thereof for use, to amend or modify the said manufactured, imported, sold or possessed medical device;

(3) issue a written order to instruct a manufacturer, importer or vendor of a medical device to refrain from manufacturing, importing or selling the medical device or perform other related acts as determined by the Board;

(4) promptly publish the result of an inspection or analysis of a medical device and publish a violation or noncompliance of (2) or (3) as public notice, and in the case where the Secretary-General deems appropriate, related persons shall also be notified;

(5) collect medical devices from a manufacturer, importer, vendor or possessor, or order a manufacturer, importer or vendor to recall the medical devices manufactured, imported or sold by oneself from the market within the time limit prescribed by the Secretary-General, and shall have the power to destroy or process a medical device as appropriate to the case if it is found that the medical device is a medical device under section 46 provided that the manufacturer, importer, vendor or possessor shall be responsible for expenses arising from the aforesaid proceedings.

CHAPTER VII ADVERTISEMENT

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

Section 57. Subject to section 56, the advertisement of a medical device must first be licensed by the licensor. A licence shall be valid for a period of not more than three years as from the date of issue.

A licence application, licensing and licence validity period under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the licensor provided that the licensor may also prescribe specific conditions of advertisement and restrictions on advertising media.

The provisions of section 33 shall apply *mutatis mutandis* to the consideration of advertisement licensing or the consideration of a change, amendment or modification of an item in the advertisement licence.

Section 58. In the case where an advertisement licence is lost, destroyed or damaged, the advertisement licensee shall submit an application for a replacement within fifteen days as from the day of knowledge of the loss, destruction or damage.

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

Section 59. A medical device advertisement must:

- (1) not be a false or exaggerated representation of the benefits, quality, quantity, standard, constituent or origin of the medical device;
- (2) not represent any person's endorsement or commendation of the medical device's benefits;
- (3) not offer a prize conditional upon the taking of chance by any means;
- (4) not represent benefits in regard to the prevention, treatment, relief or cure of a disease or symptom of a disease of which advertisement is prohibited under a Notification published by the Minister;
- (5) not contain a misleading statement on an essential substance in relation to the medical device.

Section 60. In the case where the licensor finds that an advertisement is in violation of section 57 or section 59, the licensor shall have the power to issue any of the following orders:

- (1) to make changes to the content or means of advertisement;
- (2) to prohibit the use of certain statements or means appearing in the advertisement;
- (3) to suspend the advertisement.

In an order under paragraph one, the licensor may also order the advertisement of correct information.

CHAPTER VIII COMPETENT OFFICIAL

Section 61. In the performance of duties, a competent official shall have the following powers:

- (1) enter a place of manufacture, import or sale and place of storage of a medical device during the working hours of such place in order to inspect or secure compliance with this Act;
- (2) take a reasonable quantity of medical device as a sample for inspection or analysis;
- (3) seize or attach a medical device, including any instrument, tool or object suspected of being in violation or likely to be connected to an offence, as well as the

container, packaging, label, medical device documentation and documents relating to such medical device;

(4) in the case where there is a cause for suspicion that an offence under this Act has been committed, the competent official may enter any place or vehicle to inspect or secure compliance with this Act;

(5) issue a summons for any person to testify or submit a document or evidence as a factor for consideration by a competent official.

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

A competent official identification card shall be in accordance with the form prescribed by Notification of the Minister.

Section 63. A licensee, specifications provider and person having duties related to the manufacture, import, sale or storage of medical device shall assist a competent official executing duties under section 61 and section 66 paragraph two.

Section 64. An object seized or attached under section 61(3) shall become the property of the Ministry of Public Health when it appears that:

(1) there does not appear to be an owner or no person represents oneself as the owner or possessor within ninety days as from the date of seizure or attachment;

(2) in the case where no legal action is taken and the owner or possessor does not file for a return within ninety days as from the day of receiving notice of the no-action order;

(3) in the case where legal action is taken and the state attorney gives a final order to not file a case or the court does not deliver a judgment to confiscate the object, and the owner or possessor does not file for a return within ninety days as from the day of knowledge of the final order to not file a case or the day of final judgment, as the case may be.

Section 65. In the case where an object seized or attached under section 61(3) is perishable or nearing the end of its stated shelf life, or its storage poses a risk of damage or storage costs exceeding the value of such object, the Food and Drug Administration may arrange for the market sale of such object before the case becomes final, or before such object becomes property of the Ministry of Public Health. The net proceeds, after deductions of expenses and all encumbrances, shall be seized in lieu of the object and deposited in a state bank.

Section 66. In the execution of this Act a competent official shall be an officer under the Penal Code.

Where there is reasonable cause, the Secretary-General may order a competent official to conduct a joint investigation with an investigation official in accordance with regulations prescribed by the Ministry of Public Health with the approval of the Royal Thai Police. In such a case, the competent official shall have the capacity of an investigation official under the Criminal Procedure Code.

CHAPTER IX

SUSPENSION AND REVOCATION OF ESTABLISHMENT REGISTRATION CERTIFICATE, LICENCE OR SPECIFICATIONS DECLARATION RECEIPT

Section 67. Where any establishment registrant, licensee or specifications provider violates or fails to comply with this Act, a Ministerial Regulation or Notification issued under this Act, the licensor, by the approval of the Board, shall have the power to suspend an establishment registration certificate, licence or specifications declaration receipt for a period not exceeding one hundred and twenty days for each suspension. However, in the case where an establishment registrant, licensee or specifications provider has been prosecuted for an offence under this Act, the licensor, by the approval of the Board, may suspend the establishment registration certificate, licence or specifications declaration receipt until a final judgment.

An establishment registrant, licensee or specifications provider whose establishment registration certificate, licence or specifications declaration receipt has been suspended shall not engage in the suspended operation.

Section 68. The licensor has the power to rescind the suspension of an establishment registration certificate, licence or specifications declaration receipt before the stipulated time if it appears that the establishment registrant, licensee or specifications provider has already complied with this Act, a Ministerial Regulation or Notification issued under this Act provided that the licensor shall report such rescission to the Board.

Section 69. The licensor, by the approval of the Board, has the power to revoke an establishment registration certificate, licence or specifications declaration receipt when it appears that:

(1) an establishment registrant lacks a qualification or has a disqualification, or fails to comply with section 16, as the case may be;

(2) a licensee lacks a qualification, has a disqualification or fails to comply with section 26, as the case may be;

(3) an establishment registrant, licensee or specifications provider is convicted by a final judgment of a violation of this Act;

(4) an establishment registrant, licensee or specifications provider violates an order to suspend an establishment registration certificate, licence or specifications declaration receipt.

Section 70. For the benefit of safeguarding the health and safety of consumers, the licensor, by the approval of the Board, has the power to revoke a licence or specifications declaration receipt if there subsequently appears any one of the following cases:

(1) a medical device is not in conformity with standards and cannot be rectified, a medical device unsafe for use or a counterfeit medical device;

(2) a licensee or specifications provider has altered the purpose of use or benefits of a medical device into a drug, psychotropic substance, narcotic drug, hazardous substance or cosmetic without licence;

(3) a medical device does not have the benefits stipulated in the licence or declared specifications as shown by reliable technical documentation.

Section 71. In the case where the licensor determines that a medical device which has been licensed or whose specifications have been declared has been altered into a drug, psychotropic substance, narcotic drug, hazardous substance or cosmetic, the licensee or specifications provider shall proceed in accordance with the rules, procedures, conditions and time periods prescribed by a Notification of the Secretary-General published in the Government Gazette.

In the case where no action is taken in accordance with paragraph one within the time period prescribed by the Secretary-General, the licence or specifications declaration receipt shall expire.

Section 72. An order to suspend or revoke an establishment registration certificate, licence or specifications declaration receipt shall be made as a written notice served on the establishment registrant, licensee or specifications provider. In the case where the establishment registrant, licensee or specifications provider is not found, or the establishment registrant, licensee or specifications provider does not accept service of such

order, the order shall be posted at an open and conspicuous location at the place specified in the establishment registration certificate, licence or specifications declaration receipt and the establishment registrant, licensee or specifications provider shall be deemed to have knowledge of the order as from the day of order posting.

An order to suspend or revoke an establishment registration certificate, licence or specifications declaration receipt may also be advertised in a newspaper or by any other means.

Section 73. Subject to section 46, a person whose establishment registration certificate, licence or specifications declaration receipt has been revoked may sell the remaining medical devices to an establishment registrant, licensee or specifications provider, or a person deemed appropriate by the licensor, within one hundred and eighty days as from the day of acquiring knowledge of the order to revoke the establishment registration certificate, licence or specifications declaration receipt, or the day of acquiring knowledge of the Minister's decision, except where an extension is granted by the licensor.

CHAPTER X APPEALS

Section 74. In the case where the licensor does not issue an establishment registration certificate, licence or specifications declaration receipt, or does not issue an assessment certificate under section 22, or does not renew an establishment registration certificate, licence or specifications declaration receipt, the applicant has the right to appeal against such order in writing to the Minister within thirty days as from the date of receipt of written notice of the non-issuance of establishment registration certificate, licence or specifications declaration receipt, or non-issuance of assessment certificate under section 22, or non-renewal of establishment registration certificate, licence or specifications declaration receipt, as the case may be.

A decision of the Minister shall be final.

In the case where the licensor does not grant a renewal of an establishment registration certificate, licence or specifications declaration receipt, before a decision of the Minister under paragraph two on the appeal, the Minister has the power to authorize the provisional continuation of operations upon an application by the appellant.

Section 75. An establishment registrant, licensee or specifications provider whose establishment registration certificate, licence or specifications declaration receipt is suspended or revoked has the right to submit an appeal in writing to the Minister within thirty days as from the day of acquiring knowledge of the order.

An appeal under paragraph one does not stay the suspension or revocation of an establishment registration certificate, licence or specifications declaration receipt.

A decision of the Minister shall be final.

Section 76. In the deliberation of an appeal under section 74 and section 75, the Minister shall complete the appeal deliberation within one hundred and twenty days as from the date of receipt of the appeal. If, due to necessity, a deliberation cannot be completed within such time period, a written notice shall be sent to the appellant before the expiration of the time period and the time period for deliberation of the appeal may be extended for not more than one hundred and twenty days as from the expiration of such time period.

CHAPTER XI CIVIL LIABILITY

Section 77. A manufacturer, importer or vendor of medical device must be responsible for injury arising from the use of medical device unless it can be proven that the injury was caused by force majeure, or was not caused by a defect in the medical device, or was caused by the fault of the injured person.

Section 78. A person who uses or enables the use of medical device on another person thereby causing death or injury to the body or health must be responsible for the such person's injury arising from the use of such medical device unless it can be proven that precautions have been taken in conformity with technical standards, or that the injury was caused by force majeure, or was caused by the fault of the injured person.

The provisions of paragraph one shall apply to psychological injury arising as a consequence of injury to the injured person's body or health.

Section 79. The limitation period of a claim for damages under this Chapter arising from a medical device or use of a medical device shall expire upon the lapse of three years as from the day the injured person acquired knowledge of the injury and

knowledge of the person liable for damages, provided that such period shall not be more than ten years as from the day the injury occurred due to the medical device or use of the medical device.

Section 80. A liable person under section 77 or section 78 who has paid damages to the injured person shall have the right to seek indemnification from a person who has contributed to the cause of injury. The right to seek indemnification shall be exercised within three years as from the day of payment of damages. The person seeking indemnification, however, may only seek indemnification for the proportion exceeding his/her own liability.

CHAPTER XII PENALTIES

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

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

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

Section 84. Any person who fails to comply with an order of the Board or subcommittee under section 13 shall be liable to imprisonment for a term not exceeding one month or a fine not exceeding ten thousand baht, or both.

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

Section 86. Any person who manufactures or imports a medical device under section 6(1) without 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 a fine not exceeding three hundred thousand baht, or both.

Any licensee for the manufacture or import of medical device under section 6(1) who fails to comply with section 17 paragraph three or section 18 paragraph two shall be liable to a fine not exceeding one hundred and fifty thousand baht.

Section 87. Any person who manufactures or imports a medical device under section 6(2) without a specifications declaration receipt 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 a fine not exceeding one hundred thousand baht, or both.

Any specifications provider 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, vendor or possessor of a medical device 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 a fine not exceeding one hundred thousand baht, or both.

Section 89. Any person who sells a medical device without a licence under section 24 paragraph one or section 25 paragraph one, as the case may be, shall be liable to imprisonment for a term not exceeding three years or a fine not exceeding three hundred thousand baht, or both.

Any licensee for the sale of medical device who fails to comply with section 24 paragraph three or section 25 paragraph two shall be liable to a fine not exceeding one hundred and fifty thousand baht.

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

Section 91. Any establishment registrant, licensee or specifications provider who imports or sells medical device subsequent to the expiration of an establishment

registration certification, licence or specifications declaration receipt, but has submitted an application for renewal of the establishment registration certificate, licence or specifications declaration receipt within the time period prescribed under section 30 paragraph three, shall be liable to a daily fine of one thousand baht throughout the period of non-submission of application to renew the establishment registration certificate, licence or specifications declaration receipt.

Section 92. Any establishment registrant, licensee or specifications provider who fails to comply with section 31 shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Section 93. Any establishment registrant, licensee or specifications provider who fails to comply with section 32 paragraph one shall be liable to a fine not exceeding ten thousand baht.

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

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

Section 95. Any establishment registrant under section 15, licensee under section 17 or section 24, or specifications provider under section 19 who ceases an operation without complying with section 26 paragraph one shall be liable to a fine not exceeding ten thousand baht.

Section 96. Any establishment registrant under section 15, licensee under section 17 or section 24, or specifications provider under section 19 whose establishment registration certificate, licence or specifications declaration receipt has expired, or where the licensor has rejected the renewal of the establishment registration certificate, licence or specifications declaration receipt, who fails to serve a notice under section 37 paragraph one shall be liable to a fine not exceeding ten thousand baht.

Section 97. Any licensed vendor of medical device under section 24 who has served a notice of operations cessation, whose licence has expired, or where the

licensor has rejected the renewal of the licence, who fails to serve a notice under section 38 paragraph two shall be liable to a fine not exceeding ten thousand baht.

Any licensed vendor of medical device under section 24 who has served a notice of operations cessation, whose licence has expired, or where the licensor has rejected the renewal of the licence, who sells a medical device after the expiration of the period under section 36 paragraph one shall be liable to imprisonment for a term not exceeding two years or a fine not exceeding two hundred thousand baht, or both.

Section 98. Any heir in possession of a medical device or an administrator or executor under section 39 who fails to serve a notice under section 38 paragraph two shall be liable to a fine not exceeding ten thousand baht.

Section 99. Any establishment registrant, licensee or specifications provider who violates section 40 shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Section 100. Any establishment registrant, licensee or specifications provider who fails to comply with section 41(1) or (2) shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Any establishment registrant, licensee or specifications provider who fails to comply with section 41(3), (4) or (8) shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding fifty thousand baht, or both.

Any establishment registrant, licensee or specifications provider who prepares a false record or report under section 41(3), prepares a false report under section 41(4) or provides false technical documentation under section 41(8) shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Any establishment registrant, licensee or specifications provider who fails to comply with section 41(5), (6) or (7) shall be liable to a fine not exceeding one hundred thousand baht.

Section 101. Any manufacturer, importer or vendor of a medical device under section 6(14), or operator of a medical centre which utilizes such medical device, who fails to comply with section 42 paragraph one shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or 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 vendor of a medical device 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 a fine not exceeding one hundred thousand baht, or 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. Any establishment registrant, licensee or specifications provider who manufactures or imports a medical device without complying with section 44 paragraph one shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

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 vendor of medical device who fails to comply with section 44 paragraph three shall be liable to a fine not exceeding fifty thousand baht.

Section 104. Any establishment registrant, licensee or specifications provider manufacturing or importing a medical device under section 6(13) who fails to comply with section 45 paragraph one shall be liable to a term of imprisonment not exceeding one year or a fine not exceeding one hundred thousand baht, or 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.

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

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

Section 106. Any person who manufactures or imports a medical device not in conformity with standards in violation of section 46(2) shall be liable to imprisonment for a term not exceeding three years or a fine not exceeding three hundred thousand baht, or both.

Any person who sells a medical device not in conformity with standards in violation of section 46(2) shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

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

Any person who sells a deteriorated medical device in violation of section 46(3) shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

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

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

Section 109. Any person who manufactures or imports a medical device which is not in accordance with a licence or declared specifications in violation of section 46(5) shall be liable to a fine not exceeding two hundred thousand baht.

Any person who sells a medical device which has been manufactured or imported not in accordance with a licence or declared specifications in violation of section 46(5) shall be liable to a fine not exceeding one hundred thousand baht.

Section 110. Any person who manufactures or imports a medical device for which a licence or specifications declaration receipt has been revoked in violation of section 46(6) shall be liable to imprisonment for a term not exceeding five years or a fine not exceeding five hundred thousand baht, or both.

Any person who sells a medical device for which a licence or specifications declaration receipt has been revoked in violation of section 46(6) shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Section 111. Any manufacturer, importer, research sponsor or researcher of a medical device 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, possessor or destroyer or disintegrator of medical device who fails to comply with section 52 shall be liable to a fine not exceeding five hundred thousand baht.

Section 113. Any importer or exporter of medical device who fails to comply with section 53 shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Section 114. Any manufacturer, importer or vendor of medical device 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 a fine not exceeding one hundred thousand baht, or both.

Any licensee or specifications provider 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 a fine not exceeding one hundred thousand baht, or both.

Section 115. Any person who advertises a medical device under section 6(11) or a medical device under section 46(1), (2), (3), (4) or (6) in violation of section 56 shall be liable to imprisonment for a term not exceeding two years or a fine not exceeding two hundred thousand baht, or both.

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

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

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

Section 118. Any person who fails to comply with an order of a licensor under section 60 shall be liable to imprisonment for a term not exceeding two years or a fine not exceeding two hundred thousand baht, or both, and a daily fine of one thousand baht until compliance.

Section 119. Any person who resists or obstructs the performance of duties by a competent official under section 61 shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding twenty thousand baht, or both.

A person who does not appear to testify or does not submit necessary documents or evidence under section 61(5) without reasonable excuse shall be liable to a fine not exceeding ten thousand baht.

Section 120. Any licensee, specifications provider or person having duties related to the manufacture, import, sale or storage of medical device who does not assist a competent official under section 64 shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding ten thousand baht, or both.

Section 121. Any establishment registrant, licensee or specifications provider who violates section 67 paragraph two shall be liable to imprisonment for a term not exceeding three years or a fine not exceeding three hundred thousand baht, or both.

Section 122. In the case where an offender liable to a penalty under this Act is a juristic person, the managing director, manager or person responsible for the operation of the juristic person shall also be liable to the penalty provided for such an offence unless it can be proved that he/she did not connive at or consented to the commission of the offence by such juristic person.

Section 123. In regard to an offence under this Act which is punishable only by a fine or a term of imprisonment not exceeding six months, the Secretary-General or a person designated by the Secretary-General shall have the power to settle the case in accordance with the rules prescribed by the Board. Upon the alleged person's payment of a fine in the amount required for settlement within thirty days as from the settlement offer, the case shall be deemed as settled under the Criminal Procedure Code.

In the case where an investigation official finds a person who commits an offence under paragraph one and such person consents to settlement of the case, the investigation official shall transmit the matter to the Secretary-General or person designated by the Secretary-General within seven days as from such person's expression of consent to settlement.

TRANSITORY PROVISIONS

Section 124. A manufacturer or importer of medical device under the Medical Device Act B.E. 2531 (1988) operating prior to the effective date of this Act shall submit an application for establishment registration pursuant to the provisions of this Act within ninety days as from the effective date of this Act, and such operations may be continued until a notice of refusal to register an establishment is received from the licensor, provided that the licensor shall complete deliberations within one hundred and twenty days as from the application receipt date, otherwise the applicant shall be deemed as an establishment registrant under this Act upon the expiration of such time limit.

Upon taking proceedings under paragraph one, the manufacturing or import licence issued under the Medical Device Act B.E. 2531 (1988) prior to the effective date of this Act shall continue to be valid until its expiration date.

Section 125. A licence to sell medical device issued under the Medical Device Act B.E. 2531 (1988) prior to the effective date of this Act shall continue to be valid until its expiration date.

Section 126. A specifications declaration under the Medical Device Act B.E. 2531 (1988) made prior to the effective date of this Act shall continue to be valid for an additional period of two years as from the effective date of this Act, except where a medical device whose specifications have been declared has been prescribed as a medical device requiring a licence under section 6(1), in which case the specifications provider shall proceed under section 18.

Section 127. An advertisement of medical device which has been approved by the Secretary-General of the Food and Drug Administration prior to the effective date of this Act shall continue to be valid for the period prescribed by the Secretary-General of the Food and Drug Administration.

Section 128. Licence applications and specifications declarations submitted or served under the Medical Device Act B.E. 2531 (1988) and are pending deliberations shall be deemed as licence applications and specifications declarations under this Act *mutatis mutandis*. An amendment to a licence application or specifications declaration application shall be in accordance with this Act.

Section 129. A Ministerial Regulation or Notification issued under the Medical Device Act B.E. 2531 (1988) applicable prior to the effective date of this Act shall continue to apply to the extent that it is neither contrary to nor inconsistent with this Act until the issuance of a Ministerial Regulation or Notification under this Act.

The issuance of a Ministerial Regulation or Notification under paragraph one shall be completed within two years as from the effective date of this Act. If the deadline cannot be met, the Minister shall report the reasons for such inability to the Council of Ministers.

Countersigned by:

General Surayud Chulanont

Prime Minister

SCHEDULE OF FEES

(1) Establishment registration certificate	per issue	1,000 baht
(2) Medical device manufacturing licence	per issue	100,000 baht
(3) Medical device import licence	per issue	200,000 baht
(4) Medical device sale licence	per issue	10,000 baht
(5) Medical device advertising licence	per issue	10,000 baht
(6) Medical device manufacturing specifications declaration receipt	per issue	50,000 baht
(7) Medical device import specifications declaration receipt	per issue	100,000 baht
(8) Certificate	per issue	2,000 baht
(9) Medical device assessment certificate pursuant to section 22	per issue	2,000 baht
(10) Replacement establishment registration certificate; replacement licence; replacement specifications declaration receipt; replacement medical device assessment certificate pursuant to section 22; and replacement certificate	per issue	500 baht
(11) Establishment registration application	per issue	100 baht
(12) Licence application	per issue	1,000 baht
(13) Specifications declaration application	per issue	500 baht
(14) Application for relocation or change of place of manufacture, import, sale or storage of medical device	per issue	1,000 baht
(15) Application to amend an item in an establishment registration certificate	per issue	100 baht
(16) Application to amend an item in a licence or other licensed items	per issue	1,000 baht
(17) Application to amend an item in a specifications declaration receipt or other items in the specifications declaration	per issue	500 baht
(18) Renewal of an establishment registration certificate shall be equal to the fee applicable to each issue of the pertinent type of establishment registration certificate		
(19) Renewal of a licence shall be equal to the fee applicable to each issue of the pertinent		

type of licence

(20) Renewal of a specifications declaration receipt shall be equal to the fee applicable to each issue of the pertinent type of specifications declaration receipt

(21) Other applications per issue 1,000 baht

In the issuance of a Ministerial Regulation to prescribe fees, different fee rates may be prescribed after taking into account the category, group, type of medical device, size and operation of the operator and type of amendment.

Remarks:- The reasons for promulgating this Act are as follows. Whereas the Medical Device Act B.E. 2531 (1988) has been in force for a considerable period, certain provisions are inappropriate under current circumstances where there are rapid developments in technology and medical innovations. These developments have resulted in changes and expansions in the trade and industries related to medical devices. It is expedient to revise the definitions, provisions relating to the powers of the Minister to issue Notifications, composition of the Board, licence application and licensing, cessation and transfer of operations, duties of the licensee, specifications provider and vendor, labeling and medical device documentation, control of medical devices, advertisement, powers and duties of the competent official, suspension and revocation of establishment registration certificate, licence and specifications declaration receipt, and appeals, as well as to add provisions pertaining to the registration of establishments, medical device assessments, civil liabilities, including revisions of penalties and fees for greater suitability. It is therefore necessary to enact this Act.