(Unofficial Translation)

Medical Device Act (No. 2)

B.E. 2562(2019)

HIS MAJSTY KING MAHA VAJIRALONGKORN BODINDRADEBAYAVARANGKUN

Enacted on the 26th Day of April B.E. 2562;

Being the 4th Year of the Present Reign.

His Majesty King Maha Vajiralongkorn Bodindradebayavarangkun is graciously pleased to proclaim that:

Whereas it is expedient to amend the law on medical device;

This Act contains certain provisions in relation to the restriction of rights and liberties of a person, in respect of which section 26 in conjunction with section 37 and section 40 of the Constitution of the Kingdom of Thailand so permit by virtue of law;

The rationale for restricting the rights and liberties of a person under this Act is to ensure that Thailand's medical device control measures are consistent with the ASEAN Agreement on Medical Device Directive and can better respond to the changes within medical device trading business and industry as well as to provide the general public with safety from using high quality medical devices that meet international standards; in this regard, the enactment of this Act is consistent with the conditions prescribed in section 26 of the Constitution of the Kingdom of Thailand;

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 shall be called the "Medical Device Act (No. 2) B.E. 2562 (2019)"

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Section 3 The definition of the term "Medical Device" under section 4 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following definition:

““Medical Device” means

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

(a) diagnosis, prevention, monitoring, treatment, relief or cure of disease;

(b) diagnosis, monitoring, treatment, relief or cure of injury;

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

(d) life support or aid;

(e) contraception or promotion of fertility;

(f) assistance or compensation for a disability or handicap;

(g) generation of data from the examination of specimen extracted for medical or diagnostic purposes;

(h) disinfection or sterilization of medical device.

(2) an accessory to be used together with the medical device under (1); or

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

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.”

Section 4 The following definition of the term “Accessory” shall be inserted between the definitions of the terms “Medical Device” and “Manufacturer” under section 4 of the Medical Device Act B.E. 2551:

““Accessory” means an article, apparatus or product specifically intended by manufacturer or product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose.”

Section 5 The following definition of the term “Listing person” shall be inserted between the definitions of the terms “Specification provider” and “Establishment registrant” under section 4 of the Medical Device Act B.E. 2551:

""Listing person" means the person to whom the listing receipt under this Act is granted; and in case where the listing person is a juristic person, it shall includes the person(s) who is(are) authorized by the juristic person to operate the business."

Section 6 The provisions under (1) of section 6 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(1) medical device grouping or medical device classified by its hazardous risk to health, body or life of human beings or animals or its impacts on the public health, as well as the rules, procedures and conditions for the manufacture or import of such medical device so as to provide measures to control the following medical device groupings or medical devices:

(a) medical device grouping or medical device which a manufacturer or importer is required to have a licence to manufacture or import;

(b) medical device grouping or medical device which a manufacturer or importer is required to declare its specifications; and

(c) medical device grouping or medical device which a manufacturer or importer is required to list it."

Section 7 The provisions under (2) of section 6 of the Medical Device Act B.E. 2551 shall be repealed.

Section 8 The provisions under (3) of section 6 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(3) medical device grouping or medical device which a vendor is required to have a licence, as well as the rules, procedures and conditions for selling medical devices;"

Section 9 The provisions under (17) of section 6 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(17) designation of a place within the Kingdom as a checkpoint for the inspection of imported medical device;"

Section 10 The following provisions shall be added as (19), (20), (21) and (22) of section 6 of the Medical Device Act B.E. 2551:

"(19) maximum expense rates and fees shall be collected from an applicant under part one "Medical Device Licensing Procedures" of Chapter II "Application for and Granting of Establishment Registration Certificate, Licence, Specifications Declaration Receipt and Listing Receipt";

(20) maximum registration rates and registration fees shall be collected from experts, expert entities, state agencies or private agencies, either domestic or overseas;

(21) the expenses arising from the assessment of a technical documentation, analysis, inspection of premises or inspection of medical device during the course of monitoring, inspecting or observing medical device which is performed in order to control the manufacture, import and sale of medical device;

(22) the rules, procedures and conditions for receipt and payment of any expenses arising from the medical device licensing procedures or from the monitoring, inspecting or surveillance of medical devices which is performed to control the manufacture, import and sale of medical devices."

Section 11 The following provisions shall be added as paragraph three of section 7 of the Medical Device Act B.E. 2551:

"The appointment of Qualified Member shall be in accordance with the rules, procedures and conditions prescribed by Notification of the Minister."

Section 12 The provisions under section 11 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"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 Notification under this Act;

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

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

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

Section 13 The following provisions shall be added as paragraph two of section 12 of the Medical Device Act B.E. 2551:

"The Subcommittee appointed to perform tasks under Part I Medical Device Licensing Procedures of Chapter II Application for and Granting of Establishment Registration Certificate, Licence, Specification Declaration Receipt and Listing Receipt shall comprise representatives from the Office of the Public Sector Development Commission, the association or foundation with objective in relation to the consumer protection and the association or entrepreneur whose objective is to manufacture, import or sale medical devices. In this regard, the rules for appointment of qualified members under section 7 paragraph three, shall apply to the appointment of this subcommittee mutatis mutandis. However, the subcommittee to consider registration fees and expenses shall also include representative (s) from the Ministry of Finance as member(s)."

Section 14 The title of Chapter II, "Application for and Granting of Establishment Registration Certificate, Licence and Specification Declaration Receipt" of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following title:

"CHAPTER II

APPLICATION FOR AND GRANTING OF ESTABLISHMENT REGISTRATION CERTIFICATE, LICENCE, SPECIFICATION DECLARATION RECEIPT AND LISTING RECEIPT"

Section 15 The provisions under section 17, section 18, section 19 and section 20 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

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

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

Section 18 An establishment registrant who manufactures or imports a medical device stated in a Notification under section 6(1) (a) on the effective date of such Notification and wishes to continue

with the operations must submit a licence application within the period prescribe by 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(1) (b) or (c) shall submit an application to declare specifications or listing, as the case may be, and the manufacture or import of the medical device may be carried out only upon issuance of a specifications declaration receipt or a listing receipt by the licensor.

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

A specification provider or a listing person under paragraph one must 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) (b) or (c).

Section 20 An establishment registrant who manufactures or imports a medical device stated in a Notification under section 6(1) (b) or (c) on the effective date of such Notification and wishes to continue with the operations must submit a licence application within the period prescribe by 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 19 paragraph two and paragraph three shall apply mutatis mutandis."

Section 16 The provisions under section 25 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"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 with the operations must submit a licence application within the period prescribe by 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 24 paragraph two, paragraph three and paragraph four shall apply mutatis mutandis."

Section 17 The provisions under (4) of section 27 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(4) the sale of a medical device for which a medical center or medical and public health practitioner has obtained a licence, specifications declaration receipt or listing receipt, for a particular patient or animal;"

Section 18 The provisions under (6) of section 27 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(6) the import of a medical device for a particular patients or animals;"

Section 19 The provisions under section 28 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

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

Section 20 The following provisions shall be added as paragraph three of section 29 of the Medical Device Act B.E. 2551:

"A listing receipt under Section 19 shall remain valid until the fifth year from the date of issuance of the listing receipt."

Section 21 The following provisions shall be added as section 30/1 of the Medical Device Act B.E. 2551:

"Section 30/1 In the case where a listing person wishes to renew a listing receipt, an application shall be submitted before the expiry of the listing receipt. After the submission of the application and payment of renewal fee therewith, the operations may continue until the renewal of listing receipt is rejected by the licensor.

An application to renew a listing receipt and the grant of renewal shall be in accordance with the rules, procedures and conditions prescribed by the Licensor.

A listing person whose listing 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 listing receipt may not be submitted after the lapse of more than one month as from the expiry date of the listing receipt.

In the case where the licensor rejects the renewal of listing 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 listing receipt for which a renewal was requested, except in the case of an appeal against the order rejecting the renewal of the listing receipt and the Minister orders the provisional continuation of operations of the applicant for renewal of listing receipt, if the Minister dismisses the appeal, the proportion shall be calculated from the day of appeal dismissed order. A fraction of one month amounting to fifteen days shall be regarded as one month."

Section 22 The following provisions shall be added as section 31/1 of the Medical Device Act B.E. 2551:

"Section 31/1 In the case where particulars shown in the listing receipt have been changed, the listing person shall be submitted the changes in such particulars to the licensor.

The notification of changes under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the licensor."

Section 23 Section 33 of the Medical Device Act B.E. 2551 shall be repealed.

Section 24 The following provisions shall be added as part I Medical Device Licensing Processes, sections 35/1, 35/2, 35/3, 35/4, 35/5, 35/6 and 35/7 of chapter II Application for and Granting of Establishment Registration Certificate, License, Specifications Declaration Receipt and Listing Receipt of the Medical Device Act B.E. 2551:

"PART I

MEDICAL DEVICE LICENSING PROCESSES

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Section 35/1 The medical device licensing processes in this part shall mean an act of considering applications, verifying documents, assessment of technical documents, analysing, inspection of premises or other inspections in order to grant or issue any certificate, registration document, license, specifications declaration receipt, listing receipt or certificate of assessment as well as any other consideration relating to medical devices.

The medical device licensing processes under paragraph one shall also include any action concerning the promotion of domestic medical device manufacture.

Section 35/2 In carrying out the medical device licensing processes, in addition to the competent officers of the Food and Drug Administration and the Ministry of Public Health who have been assigned to perform relevant tasks on behalf of the Food and Drug Administration, relevant experts, expert entities, state agencies or private agencies, either domestic or overseas, shall be in charge of assessment of technical documents, analyzing, inspection of premises or other inspections in order to ensure that the medical device licensing processes are implemented conveniently and effectively, and this shall apply to the medical device licensing processes performed within either central or provincial regions. Provided, however, that the aforesaid persons, entities or agencies shall be registered by the Food and Drug Administration.

The rules, procedures and conditions for medical devices licensing processes under paragraph one shall be in accordance with those prescribed by the Secretary General with the approval of the Board as published in the Government Gazette.

The fees and expenses to be collected from the applicant under the medical device licensing processes under paragraph one shall be in accordance with the rates prescribed by Notification of the Minister with the advice of the Board. In this regard, the fees and expenses to be collected shall not exceed the maximum expense rates under section 35/4(2) whereby either a whole or part of the expenses may be exempted.

Section 35/3 The Secretary-General, by the approval of the Board shall have the power to publish in the Government Gazette the rules, procedures and conditions for recruiting experts, expert entities, state agencies or private agencies, either domestic or overseas under section 35/2.

A notification under paragraph one shall contain information concerning qualifications, standards and job descriptions of the experts, expert entities, state agencies or private agencies, either domestic or overseas. In the case where a reason and necessary, either all or part of the rules, procedures and conditions for recruiting the aforesaid persons, entities or agencies may be exempted.

The registration fees to be collected from the experts, expert entities, state agencies or private agencies, either domestic or overseas, shall be in accordance with the rates prescribed by Notification of the Minister with the advice of the Board. In this regard, the registration fees to be collected shall not exceed the maximum registration fee rates under section 35/4(1) whereby either a whole or part of the registration fees may be exempted.

Section 35/4 The Minister, by the advice of the Board, shall have the power to prescribe the following by Notification:

(1) maximum registration fee rates to be collected from the experts, expert entities, state agencies or private agencies, either domestic or overseas;

(2) maximum expense rates to be collected from the applicant under the medical device licensing processes.

The maximum registration fee rates and the maximum expense rates under (1) and (2) shall take effect upon the approval of the Cabinet.

Section 35/5 The fees and expenses collected under section 35/2 paragraph three and section 35/6 paragraph three, as well as the registration fees collected under section 35/3 paragraph three shall be vested in the Food and Drug Administration or the agencies assigned by the Food and Drug Administration to perform this task on its behalf, as the case may be, without being required to remit to the Ministry of Finance as the government revenue. These fees and expenses may be spent for the following purposes:

(1) to be remunerations for any persons, entities or agencies under Section 35/2;

(2) to be operating expenses of a plan or project which has public benefit and aims for consumer protection in relation to medical devices;

(3) to be expenses for enhancing the potentials of relevant agencies and competent officers in order to develop the working system and to increase the efficiency of the medical device licensing processes;

(4) to be expenses for other tasks which are relevant and necessary for improving efficiency of the medical device licensing processes as prescribed by Notification of the Minister.

Section 35/6 In monitoring, inspecting or surveillance a medical device has obtained a license, specifications declaration receipt, listing receipt or certificate of assessment, as the case may be, in order to control the manufacture, importation and sale thereof, when there is a cause for suspicion that a medical device does not meet the required standard or is unsafe for use, the provisions in section 35/2 paragraph one and paragraph two shall apply mutatis mutandis.

The expenses for assessment of technical document, analysis, inspection of the premises, or inspection of the medical device under the paragraph one shall be paid by the applicant, establishment registrant, licensee, specifications provider, listing person, manufacturer, importer or vendor of the medical device, as the case may be.

The expenses under paragraph two shall be in accordance with the rate prescribed by Notification of the Minister with the advice of the Board. Provided, however, that the expenses to be collected shall not exceed the maximum expense rates under section 35/4(2), whereby either a whole or a part of the expenses may be exempted.

Section 35/7 The receiving under section 35/2 paragraph three, section 35/3 paragraph three and section 35/6 paragraph three as well as the payment under section 35/5 shall be made in accordance with the rules, procedures and conditions prescribed by Notification of the Minister with the advice of the Board and the approval of the Ministry of Finance."

Section 25 The provisions under section 36 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

A notice of cessation of the licensee or specifications provider under paragraph one shall specify the amount of the medical device 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 fail to serve a notice of cessation of the operation that has been issued with a licence, specifications declaration receipt or listing receipt, the licence, specifications declaration receipt or listing receipt shall also be deemed to expire.

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

Section 26 The provisions under paragraph one of section 39 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

Section 27 The title of chapter 4, "Duties of Establishment Registrants, Licensees, Specifications Providers and Vendors" of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following title:

"CHAPTER IV

DUTIES OF ESTABLISHMENT REGISTRANTS, LICENSEES, SPECIFICATIONS PROVIDERS, LISTING PERSON AND VENDORS"

Section 28 The provisions under section 40 and section 41 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 40 An establishment registrant, licensee, specifications provider or listing person shall not manufacture, import, sell or store medical devices in a place other than as specified in the establishment registration certificate, license, specifications declaration receipt or listing 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, specifications provider or listing person shall perform the following acts:

(1) control and supervise operations pertaining to manufacture, import or sale of medical devices to conform with the quality system for manufacture, import or sale of medical device 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 device defects or adverse events occurring to a consumer as well as report field safety corrective actions to the licensor, regardless of whether the defects or events occurred in the country or outside of the country, in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(5) provide a communication channel for receiving complaints, keep records of complaint and establish a complaint handling system relating to the manufacture, import or sale of medical devices, as for examination by an official in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(6) 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, specifications declaration receipt or listing receipt, as the case may be, in accordance with the rules, procedures and conditions prescribed by Notification of the Minister;

(7) provide a notice displaying the name and qualifications of the controller in case of a medical devices 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;

(8) display the establishment registration certificate or the license to sale medical devices in a conspicuous and noticeable location at the place specified in the establishment registration certificate or licence to sale;

(9) provide technical documentation confirming that one's medical device meet 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 29 The provisions under section 44 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 44 An establishment registrant, licensee, specifications provider or listing person 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 devices shall ensure that there is a label or medical device documentation, as the case may be, provided by the establishment registrant, licensee, specifications provider or listing person under paragraph one."

Section 30 The provisions under paragraph one of section 45 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

Section 31 The provisions under (5) and (6) of Section 46 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(5) medical device manufactured or imported not in conformity with a licence, declared specification or listed;

(6) medical device pertaining to which a license or specification declaration receipt has been revoked under Section 70 or which a listing receipt has been terminated under Section 70/1"

Section 32 The following provisions shall be added as section 46/1 of the Medical Device Act B.E. 2551:

"Section 46/1 No person shall sell a medical device which is not obtained a licence, specifications declaration receipt or listing receipt."

Section 33 The provisions under (3) of section 47 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(3) medical device which is falsely represented as being licensed, whose specifications has been declared or listed;"

Section 34 The provisions under (1) of section 48 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"(1) medical device having a quality or standard that is not in conformity a licence, declared specifications or listed;"

Section 35 The provisions under section 53 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

Section 36 The provisions under section 55 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"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 not

license, specifications declaration or listing, is unsafe for use, is potentially harmful to health or there is a change of standard, the Secretary General shall have following powers:

(1) issue a written order to instruct a licensee, specification provider and listing person to amend an item licensed, or stipulated in the declared specifications or listed;

(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, 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 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."

Section 37 The following provisions shall be added as paragraph four of section 57 of the Medical Device Act B.E. 2551:

"The Minister, by the advice of the Board shall have the power to specify a medical device that can be advertised directly to the medical and public health practitioners and to prescribe the rules, procedures and conditions for the advertisement exempted from requiring permission."

Section 38 The provisions under section 63 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 63 A licensee, specifications provider, listing person 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 39 The title of Chapter IX, "Suspension and Revocation of the Establishment Registration Certificate, License or Specification Declaration Receipt" of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following title:

"CHAPTER IX

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

Section 40 The following provisions shall be added as Section 70/1 of the Medical Device Act B.E. 2551:

"Section 70/1 For the purpose of protecting the consumers' health and safety, the Licensor shall be empowered to terminate the Listing Receipt if later any of the following cases happens:

(1) a particular of listed medical device is false;

(2) a listed medical device is a counterfeit medical device or not safe for use;

(3) a listing person 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;

(4) a listed medical device does not have the benefits stipulated in the listed particular as shown by reliable technical documentation."

Section 41 The provisions under section 71, section 72 and section 73 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 71 In the case where the licensor determines that a medical device which has been licensed, whose specifications have been declared or particular has been listed has been altered into a drug, psychotropic substance, narcotic drug, hazardous substance or cosmetic, the licensee, specifications provider or listing person shall proceed in accordance with the rules, procedures and 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, specifications declaration receipt or listing receipt shall expire.

Section 72 An order to suspend or revoke the establishment registration certificate, licence or specifications declaration receipt and an order to terminate the listing receipt shall be made as a written

notice served on the establishment registrant, licensee, specifications provider or listing person, as the case may be. In the case where the establishment registrant, licensee, specifications provider or listing person is not found, or the establishment registrant, licensee, specifications provider or listing person 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, specifications declaration receipt or listing receipt, and the establishment registrant, licensee, specifications provider or listing person shall be deemed to have knowledge of the order as from the day of order posting.

An order to suspend or revoke the establishment registration certificate, licence or specifications declaration receipt and an order to terminate the listing 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 or a person whose listing receipt has been terminated may sell the remaining medical devices to an establishment registrant, licensee, specifications provider or listing person 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 order to terminate the listing receipt or the day of acquiring knowledge of the Minister's decision, except where an extension is granted by the licensor."

Section 42 The provisions under section 74 and section 75 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 74 In the case where the licensor does not issue an establishment registration certificate, licence, specifications declaration receipt or listing receipt, or does not issue an assessment certificate under section 22, or does not renew an establishment registration certificate, licence, specifications declaration receipt or listing 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, specifications declaration receipt or listing receipt, or non-issuance of assessment certificate under section 22, or non-renewal of establishment registration certificate, licence, specifications declaration receipt or listing 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, specifications declaration receipt or listing 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, specifications provider whose establishment registration certificate, licence, specifications declaration receipt is suspended or revoked has the right to submit an appeal in writing to the Minister within thirty days 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, specifications declaration receipt or the termination of a listing receipt.

A decision of the Minister shall be final."

Section 43 The provisions under section 86 and section 87 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 86 Any person who manufactures or imports a medical device under Section 6(1) (a) without a license 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 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 and fifty thousand baht.

Section 87 Any person who manufactures or imports a medical device under Section 6 (1) (b) 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 two years or a fine not exceeding two hundred thousand baht, or both.

Any person who manufactures or imports a medical device under Section 6(1) (c) without a listing 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 one hundred baht.

Any listing person 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 44 The provisions under section 91 and section 92 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 91 Any licensee or specifications provider who manufactures, imports or sells medical devices subsequent to the expiration of licence or specifications declaration receipt, but has submitted an application for renewal of the 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 licence or specifications declaration receipt.

Any establishment registrant or listing person who manufactures, imports or sells medical devices subsequent to the expiration of establishment registration certificate or listing receipt, but has submitted an application for renewal of the establishment registration certificate or listing receipt within the time period prescribed under section 30 paragraph three, or section 30/1 paragraph three, respectively, shall be liable to a daily fine of five hundred baht throughout the period of non-submission of application to renew the establishment registration certificate or listing receipt .

Section 92 Any 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.

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

Section 45 The following provisions shall be added as section 92/1 of the Medical Device Act B.E. 2551:

"Section 92/1 Any Listing Person who fails to comply with section 31/1 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 46 The provisions under section 93 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 93 Any licensee or specifications provider 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 47 The provisions under section 95 and section 96 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 95 Any licensee under section 17 or section 24, or any specifications provider under section 19 who ceases an operation without complying with section 36 paragraph one shall be liable to a fine not exceeding ten thousand baht.

Any establishment registrant under section 15, or any listing person under section 19 who ceases an operation without complying with section 36 paragraph one shall be liable to a fine not exceeding five thousand baht.

Section 96 Any licensee under section 17 or section 24, or any specifications provider under section 19 whose license or specifications declaration receipt has expired, or where the licensor has rejected the renewal of the license 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.

Any establishment registrant under section 15 whose establishment registration certificate has expired, or where the licensor has rejected the renewal of the establishment registration certificate, who fails to serve a notice under section 37 paragraph one shall be liable to a fine not exceeding five thousand baht."

Section 48 The provisions under section 99 and section 100 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 99 Any licensee or specifications provider who violated 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.

Any establishment registrant or listing person who violates section 40 shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding five thousand baht, or both.

Section 100 Any licensee or specifications provider 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 a fine not exceeding one hundred thousand baht, or both.

Any licensee or specifications provider who prepares a false record or report under section 41(3), prepares a false report under Section 41(4), prepares a false record of complaints under Section 41(5) or provides false technical documentation under section 41(9) 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 section 41(5) shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding fifty thousand baht, or both.

Any licensee or specifications provider 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 49 The following provisions shall be added as section 100/1 of the Medical Device Act B.E. 2551:

"Section 100/1 Any establishment registrant or listing person who fails to comply with section 41(1), (2), (3), (4) or (9) 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 or listing person who prepares a false record or report under section 41(3), a false report under section 41(4), a false record of complaints under section 41(5) or provides false technical documentation under section 41(9) 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 or listing person who fails to comply with section 41(5) shall be liable to imprisonment for a term not exceeding three months or a fine not exceeding thirty thousand baht, or both.

Any establishment registrant or listing person 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 50 The provisions under section 103 and section 104 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 103 Any 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 establishment registrant or listing person who manufactures or imports a medical device without complying with section 44 paragraph one shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding fifty 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 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 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 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 imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both.

Any establishment registrant or listing person manufacturing or importing a medical device under section 6(13) who fails to comply with section 45 paragraph one shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding fifty 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.

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 51 The provisions under section 106 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 106 Any person who manufactures or imports a medical device which being granted the license under Section 6(1) (a) or the specifications declaration receipt under section 6(1) (b), not in conformity with standards in violation of section 46(2) shall be liable to an imprisonment for a term not exceeding three years or a fine not exceeding three hundred thousand baht, or both.

Any person who manufactures or imports a medical device which being granted the listing receipt under section 6(1) (c), not in conformity with standards in violation 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.

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 52 The provisions under section 109 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

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

Section 53 The following provisions shall be added as section 109/1 of the Medical Device Act B.E. 2551:

"Section 109/1 Any person who sells a medical device without a license or specifications declaration in violation of section 46/1 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 medical device without a listing receipt in violation of section 46/1 shall be liable to imprisonment for a term not exceeding one year or a fine not exceeding one hundred thousand baht, or both."

Section 54 The following provisions shall be added as paragraph three and paragraph four of section 110 of the Medical Device Act B.E. 2551:

"Any person who manufactures or imports a medical device for which a listing receipt has been terminated in violation of section 46(6) 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 for which a listing receipt has been terminated in violation of section 46(6), shall be liable to imprisonment for a term not exceeding six months or a fine not exceeding fifty thousand baht, or both."

Section 55 The provisions under section 113 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 113 Any importer 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 56 The following provisions shall be added as paragraph three of section 114 of the Medical Device Act B.E. 2551:

"Any listing person 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 a fine not exceeding fifty thousand baht, or both."

Section 57 The provisions under section 119, section 120 and section 121 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 119 Any person who fails to testify or submit a document 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, listing person or person having duties related to the manufacture, import, sale or storage of medical device who does not assist a competent official under section 63 shall be liable to imprisonment for a term not exceeding one month or a fine not exceeding ten thousand baht, or both.

Section 121 Any 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.

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

Section 58 The provisions under paragraph one of section 123 of the Medical Device Act B.E. 2551 shall be repealed and replaced by the following provisions:

"Section 123 In regard to an offence under this Act which is punishable only by a fine or a term of imprisonment not exceeding one year, 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."

Section 59 All the fee rates attached to the Medical Device Act B.E. 2551 shall be repealed and replaced by the fee rates at the end of this Act.

Section 60 All applications submitted prior to the effective date of this Act and are pending deliberations shall be deemed as applications under the Medical Device Act B.E. 2551 as amended by this Act, and such process may be continued in accordance with the Medical Device Act B.E. 2551 as amended by this Act. In the case where an application is inconsistent with the rules under the Medical Device Act B.E. 2551 as amended by this Act, the licensor shall have the power to order the applicant to perform an action to comply with the Medical Device Act B.E. 2551 as amended by this Act.

Section 61 A licence or specifications declaration receipt issued under the Medical Device Act B.E. 2551 (2008) prior to the effective date of this Act shall continue to be valid until its expiration date.

Section 62 A Ministerial Regulations or Notification issued under the Medical Device Act B.E. 2551 (2008) 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 the Medical Device Act B.E. 2551 as amended by this Act until the issuance of a Ministerial Regulation or Notification under the Medical Device Act B.E. 2551 as amended by this Act come into force.

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

Section 63 The Notifications issued under the Order's Command no. 77/2559(2018) of the National Council for Peace re: Enhancement of Health Product Licensing Processes dated 27th December, 2559(2018), especially the section concerning medical devices applicable prior to the effective date of this Act shall be apply to Part 1 Medical Device Licensing Processes of Chapter II Application for and Granting of Establishment Registration Certificate, Licence, Specifications Declaration Receipt and Listing Receipt of the Medical Device Act B.E. 2551 as amended by this Act. In this regard, such notifications shall be apply to the extent that it is neither contrary to nor inconsistent with the Medical Device Act B.E. 2551 as amended by this Act until the issuance of a Notification under the Medical Device Act B.E. 2551 as amended by this Act come into force.

When a notification issued under the Medical Device Act B.E. 2551 as amended by this Act come into force, the notifications issued under Order's Command No. 77/2559 of the National Council for Peace re: Enhancement of Health Product Licensing Processes dated 27th December, 2559(2016), especially the section concerning medical devices, shall be repealed.

Section 64 The Minister of Public Health shall be in charge of the execution of this Act.

Countersigned by:
General Prayut Chan-o-cha
Prime Minister

SCHEDULE OF FEES

(1)	Manufacturing Establishment registration certificate	per issue	10,000 Baht
(2)	Importation Establishment registration certificate	per issue	20,000 Baht
(3)	Medical device manufacturing licence	per issue	100,000 Baht
(4)	Medical device import licence	per issue	200,000 Baht
(5)	Medical device sale licence	per issue	10,000 Baht
(6)	Medical device advertising licence	per issue	10,000 Baht
(7)	Medical device manufacturing specifications declaration receipt	per issue	50,000 Baht
(8)	Medical device import specifications declaration receipt	per issue	100,000 Baht
(9)	Medical device manufacturing listing receipt	per issue	5,000 Baht
(10)	Medical device import listing receipt	per issue	10,000 Baht
(11)	Certificate	per issue	5,000 Baht
(12)	Medical device assessment certificate pursuant to section 22	per issue	2,000 Baht
(13)	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
(14)	Establishment registration Application	per issue	100 Baht
(15)	Licence Application	per issue	1,000 Baht
(16)	Specification declaration Application	per issue	1,000 Baht
(17)	Listing Application	per issue	1,000 Baht
(18)	Application for relocation or change of place of manufacture, import, sale or storage of medical device	per issue	1,000 Baht
(19)	Application to amend an item in an establishment registration certificate	per issue	100 Baht
(20)	Application to amend an item in a licence or other licensed items	per issue	1,000 Baht

(21)	Application to amend an item in a specifications declaration receipt or others items in the specifications declaration	per issue	500 Baht
(22)	Renewal of an establishment registration certificate shall be equal to the fee applicable to each issue of the pertinent type of establishment registration certificate.		
(23)	Renewal a licence shall be equal to the fee applicable to each issue of the pertinent type of licence.		
(24)	Renewal fee of a specifications declaration receipt shall be equal to the fee applicable to each issue of the pertinent type of specification declaration receipt.		
(25)	Renewal of a listing receipt for medical device manufacturing	per issue	2,500 Baht
(26)	Renewal of a listing receipt for medical device import	per issue	5,000 Baht
(27)	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 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 Government of the Kingdom of Thailand has signed the ASEAN Agreement on Medical Device Directive and in additional to the Medical Device Act B.E. 2551 (2008), presently, there are some provisions that are a limitation for the operations of medical device. Therefore, it is appropriated to amend the medical device control measures in accordance with the said Agreement and amend the provisions that are limited, determining the medical device group or medical device according to the level of risk that may cause harm or impact on public health, adding measures to control the manufacture or import of medical device by listing, reduce control measures for medical device exports, amendment of the rules regarding the implementation of medical device considerations and related provisions to increase efficiency in the process of allowing medical device approval including amendments of penalties and fees to be appropriated and consistent with the current situation. It is therefore necessary to enact this Act.