

Medical Device Act, B.E. 2551 (2008)

Translation

Bhumibhol Adulyadej, Rex.

Given this 26th day of February B.E 2551

Being the 63 year of the present Reign.

His Majesty King Bhumibhol Adulyadej has been graciously pleased to proclaim that,
Whereas it is expedient to revise the law on medical device;

This Act has certain provisions in relation to the restriction of rights and liberties of person and as the Section 28 together with Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand have prescribed that it may be acted by virtue of statutory provisions.

Be it, therefore, enacted an Act by His Majesty the King, by and with the advice and consent of the Parliament, as follows:

Section 1

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

Section 2

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

Section 3

There shall be repealed on the Medical Act, B.E. 2531 (1989).

Section 4

In this Act:

"Medical Device" means

- (1) Instrument, apparatus, implement, machines, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the producer to be used, alone or in combination, for human beings or animals for one or more of the specific purpose(s) of:
 - (a) Performing treatment in; the medical profession, the profession of nursing and midwifery, the profession of dentistry, the profession of medical technology, the profession of physical therapy and the profession of veterinary as prescribed by legislation concerned or performing the other medical profession and public health as prescribed by the Minister;
 - (b) Diagnosis, prevention, monitoring, treatment or alleviation of disease in human or animal;
 - (c) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury human or animal;
 - (d) Investigation, replacement, modification, or support of the anatomy or of a physiological process of human body or animal;
 - (e) Supporting or sustaining life of human or animal;
 - (f) Control of conception or help reproduction of human or animal;
 - (g) Help or help compensating disability or infirmity in human or animal;

- (h) Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human or animal body;
 - (i) Destroy or disinfect on medical device.
- (2) Accessories or constituents in the instruments, appliances, machines, products or articles under (1);
 - (3) Instrument, apparatus, machines, products or other articles prescribed by the Minister as medical device.

The achievements under the intention in the statement under (1) as occurred in human body or animal must not be from any pharmacology, immunology or oxidation reaction to create energy as its main element.

"Produce" means make, assemble, devise, packaging, repackaging, develop, transform, adjust or sterilization;

"Distribute" means sell, dispense, dispose of, exchange, lending, leasing, trade or transfer the right or possession to other person, for commercial purpose, including having in procession for sale;

"Import" means bring or order to be brought into the Kingdom;

"Export" means bring or send out of the Kingdom;

"Label" means any statement displayed on the medical device, its container or package;

"Accompanying Document" means the paper or other material on which information about the medical device is displayed by any statement, inserted or included in the container or package of the medical device, including the manual;

"Statement" means any making to appear with letter, image, design, picture, motion picture, light, sound, symbol or any act that general people can understand it.

"Advertisement" means any activity by any means to let people see, hear or know of the statement for commercial purpose, including sale promotion.

"Sales Promotion" means providing of information, invitation or any activity to attract attention to increase its sales;

"Infirmary" means infirmary under the law on infirmary and animal infirmary under the law on animal infirmary and also includes infirmary and animal infirmary of state administrative agencies.

"Medical Professional and Public Health" means operator of medical profession, dentistry, first grade veterinary medicine, physical therapy, medical technology or operator of medical profession and other public health as prescribed by the Minister.

"Licensee" means the person to whom the license is granted under this Act; and in the case where the licensee is a juristic person, it includes the person(s) who is (are) authorized by the juristic person to do the business;

"Notifier" means the person to whom the certificate of notification is granted under this Act; and in the case where the person who submits the list of particulars is a juristic person, it includes the person(s) who is (are) authorized by the juristic person to do the business;

"Registrant of Establishment" means the person granted with certificate of establishment registration under this Act; and in the case where the registrant of establishment is a juristic person, it includes the person(s) who is (are) authorized by the juristic person to do the business;

"Licensor" means the General Secretary of Food and Drug Administration (FDA) or the person authorized by the General Secretary of the Food and Drug Administration;

"Committee" means the Medical Device Committee;

"Committee Member" mean the members of the Medical Device Committee.

“Competent Official” means a person appointed by the Minister for the execution of this Act;

“Administrative Agency” means central administration, regional administration, local administration, state enterprise, public organization and other administrative agencies.

“General Secretary” means the General Secretary of Food and Drug Administration (FDA).

“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 the Act and is empowered to appoint competent officials, to issue the Ministerial Regulation imposing fees not exceeding those given in the attachment hereof, to grant fee exemptions, to issue Announcement, and to determine other takings for the execution of this Act.

The Ministerial Regulation and Announcement shall come into force after its publication in the Government Gazette.

Section 6

For the purpose of controlling medical device and protection of consumers’ safety, the Minister with the advice of the Committee shall have the power to prescribe the Announcement on:

- (1) The medical device of which producer or importer need to require a license, as well as the rules, procedures and conditions of its production and importation;
- (2) The medical device of which producer or importer need to notify the list of particulars, as well as the rules, procedures and conditions of its production or importation;
- (3) The medical device of which distributor need to require a license, as well as the rules, procedures and conditions of its distribution;
- (4) The standard of medical device that the producer, the importer or the distributor must comply with;
- (5) The quality system in production, importation or distribution of medical device;
- (6) The standard of the container, the way to use the container, as well as the materials that are not allowed to be used as a container of medical device that the producer, the importer or the distributor must comply with;
- (7) The medical device that requires to arranging a controller on its production, importation or distribution, as well as its qualifications, number and duties of the controller;
- (8) The medical device that requires technology assessment for its use to be appropriate and consistent with the public health and economic and social conditions of the country;
- (9) The medical device that can be sold only for consumers with the prescription of health care professional, as well as the rules, procedures and conditions of its distribution;
- (10) The medical device that can be sold only for infirmary or health care professional, as well as the rules, procedures and conditions of its distribution;
- (11) The medical device that is prohibited in production, importation or distribution;
- (12) The medical device prohibited on direct sale or direct market under the legislation on direct sale and direct market;
- (13) The medical device of which require to indicate duration of use, warning, precaution or instruction for use in the label or the accompanying document, as well as the rules, procedures and conditions in the demonstration;

- (14) The medical device of which requires a patient registration on using such medical device, as well as the rules, procedures and conditions of its patient registration;
- (15) The rules, procedures and conditions in the use of medical device in clinical investigation;
- (16) The rules and method of transport, storage, destruction or rendering unusable of the medical device;
- (17) At what place in the Kingdom to be the FDA Inspection Port of imported or exported medical device;
- (18) The medical device that is exempted in complying with certain control measure in this Act and the exempted measure.

Chapter 1

Medical Device Committee

Section 7

There shall be established a Committee, to be called "Medical Device Committee" consisting of the Permanent Secretary of Ministry of Public Health as the Chairman; Director General of the Medical Service Department; Director General of the Disease Control Department; Director General of the Livestock Development Department; Director General of the Medical Sciences Department; Director General of the Health Service Support Department; General Secretary of the Consumer Protection Board, General Secretary of the Food and Drug Administration, representative of the Council of State Office and representative of the Customs Department as Committee Members and there shall be no fewer than nine but no more than eleven qualified persons appointed members by the Minister. Among them, there shall be one from medical professional, one from nursing and midwifery, one first-class clinician in dentistry, one first-class veterinarian, one from medical technician, one physician, one representative of association or foundation with its objective related to the promotion or support of implementation of infirmary, one representative of association or operator with objective in the production, importation or distribution of medical device and one representative of association or foundation with objective in relation to the consumer protection for one person.

The Deputy General Secretary, who is assigned by the General Secretary, shall be a member and secretary, and the Director of Medical Device Control Division, Food and Drug Administration, shall be a member and assistant secretary.

Section 8

The qualified member shall hold office for a term of two years;

In case the qualified member is relieved from term before expiration, the Minister may appoint other person to be qualified member in replacement and the appointed person shall assume the term as remaining of such member.

In case the Minister shall appoint qualified member in adding to existing members still under the term of office, the person appointed shall take remaining term of office of the expert member who has already been appointed.

At the expiration of the term of office in the first paragraph, if it is not yet with new appointment, the qualified member who vacates office shall still be in office to continue work until a new member shall assume the post.

The qualified member who vacates office under the term may be re-appointed but shall not stay in officer exceeding two terms.

Section 9

Apart from, the expiration of the term of office, a qualified member shall vacate his/her office upon:

- (1) death;
- (2) resignation;
- (3) dismissal by the Minister due to misfeasance, bad conduct of behavior or lack of ability;
- (4) being adjudged bankrupt;
- (5) being adjudged incompetent or quasi-incompetent person
- (6) being imprisoned by a final judgment to imprisonment, except for an offense committed by negligence or petty offense.

Section 10

In the Committee meeting, an attendance of not less than one-half of the total number of the members shall be required to constitute a quorum.

If the chairman is absent from or not present at the meeting, the attending members shall elect one among themselves to preside over the meeting;

The decision of the meeting shall be taken by a majority of votes. Each member shall have one vote. In case of a tie, the person who presides over the meeting shall have another vote as the casting vote.

Section 11

The Committee shall have following powers and duties:

- (1) To provide advice or opinions to the Minister regarding the policies and measures for controlling medical device to comply with this Act;
- (2) To provide advice or opinions to the Minister on making announcements under Section 6;
- (3) To give approval on the suspension and revocation of establishment registration certificate, license or list of particulars certificate;
- (4) To perform other duties as prescribed in this Act or as assigned by the Minister.

Section 12

The Committee is empowered to appoint a Sub-Committee to perform any duties assigned by the Committee and the provisions of Section 10 shall apply to the meeting of the Sub-Committee *mutatis mutandis*.

Section 13

In the performance of its duties under this Act, the Committee and its Sub-Committee shall have power to summon any person to make a statement or to submit the concerned documents or anything else for consideration.

Section 14

In the performance of its duties under this Act, the Committee and Sub-Committee shall be a competent officer under the Criminal Code.

Chapter 2

Application for and Granting of Establishment Registration, License and List of particulars certificate

Section 15

Any person who wishes to produce or import medical device must register its establishment to the licensor.

The Application for and granting of registration of establishment in the first paragraph shall comply with the rules, procedures and conditions prescribed by the Ministerial Regulation.

Section 16

The licensor is empowered to issue certificate of establishment registration for produce or import of medical device to the registrant of establishment when it is evident that the applicant:

- (1) Be the business owner requested for the registration of establishment;
- (2) Be no less than twenty years old;
- (3) Have residence in Thailand;
- (4) Not being adjudged bankrupt;
- (5) Have never been imprisoned by a final judgment of imprisonment or a legitimate order to imprisonment for any offences stipulated by law to include dishonesty or for the offences described in this Act, except for the case where at least two years have passed subsequent to release from imprisonment on the date of registration;
- (6) Not be insane or adjudged incompetent or quasi-incompetent;
- (7) Not suffer from the illnesses prescribed by the Minister;
- (8) Have premises for the production or importation of medical device as well as the implement for the production, storage and control or quality control of the medical device, the characteristic and number of which are in accordance with those prescribed by the Ministerial Announcement;
- (9) Not have the same commercial name with or a similar commercial name to that of a registrant whose certificate of establishment registration has been suspended or revoked for less than one year;
- (10) Not be a registrant whose certificate of establishment registration is being suspended under this Act;
- (11) Not be a registrant whose certificate of establishment registration has been revoked under this Act, except for the cases where at least two years have passed subsequent to the revocation on the date of registration.

In the case where the registrant of establishment is a juristic person, the manager or the representative of the juristic person who is the business operator must have the qualifications under (2) and (3) and have no forbidden characteristics under (4) (5) (6) (7) (10) or (11).

Section 17

Registrant of establishment who wishes to produce or import medical device under Section 6 (1) shall be submitted an application for a license. The registrant can produce or import such medical device after the licensor is issued the license.

The application for and granting of license in the first paragraph shall be made in accordance with the rules, procedures and conditions as prescribed by the Ministerial Regulation.

The licensee in the first paragraph shall comply with the rules, procedures and conditions of its production or importation of medical device prescribed by the Minister under Section 6 (1).

Section 18

Registrant of establishment who produces or imports medical device as stated in the announcement under Section 6 (1) within the date of the announcement in effect and wishes to continue the operation of the business must apply for permission within thirty days as from the effective date of the announcement and at the application within scheduled time it can continue until it has order not granting any further.

The provisions of Section 17, the second paragraph and the third paragraph shall apply to enforcement by *mutatis mutandis*.

Section 19

Registrant of establishment who wished to produce or import medical device under Section 6 (2) shall apply by notifying a list of particulars and after the licensor has issued with the certificate of notification it may produce or import such medical device.

The notification of its particulars and granting of the certificate of notification on such details in the first paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the Ministerial Regulation.

The notifier in the first paragraph shall comply with the rules, procedures and conditions of its production and importation of medical device prescribed by the Minister under Section 6 (2).

Section 20

Registrant of establishment that produces or imports medical device as prescribed under Section 6 (2) during the effective date of such announcement and who wishes to continue the operation of the business must apply for permission by giving a list of particulars within thirty days as from the date of announcement in effect, and after such application it may continue the business until it has order not accepting on details notification.

The provisions of Section 19, the second paragraph and the third paragraph shall apply to enforcement by *mutatis mutandis*.

Section 21

After the announcement under Section 6 (8) have been made, the producer, the importer, the distributor or the person in possession of medical device as mentioned on the date of enforcement shall notify possession of the medical device to the licensor within sixty days as from the effective date of such announcement.

In case with the moving of the medical device in the first paragraph from one place to another place afterwards, the possessor of the medical device shall notify the licensor before such removal and in case of necessity for safety in use of such medical device, the licensor must implement inspection on the preparedness of medical device, place and personnel. If it has expense in the inspection of such preparedness, it is collected from the possessor of the medical device.

Notifying on possession in the first paragraph, the removal and inspection of preparedness including expense in implementation in the second paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the Secretary General with the approval of the Committee by publishing in the Government Gazette.

Section 22

Registrant of establishment who wishes to produce or import medical device under Section 6 (8) shall submit an application to the licensor for the assessment that such medical device has efficiency, quality, standard and safety for use including assessment of its effect and feasibility in economic and social aspects to implement the use of the medical device in appropriateness widely and fairly and after the licensor has issued the assessment certificate it may produce or import. However, in case of medical device that the producer or the importer must be granted on permission or must notify details for production or importation when the licensor has issued the license or the certificate of notification under Section 17 or Section 18, as the case may be.

The application for assessment, assessment and issuing of assessment certificate on medical device in the first paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the Secretary General with the approval of the Committee by publishing in the Government Gazette.

The Minister with the advice of the Committee is empowered to announce the expert member, expert organization, administrative agency or other agencies in the country and abroad to be the assessor of medical device in paragraph one, including imposing on rate, payment method and exemption of expense in assessment of such medical device.

Expense in assessment of medical device in the third paragraph shall be collected from the person who wishes to produce or import such medical device.

It shall be applied with Section 21, the second paragraph and the third paragraph for the case of removal of medical device as passing assessment in the first paragraph from one place to another place afterwards.

Section 23

The provision of Section 21 and Section 22 shall apply against the administrative agencies and Thai Red Cross by *mutatis mutandis*.

Section 24

Any person who wishes to distribute medical device under Section 6 (3) shall submit an application for the permission and after the licensor has issued the license it may distribute such medical device.

The permission request and issuing of license in the first paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the Ministerial Regulation.

The licensee in the first paragraph shall comply with the rules, procedures and conditions of its distribution prescribed by the Minister under Section 6 (3).

The producer or importer under Section 17 or Section 19 shall also have permission to distribute medical device produced or imported by himself or herself under the first paragraph without having to submit an application for distributing permission but it shall comply with the rules, procedures and conditions prescribed by the Minister under Section 6 (3).

Section 25

Any person who distributes medical device prescribed under Section 6 (3) during the effective date of announcement and wishes to continue the operation of the business shall submit an application for permission within thirty days as from the announcement date in effect and after such application within the time imposed it may continue the business until it has order not granting to.

The provision of Section 24, the second paragraph, the third paragraph, and the fourth paragraph shall apply to enforcement by *mutatis mutandis*.

Section 26

The licensor is empowered to issue a license to distribute medical device to the person seeking permission when it is evident that the applicant

- (1) Be the business owner requested for the license of distribution;
- (2) Have qualifications and have no forbidden characteristics under Section 16 (2), (3), (4), (5), (6) and (7);
- (3) Not have the same commercial name with or a similar commercial name to that of a registrant whose license has been suspended or revoked for less than one year;
- (4) Not be a licensee whose license is being suspended under this Act;

- (5) Not be a licensee whose license has been revoked under this Act, except for the cases where at least two years have passed subsequent to the revocation on the date of application;
- (6) Have quality system in distribution as stated under Section 6 (5);
- (7) Have controller of the distribution of the medical device under Section 6 (7).

In the case where the licensee is a juristic person, the manager or the representative of the juristic person who is the business operator must have the qualifications under Section 16 (2), (3), (4), (5) (6) and (7) and have no forbidden characteristics under (4) and (5).

Section 27

The provisions under Section 15, Section 17, Section 19 and Section 24 shall not apply to:

- (1) Producing, importing or distributing of medical device by state agency in the duty of prevention, autopsy, treatment of disease or capacity rehabilitation and Thai Red Cross;
- (2) Production of medical device specifically for disinfection in infirmary under the legislation on infirmary;
- (3) Production and distribution of medical device that medical professional and public health for use with specific patients or specific animals;
- (4) Distributing of medical device licensed or with a certificate of notification by the infirmary or the health care professional for use with specific patients or specific animals;
- (5) Production or importation of medical device for personal use or as example for use in the exhibition or education, research, analyses or test of quality and standards in limited quantity as necessary;
- (6) Import of medical device as being accessories or constituents for the production of medical device or importation of medical device for use with specific patients or animals;
- (7) Production of medical device for specimen in export;
- (8) Production or importation of medical device in accordance with the rules, procedures and conditions prescribed by the Minister with the advice of the Committee.

Person exempted with enforcement under (1), (2), (3), (4), (5), (6) and (7) must comply with the rules, procedures and conditions prescribed by the Minister with the advice of the Committee.

The General Secretary with the approval of the Committee is empowered to publish in Government Gazette to impose fees, payment methods, exemptions and persons in charge of assessment expenses in academic manner, inspection of establishment, inspection or analysis of medical device.

Section 28

The certificate of establishment registration, license or certificate of notification shall cover to employees and agent of registrant of establishment, licensee and notifier also.

It deems action of employees or agent as covered in paragraph one to be the act of the registrant of establishment, licensee or notifier also, except the registrant of establishment, the licensee or the notifier can prove that such act is impossible to anticipate or control.

Section 29

Certificate of establishment registration in Section 15, license in Section 17 and notification acknowledgment under Section 19 can be effective until 31 December of the fifth year from the year issued of such establishment registration, license and notification acknowledgment.

The license of distribution under Section 24 is effective until 31 December of the year issuing the license.

Section 30

In case the registrant of establishment, licensee or notifier wishes to extend the period in establishment registration, license or certificate of notification, it has to apply before the expiration of the establishment registration, license or certificate of notification. After the application and payment of extension fee with the submission of the application, it may continue until the licensor shall order not granting extension of establishment registration, license or certificate of notification.

Request of extension of certificate of establishment registration, license or certificate of notification and granting of extension shall be made in accordance with the rules, procedures and conditions prescribed by the Ministerial Regulation.

The registrant of establishment, the licensee or the notifier with the certificate of establishment registration, license or certificate of notification has expired not over one month may apply for extension and grace showing reason in not applying for extension within the time imposed together with the payment of extension fee but request on grace may not bring about relief as stated under Section 91.

Extension of certificate of establishment registration, license or certificate of notification at lapse of time of one month from the date of certificate of establishment registration, license or certificate of notification shall not be allowed.

In case the licensor has not granted the extension of certificate of establishment registration, license or certificate of notification, it shall be returned on extension fee to the requesting person at proportion calculated on monthly basis from the date of refusal until the date of expiration in certificate of establishment registration, license or certificate of notification as requesting for extension, except for case in appeal against such refusing order and the Minister has order the person requesting on such extension of certificate of establishment registration, license or certificate of notification to continue operation temporarily, if the Minister orders in dismissing appeal from the date of such order, its fraction of one month if it is up to fifteen days is counted as one month.

Section 31

In case the registrant of establishment, the licensee or the notifier wishes to change particulars in registration certificate of establishment, license, certificate of notification or other related particulars, it has to submit to licensor, except in moving or changing of place temporarily from urgent cause in applying for license.

The application for permission and moving or changing in place temporarily from urgent cause that it cannot apply for the permission shall be made in accordance with the rules, procedures and conditions prescribed by the Ministerial Regulation.

Section 32

In case of the certificate of establishment registration, license or certificate of notification, certificate of assessment under Section 22 or letter of certificate is lost, destruction or damage, the registrant of establishment, licensee or notifier shall submit an application for and granting of a substitute document within fifteen days as from the date of knowledge of the loss, destruction or damage thereof.

The application for and granting of a substitute documents under the first paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the Ministerial Regulation.

Section 33

The General Secretary with the approval of the Committee is empowered to announce in the Government Gazette to impose expert member, expert organization, state agency or other agencies in the country and abroad, including imposing fees and payment methods

on assessment expenses of academic documents, inspection of establishment, inspection or analysis of medical device for consideration on following:

- (1) Consideration of issuing certificate of establishment registration, license, certificate of notification or letter of certification;
- (2) Consideration on change, modification, improvement of medical device or particulars in certificate of establishment registration, license, certificate of notification or other related particulars.

In the performance of duties under the first paragraph one, the applicant is responsible for expenses.

Section 34

For the benefit of exportation, the producer shall produce medical device for export in quality, standard, label or other details as ordered by purchaser but it shall be made in accordance with the rules, procedures and conditions prescribed by the Committee as published in the Government Gazette.

It is prohibited for any person to distribute medical device in the first paragraph in the Kingdom.

Section 35

In case with any requirement abroad or international agreement on standard, efficiency, safety or foreign rules or international rules on importing of medical device in that country, the Food and Drug Administration may have agreement with such foreign agency in relation to the acceptance by inspection or certification of medical device or establishment of medical device by foreign agency, under the rules and conditions to be stipulated by the Committee, whether such foreign agency is state agency or private.

The acceptance of inspection or certification of foreign agency in the first paragraph, the General Secretary with the approval of the Committee is empowered to announce the name of foreign agency and scope of inspection or certification of medical device or establishment of medical device of foreign agency that has accepted it.

Chapter 3

Dissolution and Transfer of Business

Section 36

The registrant of establishment under Section 15, the licensee under Section 17 or Section 24 or the notifier under Section 19, who dissolves business which has been granted license or certificate of notification under this Act, shall submit a written notification of the dissolution together with the submission of certificate of establishment registration, license or certificate of notification, as the case may be, to the licensor within thirty days as from the date of dissolution and it shall be deemed that the certificate of establishment registration, license or certificate of notification expire on the date of the dissolution.

The notice on dissolution in the first paragraph shall state the remaining amount of medical device and storage place of such medical device, under the rules, procedures and conditions prescribed by the Government Gazette.

Any registrant of establishment who dissolves business but failed to give notice on the dissolution of granted business on license or certificate of notification shall be deemed that the license or certificate of notification also expires.

The registrant of establishment under Section 15, the licensee under Section 17 or Section 24 or the notifier in Section 19, who dissolves business but failed to give notice in the first paragraph, it shall be deemed that the of certificate of establishment registration, license or certificate of notification expires on the date of dissolution.

Section 37

The registrant of establishment under Section 15, the licensee under Section 17 or Section 24 or the notifier under Section 19, who does not extend the certificate of establishment registration, license or certificate of notification or the licensor does not grant extension of the of certificate establishment registration, license or certificate of notification, as the case may be, must notify the remaining amount of medical device and storage place of such medical device to the licensor within thirty days as from the date of expiration or the date the licensor does not grant extension of registration certificate of establishment, license or certificate of notification.

The notice under the first paragraph shall be made in accordance with the rules, procedure and conditions prescribed by the General Secretary and published in the Government Gazette.

Section 38

The licensee in distribution of medical device under Section 24 who has notified the dissolution of his/her business, expiration of license or the licensor does not grant extension, as the case may be, shall sell the rest of his/her medical device to other licensee or person that the licensor sees suitable within sixty days as from the date of dissolution, the expiration date of license or the date not granted on extension. However, the licensor may grants the period of extension as may be necessary.

At the lapse of time in the first paragraph and still with medical device that the distributor must have the permission under Section 24, it is prohibited for the licensee to distribute such medical device and the licensee must notify the licensor on the amount of medical device and storage place within fifteen days as from the date lapsed in the first paragraph.

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

Section 39

In case that the registrant of establishment, licensee or informer of particulars and heir or the person having the consent of heir, expresses the intention to the licensor to operate business further within ninety days as from the date the registrant of establishment, licensee or informer of particulars dies. After the licensor has examined and seeing the person has with the qualifications under Section 16 or Section 26, as the case may be, the person may continue until the establishment registration, license or certificate of notification shall expire and it deems the person expressing intention is the certificate of establishment registrant, licensee or informer of particulars under this Act as from the date the certificate of establishment registrant, licensee or notifier has passes away.

The expression of intention and inspection shall be made in accordance with the rules, procedures and conditions prescribed by the Committee and published in the Government Gazette.

It will be applied with statement under Section 38, the second paragraph and the third paragraph by mutatis mutandis with the case of heir possessing the medical device or administrator does not express intention to operate business in the first paragraph.

Chapter 4

Duties of Registrant of Establishment, Licensee, Informer of Particulars and Distributor

Section 40

It is prohibited that the registrant of establishment, the licensee or the notifier produces, imports, distributes or stores the medical device outside the place stated in the certificate of establishment registration, license or certificate of notification, except for:

- (1) Temporary storage with permission granted by the licensor in accordance with the rules, procedures and conditions prescribed by the Minister with the advice of the Committee;
- (2) Direct sale to a medical professional and public health;
- (3) Operation for the installation of medical device under the rules, procedures and conditions prescribed by the Minister with the advice of the Committee.

Section 41

The registrant of establishment, licensee or notifier shall perform as follow:

- (1) Control and supervise the operation of produce, import or distribute of medical device to comply with quality standard of production, importation or distribution of medical device under Section 6 (5);
- (2) Provide with controller in production, importation or distribution of medical device under Section 6 (7) and control/supervise such person to perform duties under Section 6 (7) in full;
- (3) Provide record of production, importation or distribution of medical device for inspection by competent official and prepare report to the licensor, however, it shall be made in accordance with the rules, procedures and conditions prescribed by the Minister;
- (4) Prepare report on performance abnormally or any adverse reactions of the medical device and report on its correction to the licensor whether it happened in the country or abroad, however, it shall be made in accordance with the rules, procedures and conditions prescribed by the Minister;
- (5) Provide a sign indicating the place of production, place of importation, place of distribution or storage place of medical device in an open place at the premises indicated in the certificate of establishment registration, license or certificate of notification, as the case may be, however, it shall be made in accordance with the rules, procedures and conditions prescribed by the Minister;
- (6) Provide a sign indicating the name and qualification of the controller in case the medical device under Section 6 (7) in an open and easily seen place at the premises indicated in the certificate of establishment registration, license or certificate of notification, however, under the rules, procedures and conditions prescribed by the Minister;
- (7) Showing of certificate of establishment registration, license or certificate of notification, in open area and easily seen at the mentioned place as stated in establishment registration, license or list of particulars certificate;
- (8) Provide with academic documents affirming the medical device has with the quality, standard, efficiency and safety for inspection or submission to competent official at request under the rules, procedures and conditions prescribed by the Secretary General and published in the Government Gazette.

Section 42

The producer, importer or distributor of medical device under Section 6 (14) or operator infirmary at the infirmary using such medical device shall provide register of patients using such medical device.

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

Section 43

The distributor of medical device under Section 6 (9) or (10) shall sell such medical device to only consumers having prescription of medical professional and public health or specifically to infirmary or health care professional.

The distributor under the first paragraph shall comply with the rules, procedures and conditions prescribed by the Minister under Section 6 (9) or (10).

Chapter 5

Labels and Accompanying Documents of Medical Device

Section 44

The registrant of establishment, licensee or notifier who produces or imports medical device shall provide with label and accompanying document of medical device by not showing any false statement or in overstating of truth.

The display of label and accompanying document of medical device shall be made in accordance with the rules, procedures and conditions prescribed by the Minister.

The distributor of medical device shall supervise the label or label and accompanying document of medical device, as the case may be, as provided by the registrant of establishment, licensee or informer of particulars under the first paragraph.

Section 45

Subject to Section 44, the registrant of establishment, licensee or notifier who produces or imports medical device under Section 6 (13) shows expiry date, warning, restriction and precaution for handling the medical device in the label or accompanying document of medical device.

The display of expiry date, warning, restriction and precaution for handling the medical device in the label or accompanying document of medical device shall be made in accordance with the rules, procedures and conditions prescribed by the Minister under Section 6 (13).

Chapter 6

The Control of Medical Device

Section 46

It is prohibited to produce, import or distribute the following medical device:

- (1) Counterfeit medical device;
- (2) Sub-standard medical device;
- (3) Deteriorated medical device;
- (4) Medical device that is unsafe to use;
- (5) Medical device produced or imported different from those granted by the license or those in the list of particulars submitted to the licenser;
- (6) Medical device that the license or the certificate of notification was revoked under Section 70.

Section 47

Counterfeit medical device means the medical device with following characteristics:

- (1) The medical device which is wholly or partly counterfeit or imitative;
- (2) The medical device which bears fraudulently statement of name, component, quality, quantity, date of manufacture and date of expiration, name of producer, place of produce, name of importer or certification mark for quality or trademark;
- (3) The medical device which bears statement of the license or the certificate of notification which is false.

Section 48

Sub-standard medical device means as follow:

- (1) The medical device of which quality or standard in non-compliance with the license or the list of particulars certificate;
- (2) The medical device of which standard in non-compliance with the Section 6 (4) or standard of packed device not complying with Section 6 (6) except in medical device granted for produce on export under Section 34.

Section 49

Deteriorated medical device means the medical device of which condition has so deteriorated that its quality is sub-standard, or the medical device that is beyond its prescribed expiry date.

Section 50

Medical device that is unsafe to use means the medical device that has the following characteristics:

- (1) Disposable medical device which has already been used;
- (2) Medical device that is produced or kept un-hygienically;
- (3) Medical device that is contaminated with foreign or potentially health- hazardous substances;
- (4) Medical device that includes degradable substances and may be toxically harmful to the user;
- (5) Medical device of which effectiveness is still doubtful;
- (6) Medical device of which designed or produced that in use may be hazardous to the user;
- (7) Medical device of which its label or accompanying document is not consisting with Section 44 or Section 45 that may be hazardous to the user.

Section 51

When having with the announcement under Section 6 (15), the producer, importer, supporter of research and the researcher of medical device in need of clinical investigation shall be made in accordance with the rules, procedures and conditions prescribed by the announcement.

Section 52

When having with the announcement under Section 6 (16), the producer, importer, distributor, possessor or destroyer or making its degeneration of medical device shall be made in accordance with the rules, procedures and conditions prescribed by the announcement.

Section 53

When having with the announcement under Section 6 (17), the importation or exportation of medical device shall pass the inspection of the competent official at the FDA inspector house.

Section 54

For the benefit of protection of health and consumer safety, in case of doubt that medical device is out of quality, standard or efficiency, unsafe for use, may be hazardous to health or in changing of standard, the General Secretary is empowered to order the producer or importer of the medical device to submit document or evidence in verifying quality, standard and safety.

During the implementation in the first paragraph, the General Secretary has the power to suspend produce, import or distribute on temporary basis until it will be verified on its quality, standard or efficiency and safety.

Section 55

For the benefit of health protection and consumer safety, it appears that medical device is with quality or standard or efficiency not consisting with the permission or details notified, not safe for use that may be hazardous to health or change in standard, the General Secretary shall have the following powers:

- (1) Issue a written order to the licensee or informer of particulars to alter the particulars of the medical device that has been granted the license or certificate of notification;
- (2) Issue a written order to the producer, importer, distributor or possessor of medical device in possession for benefit, to alter or improve the medical device that produced, imported, distributed, or in possession;
- (3) Issue a written order to the producer, importer or distributor of medical device to suspend the production, importation or distribution of medical device or other implementation related as imposed by the Committee;
- (4) Announce the inspection result or analysis of medical device and announcement on violation or non-compliance with (2) or (3) to the public as soon as possible and in case the Secretary General sees expedient to notify the involved person to know.
- (5) Collection of medical device from the producer, importer, distributor or person having possession or order the producer, importer or distributor to collect the medical device produced, imported or distributed from the market within the time period that the General Secretary has imposed and to have the power to order destroying or administer as the case should be, if found that such medical device in the device under Section 46, however, the producer, importer, distributor or person possessing the medical device to be responsible for such implementation cost.

Chapter 7 Advertisement

Section 56

It is prohibited to advertise medical device under Section 6 (11) or medical device under Section 46.

Section 57

Subject to Section 56, the advertisement of medical device shall be prior licensed from the licenser. The license on advertisement shall be not exceeding three years as from the date issuing license.

The application of license, issuing of license and license age under the first paragraph shall be made in accordance with the rules, procedures and conditions prescribed by the licensor, however, the licensor may impose specific conditions in the advertisement and limit the use of media.

It is applicable with the statement under Section 33 for the consideration of issuing of advertisement license or consideration on change, modification, improvement of particulars in the license by mutatis mutandis.

Section 58

In case the advertisement license is lost, destroyed or damaged, the licensee shall apply for its replacement license by fifteen days as from the date acknowledging on loss, destroy or damage.

The application for replacement of advertisement license shall be made in accordance with the rules, procedures and conditions prescribed by the General Secretary and published in the Government Gazette.

Section 59

The advertisement of medical device must:

- (1) Not showing falsely or fraudulently the benefits, quality, quantity, standard, component or origin source of medical device;
- (2) Not showing certification or admiration of benefits of medical device by any person;
- (3) Not organizing any reward in trying of luck in any means;
- (4) Not showing benefit of ability to prevent, treat, mitigate, healing of disease or symptom prohibited on advertisement prescribed by the Minister;
- (5) Not showing any statement that may cause misunderstanding in material part related to the medical device.

Section 60

In case the licensor seeing that the advertisement is violating Section 57 or Section 59, the licensor shall have the following powers to order:

- (1) Modify statement or advertisement method;
- (2) No use of message or certain method as shown in advertisement;
- (3) Suspension of advertisement;

Order under the first paragraph, the licensor may also order disclosing the correct information of the message.

Chapter 8 **Competent Official**

Section 61

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

- (1) To enter the premises of production, importation, distribution and storage of the medical device during working hours to inspect or control for the execution of this Act;
- (2) To take as samples a reasonable amount of the medical device for examination or analysis;

- (3) To confiscate or attach the medical device, as well as other equipment, instruments involved with the violation, including the containers, the packages, the labels, the accompanying documents and other related documents of such medical device;
- (4) In the event that there is reasonable cause of suspicion that violation of this Act has occurred, the competent official may enter into the premises or any vehicle to inspect or control for the execution of this Act;
- (5) Issue a written order to summon any person to make a statement or to submit the concerned documents and evidence necessary for consideration.

Section 62

In the performance of its duties, the competent official has to show his/her identification card to all involved persons.

The identification card of the competent official must be in the format prescribed by the Minister.

Section 63

The licensee, the notifier and the persons who are involved with the production, importation, distribution and storage of medical device shall accord facility to the competent official who performs his/her duty under Section 61 and Section 66, the second paragraph.

Section 64

The property confiscated or attached under Section 61 (3) shall be vested in the Ministry of Public Health if it evident that:

- (1) The owner is non-existent, or not having any person showing as owner or possessor by ninety days as from the date of confiscation or attachment;
- (2) In the case there is no litigation and the owner or possessor does not claim for it within ninety days as from the date instructed on the order that it has no litigation;
- (3) In the case there is litigation and the public prosecutor has issued a non-possessor order, or the court has passed a judgment not to confiscate, and the owner or possessor does not claim for it within ninety days as from the date the non-prosecution order is known or the date of the final judgment, as the case may be.

Section 65

In case the property confiscated or attached under Section 61 (3) is perishable or near its expiration as stipulated or at risk if kept for a long time, or the expenses of its keeping exceeds its value, the Food and Drug Administration may auction it prior to the finalization of the case or prior to its being vested in the Ministry of Public Health. The net proceeds of the sale, after expenses and encumbered charged have been deducted, shall be deposited in a government's bank in lieu of the property.

Section 66

In the performance of duties under this Act, the competent official shall be a competent officer under the Criminal Code.

In case of doubt, the General Secretary may order the competent official to implement investigation with the investigator under the regulations prescribed by the Ministry of Public Health with the approval of the Royal Thai Police. In this matter, the competent official shall have the status of investigator in Criminal Procedure Code.

Chapter 9

The Suspension and Revocation of the Certificate of Establishment Registration, the License or the Certificate of Notification

Section 67

In the event that a registrant of establishment, a licensee or a notifier violates or fails to comply with the Act, or any Ministerial Regulation or the announcement issued under this Act, the licensor, with the approval of the Committee, is empowered to suspend his/her registration of establishment, license, or certificate of notification for no longer than one hundred twenty days at a time. In the case where action has been taken to the court charging the registrant of establishment, licensee or notifier against violating this Act, the licensor, with the approval of the Committee may suspend the certificate of establishment registration, license or certificate of notification until the final judgment has been passed.

The registrant of establishment, the licensee or the notifier, whose certificate of establishment registration, license or certificate of notification has been suspended, is prohibited from operating the business granted permission by the certificate of establishment registration, license or certificate of notification.

Section 68

The licensor is empowered to cancel the suspension order before the expiration of the period if it is evident that the registrant of establishment, the licensee or the notifier whose certificate of establishment registration, license or certificate of notification has been suspended, has complied with this Act, or any Ministerial Regulation or announcement issued under this Act. However, the licensor must report the cancellation of such order to the Committee.

Section 69

The licensor with the approval of the Committee is empowered to revoke the certificate of establishment registration, license or certificate of notification, when it is evident that:

- (1) The registrant of establishment lacks the qualification or in prohibited characteristic or not complying with Section 16, as the case may be;
- (2) The licensee lacks the qualification or in prohibited characteristic or not complying with Section 26, as the case may be;
- (3) The registrant of establishment, licensee or notifier is declared by a final judgment that he/she has violated this Act;
- (4) The registrant of establishment, licensee or notifier has violated the suspension order in certificate of establishment registration, license or certificate of notification.

Section 70

For the benefit of health protection and consumer safety, the licensor with the approval of the Committee is empowered to revoke license or certificate of notification if it is evident that:

- (1) Medical device is non-compliance with standard and it cannot be modified or improved, medical device that is unsafe to use or counterfeit medical device;
- (2) The licensee or the notifier has changed intended for use or benefits of the medical device to be drug, psychotropic substances, narcotic, hazardous substances or cosmetic without permission;
- (3) Medical device without benefits as license or list of particulars permitted as shown from reliable academic documents.

Section 71

In case the licensor has stipulated the medical device license permitted or list the particulars given turning to be drug, drug, psychotropic substances, narcotic, hazardous substances or cosmetic, the licensee or the notifier shall implement it in compliance with the rules, procedures and conditions as the General Secretary has announced in the Government Gazette.

In case the licensee or notifier has no implementation under the first paragraph by the time stipulated by the General Secretary, it shall be deemed that the license or certificate of notification is expired.

Section 72

The order in suspension or revocation of the certificate of establishment registration, license or certificate of notification, shall be in a written notifying the registrant of establishment, licensee or notifier to acknowledge and in case the registrant of establishment, licensee or notifier cannot be founded, or the registrant of establishment, licensee or notifier does not accept the order, it shall be posted on open place and easily seen at the premise stated in the certificate of establishment registration, license or certificate of notification and it shall be deemed that registrant of establishment, licensee or informer of particulars has acknowledged it as from the posting date.

The suspension order or revocation of certificate of establishment registration, license or certificate of notification, may be advertised in newspaper or other means.

Section 73

Subject to Section 46, the revoked person on certificate of establishment registration, license or certificate of notification, may sell the rest of his/her medical device to the other registrant of establishment, licensee or notifier or the person the licensor sees expedient within one hundred eighty days as from the date acknowledging the revoking order of certificate of establishment registration, license or certificate of notification, or the date acknowledging the decision of the Minister, except the licensor shall extend such period.

Chapter 10

Appeal

Section 74

In the event the licensor does not issue the certificate of establishment registration, license or certificate of notification, or does not issue the assessment certification under Section 22 or does not grant permission to renew the certificate of establishment registration, license or certificate of notification, the applicant shall have the right to appeal in writing to the Minister within thirty days as from the date of receiving the notification of non-issuance the certificate of establishment registration, license or certificate of notification, or not issuing the assessment certification under Section 22 or non-renewal of certificate of establishment registration, license or certificate of notification as the case may be.

The decision of the Minister shall be final.

In case where the licensor does not grant permission for renewal of certificate of establishment registration, license or certificate of notification, before the Minister makes a decision on the appeal under the second paragraph, the Minister is empowered to grant permission for temporary operation of the business upon request by the appellant.

Section 75

The registrant of establishment, licensee or notifier whose certificate of establishment registration, license or certificate of notification has been suspended or revoked shall have

the right to appeal in writing to the Minister within thirty days as from the date of acknowledgement of the order.

The appeal under the first paragraph shall not imply an abatement of the suspension or revocation order of certificate of establishment registration, license or certificate of notification.

The decision of the Minister shall be final.

Section 76

The consideration on appeal under Section 74 and Section 75, the Minister may consider the appeal to be in completion within one hundred and twenty days as from the date of receiving the appeal. In case of necessity that it cannot be completed by the time stated, it shall be in a written notifying the appellant to know before the expiration of the time stated and in this matter, it may extended with appeal consideration not over one hundred twenty days as from the date of time expiration.

Chapter 11 Civil Liability

Section 77

The producer, importer or distributor of medical device shall be liable for the damage incurred in use of medical device, except it can be proved that such damage is from force majeure or it does not come from any defect in medical device or from the mistake of the injured person.

Section 78

Any person uses or implements using of medical device to other person causing damage to life, body or hygiene, must be responsible for damage to such person from the medical device, except it can be proved that he/she has performed under the carefulness according to academic standards or such damage is in force majeure or from the injured person's own mistake.

The statement under the first paragraph does not apply with the damage to the mind due to damage to body or hygiene of the injured person.

Section 79

The demand right on damages resulted from the medical device or using of medical device in this chapter shall lose the prescription period after three years as from the date injured person has known about the damage and of the person in charge of compensating the damages but it shall not be exceeding ten years as from the date of damage due to the medical device or use of such medical device.

Section 80

The person who is to liable under Section 77 or Section 78 with damages payment to the injured person has the right of recourse to the person involved in the damage by using recourse within three years as from the date paying the damages but the person in recourse shall exercise it for the excess amount in his/her liability.

Chapter 12 Penalty Provisions

Section 81

The controller of production, importation or distribution of medical device who fails to observe one's duties prescribed by the announcement under Section 6 (7) shall be liable to a fine not exceeding one thousand Baht.

Section 82

Any person who violates the announcement 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 violates the announcement 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 the Committee or Sub-committee's order under Section 13 shall be liable to imprisonment not exceeding one month or a fine not exceeding ten thousand Baht, or both.

Section 85

Any person who produces or imports medical device without having submitted a request for registration of establishment under Section 15, the first paragraph, or Section 18, the first paragraph, 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 86

Any person who produces or imports medical device under Section 6 (1) without having the license under Section 17, the first paragraph, or Section 18, the first paragraph, as the case may be, shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both.

The licensee on production or importation of medical device under Section 6 (1) who fails to comply with Section 17, the third paragraph, or Section 18, the second paragraph, shall be liable to a fine not exceeding one hundred and fifty thousand Baht.

Section 87

Any person who produces or imports medical device under Section 6 (2) without having the certificate of notification under Section 19, the first paragraph, or Section 20, the first paragraph, as the case may be, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The notifier who fails to comply with Section 19, the third paragraph, or Section 20, the second paragraph, shall be liable to a fine not exceeding fifty thousand Baht.

Section 88

The producer, importer, distributor or possessor of medical device under Section 6 (8) who fails to comply with Section 21 or Section 22, the fifth paragraph, as the case may be, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 89

Any person who distributes medical device without having the license under Section 24, the first paragraph, or Section 25, the first paragraph, as the case may be, shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both.

The licensee who distributes medical device who fails to comply with Section 24, the third paragraph, or Section 25, the second paragraph, shall be liable to a fine not exceeding one hundred fifty thousand Baht.

Section 90

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

Section 91

The registrant of establishment, licensee or notifier who produces, imports or distributes medical device after the certificate of establishment registration, license, or certificate of notification has expired but applies for its extension in certificate of establishment registration, license, or certificate of notification, within the time stated under Section 30, the third paragraph, shall be liable to a fine on daily basis of one thousand bath throughout the time during not submitting extension of certificate of establishment registration, license or certificate of notification.

Section 92

The registrant of establishment, licensee or notifier who does not comply with Section 31 shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 93

The registrant of establishment, licensee or notifier who does not comply with Section 32, the first paragraph, shall be liable to a fine not exceeding ten thousand Baht.

Section 94

Producer of medical device for export who does not comply with Section 34, the first paragraph, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Any person who violates Section 34, the second paragraph, shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both.

Section 95

The registrant of establishment under Section 15, licensee under Section 17 or Section 24, or notifier under Section 19 who dissolves business by not complying with Section 36, the first paragraph, shall be liable to a fine not exceeding ten thousand Baht.

Section 96

The registrant of establishment under Section 15, licensee under Section 17 or Section 24, or notifier under Section 19 whose certificate of establishment registration, license, or certificate of notification has expired or the licensor does not allow the extension of certificate of establishment registration, license, or certificate of notification, does not notify under Section 37, the first paragraph, shall be liable to a fine not exceeding ten thousand Baht.

Section 97

The licensee of medical device under Section 24 who has notified on dissolution, expiration of license or the licensor does not allow the extension, does not notify under Section 38, the second paragraph, shall be liable to a fine not exceeding ten thousand Baht.

The licensee on distribution of medical device under Section 24 who notifies on dissolution, expiration of license, or the licensor does not allow the extension in selling medical device at lapse of time under Section 38, the first paragraph, shall be liable to imprisonment not exceeding two years or a fine not exceeding two hundred thousand Baht, or both.

Section 98

Heir of possessor of medical device or administrator under Section 39 who does not notify under Section 38, the second paragraph, shall be liable to a fine not exceeding ten thousand Baht.

Section 99

The registrant of establishment, licensee or notifier who violates Section 40 shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 100

The registrant of establishment, licensee or notifier who does not comply with Section 41 (1) or (2) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The registrant of establishment, licensee or notifier who does not comply with Section 41 (3), (4) or (8) shall be liable to imprisonment not exceeding six months or a fine not exceeding fifty thousand Baht, or both.

The registrant of establishment, licensee or notifier who has made record or report under Section 41 (3) has prepared the report under Section 41 (4) or provide with academic information under Section 41 (8) in false shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The registrant of establishment, licensee or notifier who does not comply with Section 41 (5), (6) or (7) shall be liable to a fine not exceeding one hundred thousand Baht.

Section 101

The producer, importer or distributor of medical device under Section 6 (14) or operator of infirmary in infirmary using medical device who does not comply with Section 42, the first paragraph, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The person under the first paragraph who does not comply with Section 42, the second paragraph, shall be liable to a fine not exceeding fifty thousand Baht.

Section 102

The distributor of medical device under Section 6 (9) or (10) who does not comply with Section 43, the first paragraph, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The person under the first paragraph who does not comply with Section 43, the second paragraph, shall be liable to a fine not exceeding fifty thousand Baht.

Section 103

The registrant of establishment, licensee or notifier who produces or imports of medical device that does not comply with Section 44, the first paragraph, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The person under the first paragraph who does not comply with Section 44, the second paragraph, shall be liable to a fine not exceeding one hundred thousand Baht.

The distributor of medical device who does not comply with Section 44, the third paragraph, shall be liable to a fine not exceeding fifty thousand Baht.

Section 104

The registrant of establishment, licensee or notifier who produces or imports of medical device under Section 6 (13) who that does not comply with Section 45, the first paragraph, shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The person under the first paragraph who does not comply with Section 45, the second paragraph, shall be liable to a fine not exceeding one hundred thousand Baht.

Section 105

Any person who produces or imports counterfeit medical device in violating the Section 46 (1) shall be liable to imprisonment not exceeding ten years or a fine not exceeding one million Baht, or both.

The distributor of fake medical device in violating the Section 46 (1) shall be liable to imprisonment not exceeding five years or a fine not exceeding five hundred thousand Baht, or both.

Section 106

Any person who produces or imports sub-standard medical device in violating the Section 46 (2) shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both.

The distributor of sub-standard medical device in violating the Section 46 (2) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 107

Any person who produces or imports deteriorated medical device in violating the Section 46 (3) shall be liable to imprisonment not exceeding two years or a fine not exceeding two hundred thousand Baht, or both.

The distributor of deteriorated medical device in violating the Section 46 (3) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 108

Any person who produces or imports medical device that is unsafe to use in violating the Section 46 (4) shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both.

The distributor of medical device that is unsafe to use in violating the Section 46 (4) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 109

Any person who produces or imports medical device produced or imported different from those granted by the license or those in the list of particulars in violating the Section 46 (5) shall be liable to a fine not exceeding two hundred thousand Baht.

The distributor of medical device medical device produced or imported different from those granted by the license or those in the list of particulars in violating the Section 46 (5) shall be liable to a fine not exceeding one hundred thousand Baht.

Section 110

Any person who produces or imports medical device that the license or the certificate of notification was revoked in violating the Section 46 (6) shall be liable to imprisonment not exceeding five years or a fine not exceeding five hundred thousand Baht, or both.

The distributor of medical device that the license or the certificate of notification was revoked in violating the Section 46 (6) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 111

Any person produces, imports or supporter of research and the researcher of medical device in need of clinical investigation who does not comply with Section 51 shall be liable to a fine not exceeding five hundred thousand Baht.

Section 112

Any person produces, imports, distributes, possesses or destroys or makes its degeneration of medical device who does not comply with Section 52 shall be liable to a fine not exceeding five hundred thousand Baht.

Section 113

The importer or exporter of medical device who does not comply with Section 53 shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 114

Any person produces, imports or distributes medical device who does not comply with order of the General Secretary under Section 54, the second paragraph, or Section 55 (2) (3) or (5) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

The licensee or informer of particulars who does not comply with the General Secretary's order under Section 55 (2) shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 115

Any person advertises medical device under Section 6 (11) or medical device under Section 46 (1), (2), (3), (4) or (6) in violating the Section 56 shall be liable to imprisonment not exceeding two years or a fine not exceeding two hundred thousand Baht, or both.

Section 116

Any person advertises medical device without the license under Section 57, the first paragraph, shall be liable to imprisonment not exceeding six months or a fine not exceeding fifty thousand Baht, or both.

Section 117

Any person advertises medical device in violating Section 59 shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Section 118

Any advertiser who does not comply with order of the licensor under Section 60 shall be liable to imprisonment not exceeding two years or a fine not exceeding two hundred thousand Baht, or both and daily fine basis at one thousand Baht a day until it shall comply properly.

Section 119

Any person combats or impedes performance of the competent official under Section 61 shall be liable to imprisonment not exceeding one year or a fine not exceeding one hundred thousand Baht, or both.

Any person refuses to give statement, not sending document or necessary evidence under Section 61 (5) without reasonable cause shall be liable to a fine not exceeding ten thousand Baht.

Section 120

The licensee, notifier or person in charge of produce, import, distribute or collection of medical device who does not accord facility to the competent official under Section 63 shall be liable to imprisonment not exceeding six months or a fine not exceeding ten thousand Baht, or both.

Section 121

The registrant of establishment, licensee or notifier who violates Section 67, the second paragraph, shall be liable to imprisonment not exceeding three years or a fine not exceeding three hundred thousand Baht, or both

Section 122

In case the offender who is liable for punishment in this Act is a corporate body, the managing director, manager or person in charge in the implementation of the corporate shall be liable to the punishment as stipulated in such offense, except it can be proved on not knowing it or in agreeing with such offense of the corporate.

Section 123

The offense in this Act shall be liable to a fine only or by imprisonment not exceeding six months, the General Secretary or the designated person is empowered to settle under the rules prescribed by the Committee, and when the alleged offender has paid the fine at the amount settled by thirty days as from the date of settlement, it deems the case is over as stipulated in Criminal Procedure Act.

In case the investigator finds any person committing offense under the first paragraph, and the person agrees to be settled at the case, the investigator shall send the case to the General Secretary or the designated person within seven days as from the date the person agrees to settle.

Transitory Provisions

Section 124

Any person produces or imports medical device under the Medical Device Act, B.E. 2531 (1988) before the date in enforcement of this shall submit for establishment registration under the provisions in this Act within ninety days since this Act is in enforcement and shall continue business until it shall be instructed by the licensor is not granting the certificate of establishment registration. However, the licensor shall consider in completion by one hundred and twenty days as from the date accepting the application. If the time mentioned has elapsed, it deems the applicant has been granted the business registration under this Act.

At the completion of the first paragraph, the license on production or importation issued under the Medical Device Act, B.E. 2531 (1988) before the date in enforcement of this Act shall continue to have its effect until its expiration.

Section 125

License on distribution of medical device issued under the Medical Device Act, B.E. 2531 (1988) before the date in enforcement of this Act shall continue to have its effect until its expiration.

Section 126

Notification on particulars in Medical Device Act, B.E. 2531, before the enforcement date of this Act shall continue its effect for another two years as from the date of this Act into enforcement except for the notification medical device which has been announced to be medical device to seek permission under Section 6 (1) that the notifier has implemented under Section 18.

Section 127

Advertisement of medical device granite with the approval of the General Secretary of the Food and Drug Administration before the enforcement of this Act shall continue its effect at the time period prescribed by the General Secretary of the Food and Drug Administration.

Section 128

The application and notification as submitted or notified under the Medical Device Act, B.E. 2531 and still under the consideration shall deem to be the permission request or

application for notification under this Act by mutatis mutandis. If it has any modification on the permission request or application for notification it shall be made in accordance with this Act.

Section 129

Ministerial Regulation or Notification issued under this Medical Device Act, B.E. 2531 (1988) before this Act in enforcement shall continue its effect as it does not contravene or contradict with the provisions under this Act until it shall be of ministerial regulation or announcement issued under this Act into enforcement.

The implementation of the ministerial regulation or announcement under the first paragraph shall be in completion by two years as from the enforcement date of this Act. If it cannot be implemented, the Minister shall report such cause to the Cabinet.

Countersigned by

General Surayuth Chulanont

Prime Minister

Published in the Government Gazette Volume 125, Part 43 (Gor), dated 5th of March, B.E. 2551 (A.D. 2008)

Rate of Fees

(1) Registration of Establishment	1,000 Baht
(2) License on Production of Medical Device	100,000 Baht
(3) License on Importation of Medical Device	200,000 Baht
(4) License on Distribution of Medical Device	10,000 Baht
(5) License on Advertisement of Medical Device	10,000 Baht
(6) Notification Certificate on Production of Medical Device	50,000 Baht
(7) Notification Certificate on Importation of Medical Device	100,000 Baht
(8) Letter of Certification	2,000 Baht
(9) Certification of Assessment on Medical Device in Section 22	2,000 Baht
(10) Replacement of Registration of Establishment, License, Notification, Certificate, Certificate of Assessment on Medical Device, Section 22	500 Baht
(11) Application for Registration Establishment	100 Baht
(12) Permission Request	1,000 Baht
(13) Application on Notification of Particulars	500 Baht
(14) Application on Removal or Change in Place of Production, Importation, Distribution or Storage of Medical Device	1,000 Baht
(15) Application on Change in Particulars in Registration of Establishment	100 Baht
(16) Application on Change in License Particulars or Other Particulars as permitted	1,000 Baht
(17) Application on Change in particulars in the Notification Certificate or Other notified	500 Baht
(18) Extension of Registration of Establishment equals each copy of fee in Business Registration in that type;	
(19) Extension of License equals to fee in each copy of such license.	
(20) Extension of Notification Certificate equals to fee in each copy of such license.	
(21) Other request at copy	1,000 Baht

In issuing Ministerial Regulation to impose fees may impose the rate of fees to be different by considering with the type, group, category of medical device, in size and business of the operator and category in changing of modifications.

Disclaimer

This translation is intended to help Thais or foreigners to understand Thailand laws and regulations only, not to use as references, because it is only the original Thai version of legislation that carries legal effect. www.ThaiLaws.com, therefore, shall not be held responsible in any way for any damage or otherwise the user may incur as a result of or in connection with any use of this publication for any purposes. It's the responsibility of the user to obtain the correct meaning or interpretation of this publication or any part thereof from Thai version or by making a formal request to the appropriate or related authorities.