(Official Emblem)

Ministerial Regulation

on the Application for, and the Issuance of Manufactured or Imported Notified Medical Device

B.E. 2563 (2020)

By virtue of Section 5, paragraph one, Section 30, paragraph two, Section 31, paragraph two, and Section 32, paragraph two of Medical Device Act B.E. 2551 (2008), and Section 19, paragraph two of Medical Device Act B.E. 2551 (2008), as amended by Medical Device Act (No. 2) B.E. 2562 (2019), the Minister of Public Health has issued the following Ministerial Regulations:

Clause 1 The following shall be repealed:

(1) The Ministerial Regulation on the Application on for, and the Issuance of Manufactured Notified Medical Device B.E. 2555 (2012)

(2) The Ministerial Regulation on the Application on for, and the Issuance of Imported Notified Medical Device B.E. 2555 (2012)

Clause 2 An Establishment Registrant, as a manufacturer or importer of medical devices, who wishes to manufacture or import medical devices under Section 6, subsection (1) (b), shall submit to licensor as followed:

(1) Medical device establishment license number involving in manufacturing or importing of medical device;

(2) For a juristic person applicant, a letter showing that the applicant is appointed or authorized to be a representative to carry on the activities;

(3) Documents describing the name and description of the medical device, medical device labeling, instruction for use, executive summary and manufacturing or product owner information;

(4) Documents describing the essential principles of safety and performance of the medical devices including methods used to demonstrate conformity;

(5) Summary of design verification and validation documents;

(6) Risk analysis documents;

(7) Documents describing methods of destruction, demolition or disposal of waste substances after use;

(8) Certificate of quality system;

(9) Declaration letter describing intended use, indications, packaging, labels, and instructions for use issued by manufacturer or product owner;

(10) Declaration of conformity issued by manufacturer or product owner;

(11) Declaration of market history issued by manufacturer or product owner;

(12) Declaration of safety issued by manufacturer or product owner;

(13) Evidence in support of the permission granted by international regulatory bodies responsible for medical device, which are recognized by Thai Food and Drug Administration; and

(14) Power of attorney issued by product owner appointing the importer.

Any documentation showing a list of medical devices registered as a group shall be submitted along with the applications mentioned in paragraph one.

Clause 3 If necessary, the Secretary-General may exempt the applicant from providing any information, documentation, or evidence specified in clause 2. In this regard, the Secretary-General shall clearly state the reasons thereof.

Clause 4 Upon receiving the application, the licensor shall examine the application, including all of the information, documentation and evidence, whether all are correct and complete. If correct and complete, the licensor will issue a receipt of application to the applicant. In cases of incorrect information or lack of any documentation or evidence, the licensor shall inform the applicant immediately. If this can be corrected or completed at that moment, the licensor shall request the applicant to correct or submit additional information, documentation or evidence. If it is impossible to take such action immediately, the licensor shall record the error and inform the applicant to modify the application or submit the corrected and complete information, documentation or evidence within a designated timeframe. In the cases where the application is not filed by way of electronic means, the licensor and the applicant shall both sign such record.

In cases where the applicant fails to correct the application or provide correct and complete information, documentation or evidence within the timeframe designated by the licensor, it is deemed that the applicant does not wish to proceed with the process and the licensor shall strike the application.

Clause 5 In the cases where the application, including all information, documentation

and evidence, is correct and complete, and the applicant paid the expenses incurred in the processing of granting certificate of notified medical device, the licensor shall finalize the process within two hundred fifty days.

If the licensor rejects the application, a written notice mentioning the reasons and the right to appeal within fifteen days as from the rejection date shall be given to the applicant.

Clause 6 In the cases where the licensor grants the application, a written notice shall be given to the applicant and the applicant shall pay the certificate of notified medical device fee within sixty days after the notice is received. Following the payment, the licensor shall issue the certificate of notified medical device within seven days as from the receipt of the payment.

If the applicant fails to pay the certificate of notified medical device fee within the timeframe specified in paragraph one, it shall be deemed that the applicant does not wish to receive the certificate of notified medical device and the licensor shall strike the application.

Clause 7 The registrant regarding manufactured or imported notified medical devices, who wishes to renew certificate of notified medical device, shall file with the licensor an application for renewal of the certificate of notified medical device before its expiry date, together with the certificate of notified medical device, information, documentation or other evidence as required in the application for renewal of the certificate of notified medical device form. A renewal fee must be paid during this process.

The provisions of clauses 3, 4 and 5 shall be applied *mutatis mutandis* to the notification, submission, consideration and approval of an application for renewal of the Certificate of notified medical device.

Clause 8 In the event that the establishment licensee, as the manufacturer or importer of medical devices, is permitted to amend the following approved items in the medical device manufacturing or importing establishment license, it shall be deemed that the registrant regarding manufactured or imported notified medical devices is permitted to amend such items in the certificate of notified medical device as from when the amendment of the items in the medical device manufacturing or importing establishment license is granted.

(1) Name of the establishment registrant; and

(2) Name or address of the premises manufacturing or importing medical devices.

Clause 9 The registrant regarding manufactured or imported notified medical devices, who wishes to amend approved items in the certificate of notified medical device, other than those contained in clause 8, shall submit to the licensor an application for amendment to approved Items in the certificate of notified medical device, along with information,

documentation or evidence relevant to the items requested to be amended and other documentation or evidence as required in the application for amendment to approved Items in the certificate of notified medical device form.

The provisions in Clauses 3, 4 and 5 shall be applied *mutatis mutandis* to the notification, submission, consideration and granting of the application for amendment to approved Items in the certificate of notified medical device.

Clause 10 In cases of loss, destruction or damage of the certificate of notified medical device, the registrant shall file an application for the substitution certificate of notified medical device with the licensor within fifteen days, as from acknowledgement of the loss, destruction or damage. It is required to return and submit the damaged certificate of notified medical device or a report from the police regarding the loss or destruction of the certificate of notified medical device, as the case may be, to the licensor.

The provisions in clauses 4 and 5, paragraph one and clause 6 shall be applied *mutatis mutandis* to the licensor's consideration of the application for the duplicated certificate of notified medical device and issuance of the duplicated certificate of notified medical device.

Clause 11 In order to facilitate the processes under this Ministerial Regulation, the licensor may give notice to the applicant and the registrant by way of electronic means, along with the written notice.

Clause 12 The application, certificate of notified medical device and duplicated certificate of notified medical device hereunder shall be in accordance with as prescribed by the Secretary-general, with the agreement from the committee, as published in Government Gazette.

Clause 13 The filing of the application, granting of the certificate of notified medical device, renewal of the certificate of notified medical device, amendment to approved items in the certificate of notified medical device and issuance of the duplicated certificate of notified medical device hereunder shall be carried out mainly by way of electronic means. During any period where electronic means is not available, the application shall be filed with Medical Device Control Division at Food and Drug Administration, Ministry of Public Health or other premises prescribed by the Secretary-General, as published in Government Gazette.

Clause 14 The following certificates of notified medical device shall remain effective until their expiration or revocation: the certificate of manufactured notified medical device, issued under the Ministerial Regulation on the Application for, and the Issuance of Manufactured Notified Medical Device B.E. 2555 (2012); or the certificate of imported notified medical device, issued under the Ministerial Regulation on the Application for, and the Issuance of Imported Notified Medical

Device B.E. 2555 (2012), whereby both of them are issued as from the enforcement date of the Medical Device Act (No. 2) B.E. 2562 (2019) to the day prior to the enforcement date of this Ministerial Regulation.

Clause 15 Applications, which are filed under the Ministerial Regulation on the Application for, and the Issuance of Manufactured Notified Medical Device B.E. 2555 (2012), or the Ministerial Regulation on the Application for, and the Issuance of Imported Notified Medical Device B.E. 2555 (2012), before the enforcement date of this Ministerial Regulation; and which are pending for a licensor's consideration, shall be deemed *mutatis mutandis* as the application under this Ministerial Regulation.

In the event that an application under paragraph one differs from the application hereunder, the licensor has the power to order the applicant to make an amendment or submit additional information, documentation or evidence, as necessary, to ensure compliance with this Ministerial Regulations.

Issued on 22 December 2020.

Anutin Charnvirakul

Minister of Public Health

(Unofficial Translation)

Remarks: The reason for the issuance of this Ministerial Regulation is as followed: Pursuant to section 19, paragraphs one and two of Medical Device Act B.E.2551 (2008), as amended by the Medical Device Act (No. 2) B.E. 2562 (2019), it is stipulated that an establishment licensee, who wishes to manufacture or import medical devices under section 6, subsection (1) (b), shall file an application for the certificate of notified medical device. After the issuance of the certificate of notified medical device by the licensor, the manufacture or importation of such medical device is permitted. Since the registration and issuance of the certificate of notified medical device shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulation, it is appropriate to modify the Ministerial Regulation on the Application for, and the Issuance of Manufactured Notified Medical Device B.E. 2555 (2012) and the Ministerial Regulation on the Application for, and the Issuance of Imported Notified Medical Device B.E. 2555 (2012). In order to ensure conformity with such provisions and to be able to enforce the laws, it is necessary to enact this Ministerial Regulation.