(Official Emblem)

Ministerial Regulations

on the Application for, and the Issuance of Manufactured or Imported Licensed 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 17, 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Clause 1 The following shall be repealed: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 Application for, and the Issuance of Manufactured Licensed Medical Device B.E. 2555 (2012).

(2) The Ministerial Regulation on Application for, and the Issuance of Imported Licensed 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) (a), shall submit to the 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 assigned 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 is 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 correct 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 the certificate of licensed medical device, the licensor shall finalize within three hundred days.

If the licensor rejects the application, a written notice mentions 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 license fee within sixty days after the notice is received. Following the payment, the licensor shall issue the certificate of licensed medical device within seven days as from the receipt of the payment.

If the applicant fails to pay the certificate of licensed 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 licensed medical device and the licensor shall strike the application from the list.

Clause 7 The registrant regarding manufactured or imported licensed medical device, who wishes to renew the certificate of licensed medical device, shall file with the licensor an application for renewal of the certificate of licensed medical device before its expiry date, together with the certificate of licensed medical device, information, documentation, or other evidence as required in the application for renewal of the certificate of licensed 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 granting of an application for renewal of the certificate of licensed 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 licensed medical devices is permitted to amend such items in the certificate of licensed 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 licensed medical devices, who wishes to amend approved items in the certificate of licensed 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 licensed 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 licensed 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 licensed medical device.

Clause 10 In cases of loss, destruction, or damage of the certificate of licensed medical device, the registrant shall file an application for the substitution certificate of licensed medical device with the licensor within fifteen days, as from acknowledgment of the loss, destruction, or damage. It is required to return and submit the damaged certificate of licensed medical device or a report from the police regarding the loss or destruction of the certificate of licensed 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 licensed medical device and issuance of the duplicated certificate of licensed 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 licensed medical device, and duplicated certificate of licensed medical device hereunder shall be in accordance as prescribed by the Secretary-General, with the agreement of committee, as published in Government Gazette.

Clause 13 The filing of the application, granting of the certificate of licensed medical device, renewal of the certificate of licensed medical device, amendment to approved items in the certificate of licensed medical device, and issuance of the duplicated certificate of licensed 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 certificate of licensed medical device shall remain effective until their expiration or revocation: the certificate of manufactured licensed medical device, issued under the Ministerial Regulation on the Application for, and the Issuance of Manufactured Licensed Medical Device B.E. 2555 (2012); or the certificate of imported licensed medical device, issued under the Ministerial Regulation on the Application for, and the Issuance of Imported

Licensed Medical Device B.E. 2555 (2012), whereby both of them are issued as from the enforcement date of 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 Licensed Medical Device B.E. 2555 (2012), or the Ministerial Regulation on the Application for, and the Issuance of Import Licensed Medical Device B.E. 2555 (2012) before the enforcement date of this Ministerial Regulation, and which are pending for the 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 Regulation.

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 17, paragraphs one and two of the Medical Device Act B.E. 2551 (2008), as amended by 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) (a), shall file an application for the certificate of licensed medical device. After the issuance of the certificate of licensed medical device by the licensor, the manufacture or importation of such medical device is permitted. Since the registration and issuance of the certificate of licensed 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 Licensed Medical Device B.E. 2555 (2012) and the Ministerial Regulation on Application for, and Issuance of Imported Licensed 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.