(Official Emblem)

Ministerial Regulation

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

B.E. 2563 (2020)

By virtue of Section 5, paragraph one of Medical Device Act B.E. 2551 (2008) and Section 19, paragraph two of the 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 This Ministerial Regulation shall come into force after the period of thirty days from its publication in Government Gazette.

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) (C), 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 authorized to be a representative to carry on the activities;

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

(4) Documents describing the history of international registrations in cases where the registrations are granted in foreign countries;

(5) Documents describing sterilization validation test in cases of manufacture or importation of sterilized medical devices;

(6) Documents describing a test or a calibration test in cases of manufacture or importation of medical devices having a measuring function;

(7) Declaration of Conformity issued by manufacturer or product owner; and

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

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 listed medical device, the licensor shall finalize the process within two 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 certificate of listed medical device fee within sixty days after the notice is received. Following the payment, the licensor shall issue the certificate of listed medical device within seven days as from the receipt of the payment.

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

Clause 7 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 8 The application, certificate of listed medical device and duplicated certificate of listed 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 9 The filing of the application and the listed 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 the Medical Device Control Division at the Food and Drug Administration, the Ministry of Public Health or at other premises prescribed by the Secretary-General, as published in Government Gazette.

Clause 10 Certificates of imported medical device, which are issued under the Food and Drug Administration's Regulation B.E. 2550 (2007), regarding the criteria for certificates of imported medical devices and the importation of medical devices exempt from presenting these certificates to competent officials at food and drug checkpoints, 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, shall remain effective until their expiration or cancellation.

Clause 11 Applications, which are filed under the Food and Drug Administration's Regulation B.E. 2550 (2007), regarding the criteria for certificates of imported medical devices and the importation of medical devices exempt from presenting these certificates to competent officials at food and drug checkpoints, 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

Remarks: The reason for the issuance of this Ministerial Regulation is as followed: Pursuant to Section 19, paragraphs one and two of the 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 Registrant, who wishes to manufacture or import medical devices under Section 6, subsection (1) (c), shall file an application for listed medical device. After the issuance of the certificate of listed medical device by a licensor, the manufacture or importation of such medical device is permitted. To ensure that the registration and the issuance of the certificate of listed medical device are in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulation, it is necessary to enact this Ministerial Regulation.