(Garuda Emblem)

Ministerial Regulations
On the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices
B.E. 2563 (2020)

By virtue of section 5, paragraph one of the Medical Device Act, B.E. 2551 (2008), and section 19, paragraph two of the Medical Device Act, B.E. 2551 (2008), as amended by the Medical Device Act (No. 2), B.E. 2562 (2019), the Minister of Public Health issues the following ministerial regulations.

Clause 1 These Ministerial Regulations will take effect 30 days after issuance in the *Government Gazette*.

Clause 2 Registrants of establishments involved in the manufacturing or import of medical devices who intend to manufacture medical devices under section 6(1)(c) must submit their registration applications to the licensor, together with the following documents or evidence.

(1) The registration number of the establishment involved in the manufacturing or import of medical devices.

(2) For a juristic person applicant, certification that the person submitting the registration application is appointed or authorized by the juristic person to carry on the activity.

(3) A list of the names and description of the medical devices; the labels and specifications of the medical devices; information about the manufacturing or information about the product owner; and if applicable, any labelling documentation regarding the medical devices.

(4) Documentation of overseas registration, in the case that they have been registered overseas.

(5) Documentation of sterilization testing, for the manufacturing or import of sterilized medical devices.

(6) Documentation of testing or calibration testing, for the manufacturing or import of medical measuring devices.

(7) Declaration of conformity issued by the product manufacturer or product owner.

(8) For application regarding import of medical devices, a power of attorney issued by the product owner appointing the importer.

Clause 3 The secretary-general may exempt the applicant from providing any information, documentation, or evidence indicated in clause 2, if necessary. In this case, the secretary-general must provide explicit rationale.

Clause 4 Once the licensor receives the registration application, they must examine the correctness and completeness of the application and the supporting information, documentation, and evidence. If they are correct and complete, the licensor will issue a receipt of the application to the applicant. However, if the application is incorrect or any information, document, or evidence is missing, the licensor must notify the applicant immediately. If this can be corrected or completed at that moment, the licensor must tell the applicant make the correction or submit additional information, documents, or evidence. If the correction or

additional submission cannot be made at that moment, the licensor must record the incompleteness, and tell the applicant to modify their application, or submit additional information, documents, or evidence within the timeframe indicated by the licensor to ensure the correctness and completeness of the application. If the application is not submitted via the electronic channel, the licensor and the applicant must sign to certify the record.

If the applicant refuses to correct the application, or fails to submit additional correct and complete information, documents, or evidence, within the timeframe specified by the licensor, the applicant will be deemed to refuse to continue with the process. In this case, the licensor can dispose of the matter.

Clause 5 If the application and the supporting information, documentation, and evidence are correct and complete, and the applicant has paid the application fees, the licensor must complete the consideration process within 200 days.

If the licensor rejects the application, he or she must send written notice to the applicant, giving the reasons, and granting the applicant the right to appeal the decision, within 15 days after the date the application is rejected.

Clause 6 If the licensor approves the application, he or she must send written notice to the applicant, informing the applicant to pay the registration certification fees within 60 days after the notice is received. Once the applicant has paid the fees, the licensor will issue the certificate within seven days after the date the fees are received.

If the applicant fails to pay the certification fee within the timeframe stipulated in the first paragraph, the applicant will be deemed to no longer want the certificate. In this case, the licensor can dispose of the matter.

Clause 7 To facilitate the registration application process under these ministerial regulations, in addition to written notice, the licensor may send notice via an electronic channel to the applicant or registrant of the manufacturing or import of medical devices.

Clause 8 A registration application and the certificate of registration issued under these ministerial regulations must be in the form stipulated by the secretary-general and announced in the *Government Gazette*.

Clause 9 The submission of a registration application, and registration under these ministerial regulations must mainly proceed via electronic means. However, if electronic submission is impracticable, the application must be submitted to the Medical Device Control Division, the Office of the Food and Drug Administration, the Ministry of Public Health, or other places stipulated by the secretary-general in the *Government Gazette*.

Clause 10 The certificate of the import of medical devices issued under the Regulations of the Food and Drug Administration re: Criteria of Certificates Used in Medical Device Import, and the Import of Medical Devices of Which the Certificates are Exempted from Being Presented to Officials at the FDA Import and Export Inspection Division, B.E. 2550 (2007), from the date of the enactment of the Medical Device Act (No. 2), B.E. 2562 (2019) up to the date before the date these ministerial regulations take effect will remain in full force and effect until it expires or is revoked.

Clause 11 An application submitted under the Regulations of the Office of the Food and Drug Administration re: Criteria of Certificates Used in Medical Device Import, and the Import of Medical Devices of Which the Certificates are Exempted from Being Presented to Officials at the FDA Import and Export Inspection Division, B.E. 2550 (2007), before the date these ministerial regulations take effect and while the

consideration process is ongoing will be deemed as an application under these ministerial regulations, *mutatis mutandis*.

If there is any discrepancy between the application mentioned in the first paragraph and the application described in these ministerial regulations, the licensor has the authority to ask the applicant to amend the given particulars, or provide additional information, documents, or evidence as necessary to ensure compliance with these ministerial regulations.

Issued on 22 December 2020

Anutin Charnvirakul

Minister of Public Health

Remarks: Under section 19, paragraph one and pargraph 2, of the Medical Device Act, B.E. 2551 (2008), as amended by the Medical Device Act (No. 2), B.E. 2562 (2019), any registrant of an establishment involved in the manufacturing or import of medical devices who intend to manufacture or import medical devices under section 6(1)(c) must submit their application for registration. Only after the certificate of registration has been granted, will they be allowed to manufacture or import the medical devices. The registration and issuance of the certificate of registration must comply with the rules, procedures, and conditions prescribed in the ministerial regulations. Therefore, these ministerial regulations are hereby implemented.