(Garuda Emblem)

Ministerial Regulations
On the Application for, and the Issuance of, a Medical Device Manufacturing License or a Medical Device Import License
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 the Medical Device Act, B.E. 2551 (2008), and section 17, paragraph two of the 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Clause 1 The following ministerial regulations will be repealed.

(1) The Ministerial Regulations on the Application for, and the Issuance of a Medical Device Manufacturing License, B.E. 2555 (2012)

(2) The Ministerial Regulations on the Application for, and the Issuance of a Medical Device Import License, B.E. 2555 (2012)

Clause 2 Registrants of establishments involved in the manufacturing or import of medical devices who intend to manufacture or import medical devices under section 6(1)(a) must submit their 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 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 documentation, and the summary of the medical devices; and information about the manufacturing or information about the product owner.

(4) Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity.

(5) Summary of design verification and validation documents.

(6) Documentation showing risk analysis.

(7) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use.

(8) Certification of quality systems.

(9) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner.

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

(11) Certification showing the history of the sale of medical devices by the product manufacturer or owner.

(12) Certification of safety and security offered by the product manufacturer or owner.

(13) Certification of permission issued by authorities in charge of, and with the power to engage in, the supervision over medical devices in the relevant foreign country; these authorities must be accepted by the Office of the Food and Drug Administration.

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

Any documentation showing a list of medical devices registered in group registration must be submitted together with the application described in the first paragraph.

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

Clause 4 Once the licensor receives the 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. On the other hand, 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 inform the applicant to make the correction or submit additional information, documents, or evidence. On the other hand, if the correction or additional submission cannot be made at that moment, the licensor must record the incompleteness, and inform 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 300 days.

If the licensor rejects the application, the licensor 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, telling the applicant to pay the license fees within 60 days after the notice is received. Once the applicant has paid the license fees, the licensor will issue the license within seven days after the date the fees are received.

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

Clause 7 Any medical device manufacturing licensee or medical device import licensee wishing to apply for the renewal of their license must submit their application to the licensor before the

expiration date of the license, together with the license, and other information, documents, or evidence as indicated in the license renewal application form, and must pay renewal fees to support the application.

The provisions in clause 3, clause 4, and clause 5 will apply to the license renewal application, and the submission, consideration, and approval of the license renewal application *mutatis mutandis.*

Clause 8 If the registrant of an establishment involved in the manufacturing or import of medical devices is permitted to amend any of the following particulars, which have been approved and provided in the establishment registration certificate, the medical device manufacturing licensee or medical device import licensee will be deemed to have been permitted to amend the particulars given in the medical device manufacturing license or the medical device import license, beginning from the date the amendments of the particulars in the establishment registration certificate are permitted.

(1) The name of the registrant of the establishment involved in the manufacturing or import of medical devices.

(2) The name or location of the facility used for the manufacturing or import of medical devices.

Clause 9 Any medical device manufacturing licensee or medical device import licensee wishing to amend any particular approved and provided in their license other than those indicated in clause 8 must submit a request for permission for the amendment to the licensor, together with information, documents, or evidence relevant to the particulars they wish to amend, and other documents or evidence as stipulated in the amendment request form.

The provisions in clause 3, clause 4, and clause 5 will apply to the preparation, submission, consideration, and approval of the request to amend the particulars in the license *mutatis mutandis*.

Clause 10 If the license is lost, destroyed, or damaged, the medical device manufacturing licensee or medical device import licensee must submit a request for a license substitute within 15 days after their acknowledgement of the loss, destruction, or damage. To support the request, the licensee must return the damaged license, or present evidence of police report of its loss or destruction.

The provisions in clause 4; clause 5, paragraph one; and clause 6 will apply to the consideration and approval of the request for the license substitute *mutatis mutandis*.

Clause 11 To facilitate the application process under these ministerial regulations, in addition to written notice, the licensor may send notice via an electronic channel to the applicant and the medical device manufacturing licensee or medical device import licensee.

Clause 12 An application or request, and the license and license substitute made and issued under these ministerial regulations, must be prepared in the format stipulated by the secretary-general, with agreement from the competent committee, and announced in the *Government Gazette*.

Clause 13 The submission of an application or request, permission, license renewal, amendments to the particulars given in a license, and issuance of a license substitute under these ministerial regulations must mainly proceed via electronic means. However, if the electronic submission is impracticable, these documents 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 by publishing in the *Government Gazette*.

Clause 14 A medical device manufacturing license issued under the Ministerial Regulations on the Application for, and the Issuance of a Medical Device Manufacturing License, B.E. 2555 (2012), or a medical device import license issued under the Ministerial Regulations on the Application for, and the

Issuance of a Medical Device Import License, B.E. 2555 (2012), from the date of the issuance 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 15 An application submitted under the Ministerial Regulations on the Application for, and the Issuance of a Medical Device Manufacturing License, B.E. 2555 (2012), or the Ministerial Regulations on the Application for, and the Issuance of a Medical Device Import License, B.E. 2555 (2012), 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 17, paragraph one and pargraph two, 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)(a) must submit their application for a license. Only after the license has been granted, will they be allowed to manufacture or import the medical devices. The application for, and issuance of the license must comply with the rules, procedures, and conditions prescribed in the ministerial regulations. Therefore, the Ministerial Regulations on the Application for, and the Issuance of a Medical Device Manufacturing License, B.E. 2555 (2012), and the Ministerial Regulations on the Application for, and the Issuance of a Medical Device Import License, B.E. 2555 (2012), should be revised to be in line with the aforementioned provisions, and for the purpose of legal enforcement. Therefore, these ministerial regulations are hereby implemented.