(Official Emblem)

Notification of the Food and Drug Administration

Re: Designation of Unrequired Submission of Information, Documentation, or Evidence under the Ministerial Regulation on the Application for, and the Issuance of Manufactured or Imported Licensed Medical Device
B.E. 2564 (2021)

To prevent a shortage of medical devices and to facilitate processes in the submission of the application for the certificate of manufactured or imported licensed medical device during the period of modifying risk levels of medical devices, under the Medical Device Act (No. 2) B.E. 2562 (2019), applicant is not required to submit information, documentation or evidence under the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December 2020, as necessary and appropriate.

By virtue of Clause 3 of the Ministerial Regulation on the Application for, and the Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, the Secretary-General of the Food and Drug Administration issued a notification as followed:

Clause 1 An establishment registrant as a manufacture of medical devices, whose manufacturing establishment license expires on 31 December, 2021; or an establishment registrant as an importer of medical devices, whose certificates of Imported medical devices remains effective for a period not exceeding one year as from the enforcement of this notification who wishes to modify risk level of medical devices pursuant to the Ministry of Public Health's notification Re: A Group of Medical Devices or Medical Devices Requiring Certificate of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 29 December, 2020, shall submit the application to the licensor, whereby the submission of the following information, documentation or evidence as stated in the Ministerial Regulation on the

Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, is not required:

(1) An executive summary under Clause 2, subsection (3) thereof;

(2) Documents describing the essential principles of safety, performance of the medical devices and methods used to demonstrate conformity under Clause 2, subsection (4) thereof;

(3) Summary of design verification and validation documents under Clause 2, subsection (5) thereof;

(4) Risk analysis documents under Clause 2, subsection (6) thereof;

(5) Documents describing methods of destruction, demolition or disposal of waste substances after use under Clause 2, subsection (7) thereof;

(6) Certificate of quality system under Clause 2, subsection (8) thereof;

(7) Declaration letter describing intended use, indications, packaging, labels, and instructions for use issued by manufacturer or product owner under Clause 2, subsection (9) thereof;

(8) Declaration of market history issued by manufacturer or product owner under Clause 2, subsection (11) thereof;

(9) Declaration of safety issued by manufacturer or product owner under Clause 2, subsection (12) thereof; and

(10) Evidence in support of the permission granted by international regulatory bodies responsible for medical device, which are recognized by Thai Food and Drug Administration under Clause 2, subsection (13) thereof.

Clause 2 An establishment registrant, as a manufacturer or importer of medical devices, other than as mentioned in Clauses 1 and 3, who wishes to apply for the certificate of licensed medical device, shall submit the application to the licensor, whereby the submission of the following information, documentation or evidence as stated in the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, is not required, within the period of three years as from the enforcement date of this notification.

(1) Documents describing the essential principles of safety and performance of the medical devices including methods used to demonstrate conformity under Clause 2, subsection (4) thereof;

(2) Summary of design verification and validation documents under Clause 2, subsection (5) thereof;

(3) Documents describing methods of destruction, demolition or disposal of waste substances after use under Clause 2, subsection (7) thereof;

(4) Declaration letter describing intended use, indications, packaging, labels, and instructions for use issued by manufacturer or product owner under Clause 2, subsection (9) thereof;

(5) Declaration of market history issued by manufacturer or product owner under Clause 2, subsection (11) thereof;

(6) Declaration of safety issued by manufacturer or product owner under Clause 2, subsection (12) thereof; and

(7) Evidence in support of the permission granted by international regulatory bodies responsible for medical device, which are recognized by Thai Food and Drug Administration under Clause 2, subsection (13) thereof.

In cases where there are documents describing methods of destruction, demolition or disposal of waste substances after use under Clause 2, subsection (7) of the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, such documents shall be submitted along with the application.

Clause 3 An establishment registrant who wishes to submit the application for the certificate of licensed medical device as followed:

(1) HIV-related test kits under the Ministry of Public Health's Notification Re: HIV-Related Test Kit, dated 2 November, 2009 and the Ministry of Public Health's Notification Re: HIV-Related Test Kit (No. 2) B.E. 2562 (2019), dated 19 March, 2019.

(2) HIV self-testing kits under the Ministry of Public Health's Notification Re: HIV Self-Testing Kit B.E. 2562 (2019), dated 19 March, 2019.

(3) Hyaluronic acid for correction of skin problems under the Ministry of Public Health's Notification Re: Hyaluronic Acid for Correction of Skin Problems B.E. 2562 (2019), dated 9 August, 2019.

(4) Silicone breast implants under the Ministry of Public Health's Notification Re: Silicone Breast Implants B.E. 2562 (2019), dated 7 November, 2019.

(5) Human blood bags under the Ministry of Public Health's Notification Re: Human Blood Bags, dated 9 March, 2016.

(6) Condoms under the Ministry of Public Health's Notification Re: Condoms B.E. 2556 (2013), dated 18 September, 2013.

(7) Ophthalmic Viscosurgical Devices (OVD) under the Ministry of Public Health's Notification Re: Ophthalmic Viscosurgical Devices (OVD) B.E. 2557 (2014), dated 24 November, 2014.

To submit the application to the licensor in accordance with paragraph one, the following information, documentation or evidence, as stated in the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, is not required, within the period of three years as from the enforcement date of this notification:

1) Documents describing methods of destruction, demolition or disposal of waste substances after use under Clause 2, subsection (7) thereof;

2) Declaration letter describing intended use, indications, packaging, labels, and instructions for use issued by manufacturer or product owner under Clause 2, subsection (9) thereof;

3) Declaration of market history issued by manufacturer or product owner under Clause 2, subsection (11) thereof;

4) Declaration of safety issued by manufacturer or product owner under Clause 2, subsection (12) thereof; and

5) Evidence in support of the permission granted by international regulatory bodies responsible for medical device, which are recognized by Thai Food and Drug Administration under Clause 2, subsection (13) thereof.

In cases where there is documentation or evidence under paragraph two, it shall be submitted along with the application.

Clause 4 The notified medical device registrant regarding manufactured or imported Ophthalmic Viscosurgical Devices (OVD), which is classified as licensed medical device pursuant to the Ministry of Public Health's notification Re: A Group of Medical Devices or Medical Devices Requiring Certificate of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 29 December 2020, whose registration was granted before the enforcement date of this notification, and wishes to continue business, shall submit the application for the certificate of licensed medical device in accordance with the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020 before the expiry date of the certificate of notified medical device, whereby

submission of information, documentation or evidence under Clause 2 of the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020, is not required.

Following the submission of such application within the designated timeframe, the licensor shall issue the certificate of licensed medical device, whereby it is deemed that the formerly submitted documents in support of the notified medical device must become *mutatis mutandis* approved under the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020.

Clause 5 In cases where the registrant, who wishes to renew the certificate of manufactured or imported licensed medical device pursuant to this notification, shall submit the required complete information, documentation or evidence as stipulated in Clause 2 of the Ministerial Regulation on the Application for, and Issuance of Manufactured or Imported Licensed Medical Device B.E. 2563 (2020), dated 22 December, 2020.

Clause 6 This notification shall come into force upon its publication in Government Gazette.

Issued on 2 February, 2021.

Paisarn Dunkum

Secretary-General

Food and Drug Administration