(Official Emblem)

Notification of the Food and Drug Administration

Re: Designation of Unrequired Submission of Information, Documentation or Evidence under the Ministerial Regulation on Application for, and the Issuance of Manufactured or Imported Notified 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 notified 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 the Issuance of Manufactured or Imported Notified Medical Device B.E. 2563 (2020), as necessary and appropriate.

By virtue of Clause 3 of the on the Ministerial Regulation on the Application for, and the Issuance of Manufactured or Imported Notified 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 the manufacture of medical devices, whose Medical Device Manufacturing Establishment Registration expires on 31 December 2021; or an Establishment Registration for the importation of medical devices, whose Certificate for Import of Notified Medical Devices remains effective for a period not exceeding one year as from the enforcement of this Notification, may request the change of a medical device's risk level pursuant to the Ministry of Public Health's Notification Re: A Group of Medical Devices or Medical Devices Requiring Certificate of Manufactured or Imported Notified Medical Device (No. 2) 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 Notified 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 and performance of the medical devices including 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 the manufacture or importation of medical devices, other than as mentioned in Clauses 1 and 3, who wishes to apply for registration, shall file an Application with 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 Notified 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) Risk analysis documents under Clause 2, subsection (6) thereof;

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

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

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

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

(8) 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 Notified 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 wish to submit the application for the certificate of Notified medical device as followed:

(1) Surgical gloves under the Ministry of Public Health's Notification Re: Surgical Gloves (No. 31), dated 10 May 2004.

(2) HIV-related test kits under the Ministry of Public Health's Notification Re: HIV-Related Test Kit, dated 2 November 2009.

(3) Contact lenses under the Ministry of Public Health's Notification Re: Contact Lenses, dated 31 August 2010.

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

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

(6) Methamphetamine test devices (urine) under the Ministry of Public Health's Notification Re: Methamphetamine Test Devices (Urine) B.E. 2556 (2013), dated 17 September

2013, and the Ministry of Public Health's Notification Re: Methamphetamine Test Device (Urine) (No. 2) B.E. 2559 (2016), dated 26 September 2016.

(7) Concentrate for haemodialysis under the Ministry of Public Health's Notification Re: Concentrate for Haemodialysis, dated 3 October 2017.

(8) Teeth-whitening products under the Ministry of Public Health's Notification Re: Teeth-Whitening Products Designated as Medical Devices B.E. 2561 (2018), dated 27 August 2018.

(9) Contact lens care products under the Ministry of Public Health's Notification Re: Contact Lens Care Products B.E. 2562 (2019), dated 3 April 2019.

(10) Alcohol-based disinfection products for humans, animals and medical devices under the Ministry of Public Health's Notification Re: Alcohol-Based Disinfection Products for Humans, Animals and Medical Devices B.E. 2562 (2019), dated 9 August 2019.

(11) Physical therapy devices or products under the Ministry of Public Health's Notification Re: A Group of Medical Devices or Medical Devices Requiring Certificate of Manufactured or Imported Notified Medical Device B.E. 2563 (2020) , dated 31 January 2020.

To submit of the Applications with the licensor under paragraph one, the following information, documentation or evidence, as stated in the Ministerial Regulation on Application for, and issuance of Manufacture or Importation Notified Medical Devices B.E. 2563 (2020), dated 22 December 2020, 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 Licensed medical device registrant regarding manufactured or imported of surgical gloves, condoms, contact lenses, and HIV-related test kits, which are classified as a Notified medical device pursuant to the Ministry of Public Health's Notification Re: A Group of Medical Devices or Medical Devices Requiring certificate of Manufacturer or Importer of Notified Medical Device (No. 2) B.E. 2563 (2020), dated 29 December 2020, whose registration was granted before the enforcement date of this Notification, and wish to continue business, shall submit the application for certificate of Notified medical device in accordance with the Ministerial Regulation on Application for, and Issuance of Manufactured or Imported Notified Medical Device B.E. 2563 (2020), dated 22 December 2020, before the expiry date of certificate of Notified medical device, whereby submission of information, documentation or evidence under Clause 2 of the Ministerial Regulation on Application for, and Issuance of Manufactured or Imported Notified 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 Notified Medical Device, whereby the formerly submitted documents in support of the license medical device are deemed *mutatis mutandis* approved under the Ministerial Regulation on Application for, and issuance of Manufacture or Importation Notified Medical Devices 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 notified medical device pursuant to this this notification, shall submit the required complete information, documentation or evidence as stipulated in Clause 2 of the Ministerial Regulation on Application for, and issuance of Manufacture or Importation Notified Medical Devices 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