Notification of the Office of the Food and Drug Administration
re: No Requirement for Declarer of Specifications Regarding the Manufacturing or Import of Medical Devices, to Submit Information, Documents, or Evidence as Required under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices
B.E. 2564 (2021)

To prevent a shortage of medical devices, and to facilitate the submission of applications to declare specifications regarding the manufacturing or import of medical devices, during the period of adjustment to risk levels with regard to the control over medical devices pursuant to the Medical Device Act (No. 2), B.E. 2562 (2019), applicants are not required to submit information, documents, or evidence under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, dated 22 December 2020, as reasonable and necessary.

By virtue of clause 3 of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, dated 22 December 2020, the Secretary-General of the Food and Drug Administration issues the following Notification.

Clause 1 Registrants of establishments involved in the manufacturing of medical devices whose registration certificates expire on 31 December 2021, or registrants of establishments involved in the import of medical devices whose import certificates will expire no longer than one year after this Notification takes effect wishing to modify the level of control over medical devices, in accordance with the Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which Manufacturers and Importers Must Declare Specifications (No. 2), dated 29 December 2020, shall submit their requests to declare specifications to the licensor without having to provide the following information, documents, or evidence.

(1) Summary of medical devices as required under clause 2(3) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(2) Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity, as required under clause 2(4) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(3) Summary of design verification and validation documents, as required under clause 2(5) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(4) Documentation showing risk analysis, as required under clause 2(6) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(5) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the

Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(6) Certification of quality systems as required under clause 2(8) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(7) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(8) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(9) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(10) 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 accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

Clause 2 Registrants of establishments involved in the manufacturing or import of medical devices other than those indicated in clause 1 and clause 3 who wish to declare specifications must submit the application for declaration of specifications to the licensor without having to provide the following information, documents, or evidence, within three years after the date this Notification takes effect.

(1) Documentation showing essential principles of safety and performance of medical device and method used to demonstrate conformity, as required under clause 2(4) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(2) Summary of design verification and validation documents, as required under clause 2(5) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(3) Documentation showing risk analysis, as required under clause 2(6) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the

Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(4) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(5) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(6) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(7) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(8) 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 accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

However, if the applicant has any documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020, it must be submitted together with the application.

Clause 3 For registrants of establishments involved in the manufacturing or import of any of the following medical devices who wish to declare specifications:

(1) surgical gloves, pursuant to the Notification of the Ministry of Public Health (No. 31), B.E. 2547 (2004) re: Surgical Gloves, dated 10 May 2004;

(2) HIV-related test kits pursuant to the Notification of the Ministry of Public Health re: HIV-Related Test Kits, dated 2 November 2009;

(3) contact lenses, pursuant to the Notification of the Ministry of Public Health re: Contact Lenses, dated 31 August 2553 (2010);

(4) condoms, pursuant to the Notification of the Ministry of Public Health re: Condoms, dated 18 September 2013;

(5) viscoelastic substances used in eye surgeries, pursuant to the Notification of the Ministry of Public Health re: Viscoelastic Substances Used in Eye Surgeries, B.E. 2557 (2014), dated 24 November 2014;

(6) amphetamine testing kits used for urine drug tests, pursuant to the Notification of the Ministry of Public Health re: Amphetamine Testing Kits Used for Urine Drug Tests, B.E. 2556 (2013), dated 17 September 2013, and the Notification of the Ministry of Public Health re: Amphetamine Testing Kits Used for Urine Drug Tests (No. 2), B.E. 2559 (2016), dated 26 September 2016;

(7) hemodialysis concentrate products, pursuant to the Notification of the Ministry of Public Health re: Hemodialysis Concentrate Products, dated 3 October 2017;

(8) teeth whitening products, pursuant to the Notification of the Ministry of Public Health re: Determination that Teeth Whitening Products are Medical Devices, B.E. 2561 (2018), dated 27 August 2018;

(9) contact lens care products, pursuant to the Notification of the Ministry of Public Health re: Contact Lense Care Products, B.E. 2562 (2019), dated 3 April 2019;

(10) products containing alcohol used as sanitizers for humans, animals, and medical devices, pursuant to the Notification of the Ministry of Public Health re: Products Containing Alcohol Used as Sanitizers for Humans, Animals, and Medical Devices, B.E. 2562 (2019), dated 9 August 2019; or

(11) physical therapy devices or products, pursuant to the Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which Manufacturers and Importers Must Declare Specifications, dated 31 January 2020;

To submit the application for declaration of specifications to the licensor in accordance with the first paragraph, the following information, documents, and evidence are not required for three years after the date this Notification takes effect.

1) Documentation showing how waste generated through the use of these medical devices will be destroyed, compounded, or disposed of after use, as required under clause 2(7) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

2) Certification of the intended use, indications, and packaging; the certification of labels; and user manuals issued by the product manufacturer or owner, as required under clause 2(9) of the the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

3) Certification showing the history of the sale of medical devices by the product manufacturer or owner, as required under clause 2(11) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

4) Certification of safety and security offered by the product manufacturer or owner, as required under clause 2(12) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

5) 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 accepted by the Office of the Food and Drug Administration, as required under clause 2(13) of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

However, if the applicant has information, documents, or evidence indicated in the second paragraph, the information, documents, or evidence must also be submitted together with the application to declare specifications.

Clause 4 Any person granted a license to manufacture or import surgical gloves, condoms, contact lenses, or HIV-related test kits, which are categorized as group of medical devices or medical devices, of which the specifications must be declared under the Notification of the Ministry of Public Health re: Groups of Medical Devices or Medical Devices for Which Manufacturers and Importers Must Declare Specifications (No. 2), B.E. 2563 (2020), dated 29 December 2020, before this Notification takes effect, and wishing to continue their business, must make their request to declare specifications under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, dated 22 December 2020, before the license expires. In this case, no information, documents, or evidence indicated in clause 2 of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020, is required.

If a request to declare specifications has been made within the specified timeframe, the licensor will issue a receipt of the specifications, and the documents supporting the licensing that have already been submitted will be deemed to support the specifications of medical devices under the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

Clause 5 Any applicant wishing to renew the receipt of specifications regarding the manufacturing or import of medical devices under this Notification, must submit complete information, documents, and evidence, as prescribed in clause 2 of the Ministerial Regulations on the Declaration of Specifications and the Issuance of Receipts for the Declaration of Specifications Regarding the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

Clause 6 This Notification takes effect from the date of its publication in the *Government Gazette*.

Issued on 2 February 2021

Paisarn Dunkum

Secretary-general of the Food and Drug Administration