Notification of the Office of the Food and Drug Administration re: No Requirement for Applicants for the Registration of the Manufacturing or Import of Medical Devices to Submit Information, Documents, or Evidence as Required under the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of 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 for registration of manufacturing or import, 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 Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020, as reasonable and necessary.

By virtue of clause 3 of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), 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 later 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 that Must Be Registered by Manufacturers and Importers, B.E. 2563 (2020), dated 29 December 2020, shall submit their application for registration to the licensor without having to provide the following information, documents, or evidence.

(1) Documentation of a history of overseas registration (if applicable), under clause 2(4) of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(2) For the manufacturing or import of sterile medical devices, documentation of sterility testing, under clause 2(5) of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(3) For the manufacturing or import of medical devices used for measurement, documentation of testing or calibration testing, under clause 2(6) of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

(4) Declaration of conformity issued by the product manufacturer or owner, under clause 2(7) of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

Clause 2 Applicants who wish to renew their certificates of the registration of the manufacturing or import of medical devices under this Notification must provide complete information, documents, or evidence, as indicated in clause 2 of the Ministerial Regulations on the Registration, and Issuance of the Certificate of Registration, of the Manufacturing or Import of Medical Devices, B.E. 2563 (2020), dated 22 December 2020.

Clause 3 This Notification takes effect from 17 March 2021.

Issued on 2 February 2021

Paisarn Dunkum

Secretary-general of the Food and Drug Administration