(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 Listed 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 listed 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 Listed 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 Listed 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 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 Listed 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 Listed Medical Device B.E. 2563 (2020), dated 22 December 2020, is not required:

(1) Documents describing the history of international registrations in cases where the registrations are granted in foreign countries under Clause 2, subsection (4) thereof;

(2) Documents describing sterilization validation test in cases of manufacture or importation of sterilized medical devices under Clause 2, subsection (5) thereof;

(3) Documents describing a test or a calibration test in cases of manufacture or importation of medical devices having a measuring function under Clause 2, subsection (6) thereof;

(4) Declaration of Conformity issued by manufacturer or product owner under Clause 2, subsection (7) thereof;

Clause 2 In cases where the registrant, who wishes to renew the Certificate of manufactured or imported listed 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 Application for, and issuance of Manufacture or Importation Listed Medical Devices B.E. 2563 (2020), dated 22 December 2020.

Clause 3 This Notification shall come into force from 17 march B.E.2564 (2021).

Issued on 2 February 2021.

Paisarn Dunkum

Secretary-General

Food and Drug Administration