WORLD TRADE ORGANIZATION

G/TBT/N/TPKM/551

15 November 2024

(24-8082)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Food and Drug Administration, Ministry of Health and Welfare **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Please submit comments to: WTO TBT Enquiry Point, Email: tbteng@bsmi.gov.tw
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits (excl.those of heading 3006); certified reference materials (HS code(s): 3822)
5.	**Title, number of pages and language(s) of the notified document:** Draft Amendments to the Attachment 1 of Article 3, the Attachment 2 of Article 6 and the Attachment 3 of Article 17 of the "Regulations Governing Border Inspection and Examination of Imported Medical Device; (12 page(s), in English), (8 page(s), in Chinese)
6.	**Description of content:** In response to the amendments to the Tariff Codes, and the "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics," Attachment 1 to Attachment 3 of the "Regulations for the Inspection and Examination of Imported Medical Devices" are proposed to be modified based on the current situation.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** Medical Devices Act; Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined

10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** WTO TBT Enquiry Point Bureau of Standards, Metrology and Inspection Ministry of Economic Affairs No. 4, Sec. 1, Jinan Rd., Zhongzheng Dist. Taipei City 100, Taiwan Tel: +(886-2) 23431916 Fax: +(886-2) 23431804 Email: tbteng@bsmi.gov.tw https://members.wto.org/crnattachments/2024/TBT/TPKM/24_07782_00_e.pdf https://members.wto.org/crnattachments/2024/TBT/TPKM/24_07782_00_x.pdf