NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **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 AdministrationMinistry of Health and WelfareNo.161-2, Kunyang St, Nangang District, Taipei City 115209, TaiwanTel.: (886-2)2787-8085Email: hsinchiaoho@fda.gov.tw**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:**  |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **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):** COVID-19 Antigen Home/Self Test (HS code(s): 3002) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Amendments to the Regulations for the Inspection and Examination of Imported Medical Devices; (6 page(s), in Chinese and English) |
| **6.** | **Description of content:** To respond to the new coronavirus pandemic and to ensure the quality of medical devices for protecting the safety and well-being of the public, the Food and Drug Administration proposes to conduct inspection and examination for imported COVID-19 Antigen Home/Self Tests. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** Medical Devices Act |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** Not Applicable |
| **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 PointBureau of Standards, Metrology and InspectionMinistry of Economic AffairsNo. 4 , Sec. 1, Jinan Rd., Zhongzheng Dist.Taipei City 100, TaiwanTel: +(886-2) 23431916Fax: +(886 2) 23431804Email: tbtenq@bsmi.gov.tw<https://gazette.nat.gov.tw/egFront/detail.do?metaid=133222&log=detailLog><https://members.wto.org/crnattachments/2022/TBT/TPKM/22_4443_00_x.pdf><https://members.wto.org/crnattachments/2022/TBT/TPKM/22_4443_00_e.pdf> |