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 Administration  Ministry of Health and Welfare  No.161-2, Kuntang St,  Nangang District, Taipei City 115-61, Taiwan  Tel.: (886-2) 2787-7524  Fax: (886-2) 3322-9492  Email: [Kenneth@fda.gov.tw](mailto:Kenneth@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 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical Devices; Medical equipment (ICS 11.040) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Amendment of Annex I to Article 3 and Article 8 of the "Regulations for Governing the Management of Medical Device" (10 page(s), in English; 7 page(s), in Chinese) |
| **6.** | **Description of content:** In view of the wide range of scientific fields involved in medical equipment and the complication of medical devices in terms of their varieties, items and components resulted from innovation of technology, the Ministry of Health and Welfare is proposing amendment to Annex I to Article 3 of the "Regulations for Governing the Management of Medical Device" in order to clarify the classification description and intended use situations as well as to harmonize with international regulatory trends. Considering a transition period is necessary for manufacturers to comply with the new requirements, amendment to Article 8 of the Regulation is also proposed. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection; Harmonization |
| **8.** | **Relevant documents:**   * The Pharmaceutical Affairs Act |
| **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, Section 1 Jinan Road,  Zhongzheng District,Taipei City 100, Taiwan  Tel.: (886-2) 2343-1801  Fax: (886-2) 2343-1804  E-mail: [tbtenq@bsmi.gov.tw](mailto:tbtenq@bsmi.gov.tw)  <https://members.wto.org/crnattachments/2019/TBT/TPKM/19_1753_00_e.pdf>  <https://members.wto.org/crnattachments/2019/TBT/TPKM/19_1753_00_x.pdf> |