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 (FDA) Ministry of Health and Welfare  No.161-2, Kunyang St., Nangang Dist. Taipei City 115-61, Taiwan Tel: +(886-2) 2787-7525 Fax: +(886-2) 2653-2006 E-mail: [lucy@fda.gov.tw](mailto:lucy@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 [****X],** **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 equipment (ICS 11.040) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration (Draft) (22 page(s), in English; 18 page(s), in Chinese) |
| **6.** | **Description of content:** According to Article 29 of the Medical Device Act, the Food and Drug Administration, Ministry of Health an Welfare proposes to draft the ''Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration'' to govern the approval and listing of medical device. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection |
| **8.** | **Relevant documents:**   * Medical Device 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  The 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) 3343-5140 Fax: +(886-2) 2343-1804 E-mail: [tbtenq@bsmi.gov.tw](mailto:tbtenq@bsmi.gov.tw)  <https://members.wto.org/crnattachments/2020/TBT/TPKM/20_7352_00_e.pdf>  <https://members.wto.org/crnattachments/2020/TBT/TPKM/20_7352_00_x.pdf> |