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 Dist.Taipei City 115209, TaiwanTel: +(886-2) 2787-8078Email: menghan1215@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 of the Enforcement Rules of Medical Devices Act (8 page(s), in English; 9 page(s), in Chinese) |
| **6.** | **Description of content:** With a view to implementing the Medical Devices Act, which was promulgated on 15 January 2020, the Ministry of Health and Welfare is proposing to draft the ''Enforcement Rules of Medical Device Act'' to provide further details. The provisions of the draft enforcement rules include: terms, registration of medical device firms, regulations on labeling, regulations on approval of medical device advertisements and rewards for reporting violations, etc. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Protection of human health or safety |
| **8.** | **Relevant documents:** * Medical Devices Act <http://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030106>
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| **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 PointBureau of Standards, Metrology and InspectionMinistry of Economic AffairsNo.4 , Sec. 1, Jinan Rd., Zhongzheng Dist.Taipei City 100, TaiwanTel: +(886 2) 3343-5140 Fax: +(886 2) 2343-1804 E-mail: tbtenq@bsmi.gov.tw<https://members.wto.org/crnattachments/2021/TBT/TPKM/21_0161_00_et.pdf><https://members.wto.org/crnattachments/2021/TBT/TPKM/21_0161_00_x.pdf> |