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 Bldg. F, No.99, Ln. 130, Sec. 1, Academia Rd. Nangang District, Taipei City 11561, Taiwan Tel.: (886-2)2787-8087 Email: [nlopolymer@fda.gov.tw](mailto:nlopolymer@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; Biological evaluation of medical devices (ICS 11.100.20) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft of Regulations on Good Clinical Practice for Medical Devices (15 page(s), in English; 19 page(s), in Chinese) |
| **6.** | **Description of content:** According to the design, conduct, recording, and reporting of clinical investigations, the regulation is intended to develop a complete management mechanism for clinical investigations on medical devices, to protect the rights, safety, and well-being of subjects and to ensure that the conduction of clinical investigations conforms to ethical and scientific principles. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** To protect the rights, safety, and well-being of subjects and to ensure that the conduction of clinical investigations conforms to ethical and scientific principles; 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:** 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_3958_00_e.pdf>  <https://members.wto.org/crnattachments/2020/TBT/TPKM/20_3958_00_x.pdf> |