



6 January 2022

(22-0094)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</u> 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, Kunyang St., Nangang Dist. Taipei City 115209, Taiwan Tel: +(886-2) 2787-7577 Email: ginjet@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 Medical Device Product Items That Shall Accord Specification, Testing Method and Performance (1 page(s), in English; 2 page(s), in Chinese)
6.	Description of content: The Food and Drug Administration (FDA) is proposing to draft the "Medical Device Product Items That Shall Accord Specification, Testing Method and Performance." The regulation is intended to develop a complete management mechanism for medical devices, to request the quality of medical devices and protect the safety and well-being of the public.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8.	Relevant documents: Medical Devices Act http://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030106
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 , 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

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