



31 January 2017

(17-0616)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION 臺灣 通知—醫療器材

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 臺灣</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 District Taipei City 115-61, Taiwan Tel.: (886-2) 2787-7526 Fax: (886-2) 2787-8287 Email: shoulder0705@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 devices 醫療器材
5. Title, number of pages and language(s) of the notified document: Draft for Medical Devices Act (25 pages, in English; 15 pages, in Chinese)
6. Description of content: This Act is established to manage the safety, effectiveness, and quality of medical devices and to ensure the health of citizens. 本法案係為管理醫療器材之安全、效能及品質及維護國民健康。
7. Objective and rationale, including the nature of urgent problems where applicable: Prevention of deceptive practices and consumer protection
8. Relevant documents: -
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
4, Chinan Road, Section 1 Taipei City 100, Taiwan
Tel.: (886-2) 2343-1813
Fax: (886-2) 2343-1804
E-mail: tbtenq@bsmi.gov.tw

https://members.wto.org/cnattachments/2017/TBT/TPKM/17_0531_00_x.pdf

https://members.wto.org/cnattachments/2017/TBT/TPKM/17_0531_00_e.pdf