



18 April 2017

(17-2097)

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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.	<b>Notifying Member:</b> <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU 臺灣</u>  <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b>  Food and Drug Administration Ministry of Health and Welfare No.161-2, Kunyang St., Nangang District Taipei City 115-61, Taiwan Tel.: (886-2) 2787-7581 Fax: (886-2) 2787-8287 Email: <a href="mailto:hsiuhuipeng@fda.gov.tw">hsiuhuipeng@fda.gov.tw</a>  <b>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:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical Devices 醫療器材
5.	<b>Title, number of pages and language(s) of the notified document:</b> General Information for the Draft Amendment of Annex I to Article 3 and Annex II to Article 4 of the "Regulations for Governing the Management of Medical Device" (18 pages, in English; 14 pages, in Chinese)
6.	<b>Description of content:</b> To ensure the safety of public health, the Food and Drug Administration (TFDA) of the Ministry of Health and Welfare (MOHW) intends to amend the current "Regulations for Governing the Management of Medical Device". By this amendment, Annex I and Annex II of "Regulations for Governing the Management of Medical Device" are modified to represent the state of the art of medical device regulation.  為確保公共衛生安全，衛生福利部食品藥物管理署擬修訂現行醫療器材管理辦法。修訂醫療器材管理辦法附件一和附件二。
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Prevention of deceptive practices and consumer protection
8.	<b>Relevant documents:</b> The Pharmaceutical Affairs Act
9.	<b>Proposed date of adoption:</b> To be determined  <b>Proposed date of entry into force:</b> 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:**

TPKM-WTO/TBT Enquiry Point  
Bureau of Standards, Metrology and Inspection  
Ministry of Economic Affairs  
No. 4, Section 1, Jinan Road,  
Zhongzheng District, Taipei City 100, Taiwan  
Tel.: (886-2) 2343-1813  
Fax: (886-2) 2343-1804  
E-mail: [tbtenq@bsmi.gov.tw](mailto:tbtenq@bsmi.gov.tw)

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