WORLD TRADE ORGANIZATION

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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.	**Notifying Member:** THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU 臺灣 **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 [ ], 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:** General Information on Draft Partial Amendment to the Regulation for Registration of Medical Devices (41 pages, in English; 22 pages, in Chinese)
6.	**Description of content:** This Regulation was established in accordance with Paragraph 3, Article 40 of the Pharmaceutical Affairs Act to meet the needs for registration and market approval of medical devices and management of permit licenses, and was promulgated and came into force as per the Decree of Wei-Shu-Yao-Zi No. 0930328238 on 30 December 2004. This Regulation has undergone five amendments since then. In order to improve the registration and market approval process and ensure the safety and efficacy of medical devices on the market, a draft partial amendment to the Regulation for Registration of Medical Devices has been formulated. The main points of the amendment are as follows: 1. With the provisions of Paragraph 3 of Article 3 and Article 13 of the Regulations for Registration of Medicinal Products as reference, it is stipulated that a Chinese or English translation shall be provided if the documents submitted are not made in Traditional Chinese or English (amendment to Article 3). 2. Considering that the current relationship between the commissioning company and the commissioned manufacturing factory is not proved by a manufacture certificate but by a commissioning contract signed by the parties and other relevant documents in accordance with the Regulations for Medicament Contract Manufacture and Analysis, the relevant provisions that require a clear description of the relationship between the commissioning company and the commissioned manufacturing factory in a manufacture and free sale certificate of the country of origin, as set forth in the

latter part of Paragraph 3, are deleted (amendment to Article 7).

3. To meet the needs for e-government, online application services have become available for Class I medical devices. The applicant may sign or affix their seal to confirm their identity if an application is submitted in writing. However, if a registration application is submitted online, the identity of the applicant must be confirmed by means of electronic signature since the applicant is unable to sign or affix their seal. As a result, the latter part of the paragraph explicitly stipulates that those submitting an application online shall do so with the IC card issued by the Certificate Authority of the Ministry of Economic Affairs (amendment to Articles 14 and 16).

4. Changes in the specifications or efficacy of a medical device shall be done after evaluated by the original designer or manufacturer of the product, so as to ensure the safety and efficacy of the product. Therefore, the amendment requires that the comparison and explanation of the changed specifications or efficacy and the originally approved specifications or efficacy submitted for the purpose of applying for change of the specifications or efficacy on a permit license shall be issued by the original medical device manufacturer (amendment to Articles 24 and 26).

5. Paragraph 6 is added to prevent the change of the address of a medical device manufacturing factory from resulting in any inconsistency with its medical device previously approved for registration and market approval in terms of the quality, safety, and efficacy. The central competent authority may order the applicant to submit relevant supporting documents to confirm the consistency with its medical device previously approved for registration and market approval (amendment to Article 28).

6. To avoid other factors that affect the safety and efficacy of the product concerned due to extension or change of a permit license, the rights of the central health competent authority to order the applicant to submit relevant documents are reserved, thereby ensuring the efficacy and safety of the product (amendment to Article 35).

7. To collect complete information on the instructions of Class I medical devices and improve the management after launch to the market, it is explicitly stipulated that Class I medical device permit license holders shall upload the instructions, labels, and outer box documents to the information system specified by the central health competent authority within one (1) month after obtaining permit licenses or within six (6) months after the amendment to this Regulation comes into force if they obtain Class I medical device permit licenses before the amendment to this Regulation comes into force. Moreover, such uploading is listed as a requirement for applying for extension of Class I medical device permit licenses (amendment to Articles 35 and 36).

8. Since the review process for medical devices exclusively for export is different from that for domestically manufactured medical devices, it is explicitly stipulated that the Chinese and English names of medical devices exclusively for export shall not be the same as those of domestically manufactured medical devices. Thus, any confusion between medical devices exclusively for export and domestically manufactured medical devices can be avoided (amendment to Article 37).

本準則係為辦理醫療器材查驗登記審查及許可證管理需要，依據藥事法第四十條第三項規定訂定，並於九十三年十二月三十日以衛署藥字第O九三O三二八二三八號令發布施行，期間歷經五次修正。然為精進查驗登記審查作業，確保上市醫療器材之安全效能，爰擬具「醫療器材查驗登記審查準則」部分條文修正草案，其修正要點如下：

一、參照藥品查驗登記審查準則第三條第三項及第十三條規定，明定送審資料倘非以正體中文或英文製作者，應檢附中文或英文譯本（修正條文第三條）。

二、考量現行委託者及受託製造廠關係，非以製造證明佐證，而係依據藥物委託製造及檢驗作業準則規定，由雙方簽立之委託製造契約等相關文件證明雙方關係，故刪除第三項後段，有關出產國許可製售證明應載明委託者及受託製造廠雙方關係相關規定。（修正條文第七條）。

三、為配合電子化政府需求，對於低風險之第一等級醫療器材，增列網路申請服務，以書面申請者，可由申請商簽名或蓋章證明身分，而以網路申請登記者，因申請人無法簽名或蓋章，故必須透過電子簽章方式，識別申請者身分，爰於該項後段敘明以網路申請時，應以經濟部工商憑證管理中心簽發之工商憑證為

	之（修正條文第十四條及第十六條）。 四、因醫療器材產品之規格、效能變更，應係由產品原設計製造者評估後為之，方能確保產品之安全性及效能，故修正許可證規格、效能變更申請所出具之擬變更規格、效能與原核准者之差異比較及說明，應由醫療器材原廠出具（修正條文第二十四條及第二十六條）。 五、為避免醫療器材製造廠廠址變更有致醫療器材產品品質、安全及效能與原查驗登記核准不符之情形，新增第六項規定，中央主管機關得命申請商檢具相關證明文件，確認與原查驗登記核准相符（修正條文第二十八條）。 六、為避免許可證展延變更時，有其他影響產品安全性及效能之因素，爰保留中央衛生主管機關要求申請商檢附相關資料之權利，以確保產品之效能及安全。（修正條文第三十五條）。 七、為健全第一等級醫療器材仿單資料，精進上市後管理，遂明定第一等級醫療器材許可證持有者應於領證後一個月內，本準則修正施行前已取得第一等級醫療器材許可證者，應於本準則修正施行後六個月內，至中央衛生主管機關指定之資訊系統，辦理仿單、標籤、外盒文件之上傳作業，並列為第一等級醫療器材展延申請之要件（修正條文第三十五條、第三十六條）。 八、因外銷專用醫療器材之審查程序與國產醫療器材不同，為避免外銷專用醫療器材與國產醫療器材混淆，爰敘明外銷專用醫療器材之中英文品名不得與國產醫療器材之中英文品名相同之規定（修正條文第三十七條）。
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection
8.	**Relevant documents:** The Pharmaceutical Affairs 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:** 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) 2343-191 Fax: (886-2) 2343-1804 E-mail: tbteng@bsmi.gov.tw http://members.wto.org/crnattachments/2016/TBT/TPKM/16_5006_00_e.pdf http://members.wto.org/crnattachments/2016/TBT/TPKM/16_5006_00_x.pdf