WORLD TRADE ORGANIZATION

G/TBT/N/VNM/205

16 August 2021

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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:** VIET NAM **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Department of Medical devices and Construction Ministry of Health Number 138A, Giảng Võ Str, Ba Đình District, Hà Nội, Vietnam Tel: (84-24) 62732272 Fax: (84-24) 62732279 Email: dmec@moh.gov.vn **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 equipment (ICS 11.040)
5.	**Title, number of pages and language(s) of the notified document:** Draft Decree on management of medical devices (64 page(s), in Vietnamese)
6.	**Description of content:** This draft Decree specifies regulations on the management of medical devices, including: classification; manufacturing, circulating, trading, exporting, importing and providing medical devices services; information, advertising, labelling; declare prices of medical devices and manage and use medical equipment at medical facilities. 1. Medical devices that has been manufactured in Vietnam or imported into Vietnam before the effective date of this Decree may continue to be sold until it is liquidated according to the provisions of Clause 1, Article 22 of the Law on Management and Use of State Property or by the expiration of the time limit stated in the Certificate of Circulation of Registration. 2. The issuance of circulation registration numbers for domestically produced medical devices or medical devices that is an in vitro diagnostic biological product shall comply with current law provisions with the following validation: a) For domestically produced medical devices, which has been granted a certificate of free sale, the free-sale registration number is valid until the expiration of the time stated on the certificate of circulation registration. b) For medical devices that is an in vitro diagnostic biological product, which has been granted a certificate of circulation in accordance with the 2005 Law on Pharmacy and guiding documents on the implementation of this Law, the issued free-sale registration number shall be valid until the end of the time stated on the certificate of circulation registration.

	c) Imported medical devices that is an in vitro diagnostic biological product submitted before December 31, 2021, shall be granted an import license in accordance with the Law on Pharmacy 2005 and is valid until the end of 31 December 2022; 3. Class B medical devices that has been granted a free-sale registration number before the effective date of this Decree shall be valid for an indefinite period. 4. Applications for circulation registration submitted before 1 January 2022 must comply with the provisions of Articles 34 and 35 of this Decree. 5. Labels of medical devices that have been manufactured in Vietnam or imported into Vietnam before the date specified in Clause 2 of this Article may continue to be used until the expiry of the useful life of the equipment or until it is liquidated according to the provisions of Clause 1, Article 22 of the Law on Management and Use of State Property or by the expiration of the time limit stated in the Certificate of Circulation of Registration.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Quality requirements
8.	**Relevant documents:** Decree No. 36/2016/NĐ-CP dated on May 15, 2016 of the Government on management of medical devices; Decree No. 169/2018/NĐ-CP dated on Dec 31, 2018 of the Government on amending Decree No. 36/2016/NĐ-CP; Decree number 03/2020/NĐ-CP dated on Jan 1st, 2020 of the Government on amending Article 68 of Decree No. 36/2016/NĐ-CP.
9.	**Proposed date of adoption:** 18 October 2021 **Proposed date of entry into force:** 1 January 2022
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:** Department of Medical devices and Construction Ministry of Health Number 138A, Giảng Võ Str, Ba Đình District, Hà Nội, Vietnam Tel: (84-24) 62732272 Fax: (84-24) 62732279 Email: dmec@moh.gov.vn https://members.wto.org/crnattachments/2021/TBT/VNM/21_5213_00_x.pdf