



24 April 2023

(23-2915)

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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>REPUBLIC OF KOREA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Ministry of Food and Drug Safety 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: Documents are available from the Ministry of Food and Drug Safety website (www.mfds.go.kr). International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: intmfds@korea.kr
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medical Devices
5. Title, number of pages and language(s) of the notified document: Proposed partial amendments to the Regulation on Stability Test Standard for Medical Devices; (15 page(s), in Korean)
6. Description of content: The proposed amendments to the Regulation on Stability Test Standard for Medical Devices is as follows: 1) Measurement period for stability test - For the measurement period, at least one time point, including the last time point, can be set for long-term preservation tests and accelerated aging tests of medical devices using raw materials without physical or chemical changes, such as metals, when the data at the start of the test is replaced. 2) Clarification of test items - Test items are divided into biological safety tests, performance tests, and other tests in accordance with the <Regulations on Medical Device Permission, Notification, Review, etc.> and <Regulation on In Vitro Diagnostic Medical Device Permission, Notification, Review, etc.>

7.	Objective and rationale, including the nature of urgent problems where applicable: Cost saving and productivity enhancement
8.	Relevant documents: MFDS NOTIFICATION No. 2023-186, 14 April, 2023
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: Technical Barriers to Trade(TBT) Division Korean Agency for Technology and Standards (KATS) 93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, Republic of Korea, 369-811 Tel.: (+82) 43 870 5315 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2023/TBT/KOR/23_9247_00_x.pdf