



11 December 2017

(17-6809)

Page: 1/1

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:
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
5. Title, number of pages and language(s) of the notified document: Amendment of "Medical Device Act Enforcement Regulation" (27 page(s), in Korean)
6. Description of content: Expanding scope of exemptions from manufacturing and import business licenses, clarifying scope of medical device advertisements, overhauling recall procedures for medical devices, establishing the management standards for integrated information of medical devices and Integrated Medical Device Information System (IMDIS) including UDI (Unique Device Identification), rationalizing GSP (Good Supply Practice).
7. Objective and rationale, including the nature of urgent problems where applicable: Improving efficiency of medical device safety management by laying down detailed standards of operating for integrated information management of medical devices.
8. Relevant documents: MFDS NOTIFICATION No. 2017-427 (30.11.2017)
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 [] 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, 27737 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr