



11 December 2017

(17-6811)

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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

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| 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 [X], 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 "Regulation on Medical Device Groups and Class by Group" (12 page(s), in Korean) |
| 6. Description of content: Revising the classes upwards for Slit light ophthalmic microscopes, Ophthalmic light microscopes and Ophthalmic cameras, etc. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Improving public health by reinforcing safety management for ophthalmic medical devices. |
| 8. Relevant documents: MFDS Notification No. 2017-416 (21.11.2017) |
| 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 [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, 27737 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr |