NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Republic of Korea **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:** International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Chengju-si, Chungcheongbuk-do, 363-700Republic of KoreaTel: (+82) 43 719-1564Fax: (+85) 43 719-1550Email: wtokfda@korea.kr |
| **3.** | **Notified under Article 2.9.2 [****], 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 "Regulations on standard specification of medical devices” (31 page(s), in Korean)   |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety (MFDS) has newly established standard specifications for 'Syringe, filter', 'Needle, filter' and 'Needle, filter, reusable' to clarify the test specifications and methods for quality control of filtration performance of these products. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Promoting the health and safety of patients and medical professionals |
| **8.** | **Relevant documents:** * Ministry of Food and Drug Safety Advance Notice No. 2019-031 (2019.1.18.)
 |
| **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) DivisionKorean Agency for Technology and Standards (KATS)93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, Republic of Korea, 27737Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682E-mail: tbt@kats.go.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_0387_00_x.pdf> |