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:** Documents are available from the Ministry of Food and Drug safety website ([www.mfds.go.kr](http://www.mfds.go.kr)). Also available from: International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159Republic of Korea Tel: (+82) 43 719-1564Fax: (+82) 43-719-1550Email: intmfds@korea.kr |
| **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:** Enforcement Rules on Support, etc. for Innovative Medical Devices (55 page(s), in Korean) |
| **6.** | **Description of content:** The enforcement rules prescribe the procedures and methods for modular review and priority review of medical devices which aim to support the development and commercialization of innovative medical devices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Adoption of Domestic regulation following the enactment and publishing of the Act |
| **8.** | **Relevant documents:** * MFDS NOTIFICATION No. 2019-531 (28 November 2019)
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| **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@korea.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_7231_00_x.pdf> |