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 Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu Cheongju-si, Chungcheongbuk-do, 28159  Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) Website: [www.mfds.go.kr](http://www.mfds.go.kr) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **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:** Amendments to the "Enforcement Rule of the Medical Devices Act" (11 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is amending the "Enforcement Rule of the Medical Devices Act" for the following purposes:   1. To adjust fees such as medical device licenses and examinations according to the inflation rate 2. To increase personnel for professional reviews in response to the increase in the number of high-tech products 3. To revise provisions on the fees for medical device approvals and reviews in order to expedite the approval and review processes |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The amendments aim to address the limitations found in the operation of the Act; Other |
| **8.** | **Relevant documents:**  Ministry of Food and Drug Safety Public Notice No. 2020-399 (16 September 2020) |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 26 October 2020 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Korea WTO TBT Enquiry Point Technical Barriers to Trade (TBT) Division Korean Agency for Technology and Standards (KATS) 93 Isu-ro Maengdong-myeon Eumseong-gun Chungchungbuk-do  27737 +(82) 43 870 5525 +(82) 43 870 5682 (Fax) [tbt@korea.kr](mailto:tbt@korea.kr) <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_5781_00_x.pdf> |