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 [****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:** Amendments to the "Enforcement Rule of the Medical Devices Act" (29 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" as stated below:  Although the Medical Devices Act specifies that the renewal of approvals/certifications/reporting of manufacturing or imports is mandatory, the renewal system has not been operated effectively since the Act did not stipulate the setting of validity period for the renewals. Thus, the revised Medical Devices Act, promulgated to be in effect on 8 October 2020, sets a five-year validity period for the renewals. In this regard, the revised Enforcement Rule of the same Act sets forth the details of procedures and methods for the renewal. |
| **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 |
| **8.** | **Relevant documents:**   * MFDS Public Notice No. 2020-227 (8 June 2020); * G/TBT/N/KOR/811 (15 February 2019); * G/TBT/N/KOR/861 (30 September 2019). |
| **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, 369-811 Tel.: (+82) 43 870 5525  Fax: (+82) 43 870 5682 E-mail: [tbt@korea.kr](mailto:tbt@korea.kr)  Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_3804_00_x.pdf> |