NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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 Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-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) |
| **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 Device |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed amendments of "Standards of Medical Device Good Manufacturing Practices" (5 page(s), in Korean) |
| **6.** | **Description of content:** The "Standards of Medical Device Good Manufacturing Practices" is being amended by the Ministry of Food and Drug Safety (MFDS) as follows: GMP change audit exemption of location changes for Software as Medical Devices (SaMD) manufacturers |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  MFDS NOTIFICATION No. 2022-38(2022.1.19.) |
| **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:**  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/2022/TBT/KOR/22_0904_00_x.pdf> |