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). 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) 43 719-1561  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 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **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:** Proposed amendment of the "Regulations on Renewal of Manufacturing Permission, etc."; (13 page(s), in Korean) |
| **6.** | **Description of content:** The Korean Ministry of Food and Drug Safety is proposing to amend the "Regulations on Renewal of Manufacturing Permission, etc." as follows:  1) Reorganizing the requirement attached documents considering the characteristics of each medical device product  2) Incorporating key review points for each renewal cycle, etc. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  MFDS NOTIFICATION No. 2023-447, (9 September 2023) |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 5 October 2023 |
| **11.** | **Texts available from: National enquiry point [****]** **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 5315 Fax: (+82) 43 870 5682  E-mail: [tbt@kats.go.kr](mailto:tbt@kats.go.kr) Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2023/TBT/KOR/23_12356_00_x.pdf> |