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 OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159Republic of KoreaTel: (+82) 43 719-1561Fax: (+82) 43-719-1550Email: 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 product2) 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) DivisionKorean Agency for Technology and Standards (KATS)93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, Republic of Korea, 369-811Tel.: (+82) 43 870 5315 Fax: (+82) 43 870 5682E-mail: tbt@kats.go.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2023/TBT/KOR/23_12356_00_x.pdf> |