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 (MFDS) website: www.mfds.go.kr  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) |
| **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 amendments to the "Regulation on the Permission, Notification, Review, etc of Medical Devices"; (51 page(s), in Korean) |
| **6.** | **Description of content:** The Korean Ministry of Food and Drug Safety is proposing the amendments of the "Regulation on the Permission, Notification, Review, etc of Medical Devices" as follows:  **1)** Add clinical evaluation data to the types of clinical trial data and provide a guidance on how to fill out each item.  **2)** A person who wishes to receive confirmation that the product is identical to a Class 2 medical device that has already been certified should submit relevant materials to the head of the National Institute of Medical Device Safety Information.  **3)** Stipulate the procedure for accepting a manufacture/import notification of a medical device in accordance with the Enforcement Rule of the Medical Devices Act, as amended on 7 August 2024.  **4)** Establish a new definition of medical device cybersecurity and require related information to be included in the application.  **5)** Add newly developed medical devices to the list of products subject to expedited review and restrict the exemption from submission of clinical test data through equivalence review for newly developed medical devices during the post-marketing surveillance period.  **6)** Provide examples requiring the submission of clinical test data for clarification of the scope of submitted materials. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  MFDS NOTIFICATION No. 2025-195, 30 April 2025 |
| **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 Regulatory Policy Division  Korean Agency for Technology and Standards (KATS)  93 Isu-ro Maengdong-myeon Eumseong-gun  Chungchungbuk-do  27737  Tel: +(82) 43 870 5315  Fax: +(82) 43 870 5682  Email: [tbt@korea.kr](mailto:tbt@korea.kr)  Website: <https://www.knowtbt.kr>  <https://www.mfds.go.kr/brd/m_209/view.do?seq=44096&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1>  <https://members.wto.org/crnattachments/2025/TBT/KOR/25_03224_00_x.pdf> |