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) 43 719-1564  Fax: (+82) 43-719-1550  Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****],** **5.6.2 [****X],** **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 partial amendments to the Regulations on Standard Specification of Medical Devices; (5 page(s), in Korean) |
| **6.** | **Description of content:** The proposed amendments to the Regulations on Standard Specification of Medical Devices are as follows:  1) Establishment of Medical Device Standards  - Establishment of new standards and specifications to ensure product safety and performance of 7 types of medical devices, including high-intensity focused Ultrasonic surgical systems and mammographic x-ray systems (stationary, analogue).  2) Align With International Standards  - Ensuring product performance and safety by applying the international standards (IEC, ISO) of test criteria and methods to 23 types of medical devices, including anaesthesia systems (gas) and incubators (infant). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  MFDS NOTIFICATION No. 2023-023, 18 January, 2023 |
| **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 [****]** **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@kats.go.kr](mailto:tbt@kats.go.kr) Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2023/TBT/KOR/23_0673_00_x.pdf> |