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 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, 363-700  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):** In Vitro Diagnostic Medical Devices (HS code 3822.00) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed amendments to the "Enforcement Rule on the Act on In Vitro Diagnostic Medical Devices"; (22 page(s), in Korean) |
| **6.** | **Description of content:** MFDS is proposing to amend the "Enforcement Rule on the Act on In Vitro Diagnostic Medical Devices" as follows:  A. Enable the elimination of the manufacturer's address on the outer packaging of small size In Vitro Diagnostic Medical Devices.  B. Enable the elimination of duplicate information written on both the outer packaging and attached documents of In Vitro Diagnostic Medical Devices.  C. Simplified the submission data required for the application of Clinical Performance Study Plan approval of low-risk In Vitro Diagnostic Medical Devices |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Protection of human health or safety; Cost saving and productivity enhancement |
| **8.** | **Relevant documents:**  MFDS NOTIFICATION No. 2022-371 (23 August 2022) |
| **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 5521 Fax: (+82) 43 870 5682  E-mail: [tbt@korea.kr](mailto:tbt@korea.kr) Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2022/TBT/KOR/22_5811_00_x.pdf> |