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:** International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159Republic of Korea Tel: (+82) 43-719-1569Fax: (+82) 43-719-1550Email: intmfds@korea.krWebsite: [www.mfds.go.kr](http://www.mfds.go.kr) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **5.7.1 [****],** **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:** Amendment of "Placement and Management of Unique Device Identifiers on Medical Devices" (5 page(s), in Korean) |
| **6.** | **Description of content:** Ministry of Food and Drug Safety of Republic of Korea is amending the "Placement and Management of Unique Device Identifiers on Medical Devices" as stated below:The revision of the Notifications intended that license holders for manufacturing or importing medical devices shall place UDIs in human readable formats when they apply UDIs to medical devices using data matrix barcode on the package label or device itself. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling |
| **8.** | **Relevant documents:** MFDS Public Notice No. 2021-362 (26 July 2021) |
| **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 PointTechnical Barriers to Trade (TBT) DivisionKorean Agency for Technology and Standards (KATS)93 Isu-ro Maengdong-myeon Eumseong-gunChungchungbuk-do 27737+(82) 43 870 5525+(82) 43 870 5682 (Fax)tbt@korea.kr<http://www.knowtbt.kr><https://members.wto.org/crnattachments/2021/TBT/KOR/21_5394_00_x.pdf> |