WORLD TRADE ORGANIZATION

G/TBT/N/KOR/1223

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Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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 (MFDS) **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 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
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):** Digital Medical Products
5.	**Title, number of pages and language(s) of the notified document:** Proposed establishment of the "Enforcement Dcree of the Digital Medical Products Act" and the "Enforcement Rule of the Digital Medical Products Act"; (207 page(s), in Korean)
6.	**Description of content:** < Enforcement Decree of the Digital Medical Products Act > The purpose of this Decree is to prescribe matters mandated by the Digital Medical Products Act for its enactment and enforcement. The matters are as follows: A. details necessary for establishment and implementation of a comprehensive plan for digital medical products B. media and methods of advertising digital medical device software for professionals C. facility standards for medicines combined with digital technology D. procedures and methods for designating institutions for fostering professional human resources, centers for regulatory support, and agencies for certification E. other matters

	< Enforcement Rule of the Digital Medical Products Act > The purpose of this Rule is to prescribe matters mandated by the Digital Medical Products Act and the Enforcement Decree of that Act for its enactment and enforcement. The details are as follows: A. the scope of and classification standards for digital technology B. permission (certification and reporting) considering the characteristics of digital medical devices C. clinical trials (clinical performance tests) D. standards for quality control E. labeling, follow-up management methods and procedures F. certification of excellent management systems G. manufacturing and import of medicines combined with digital technology H. impact assessment for supporting the development of digital medical products I. other metters
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Adoption of Domestic Law
8.	**Relevant documents:** MFDS NOTIFICATION No.2024-355, 31 July 2024
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, 27737 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2024/TBT/KOR/24_05046_00_x.pdf