



15 November 2024

(24-8104)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| 1. Notifying Member: <u>REPUBLIC OF KOREA</u> 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: 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 Website: www.mfds.go.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 amendment to the "Regulation on Labelling and Description of Medical Devices"; (6 page(s), in Korean) |
| 6. Description of content: The amendment aims to allow manufacturers and importers of medical devices to select and display a primary address where permanent contacts or visits are possible, rather than listing all addresses included in their manufacturing (import) business license on the container or exterior packaging of medical devices. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Consumer information, labelling |
| 8. Relevant documents: MFDS NOTIFICATION No.2024-512 (5 November 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 [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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