



16 February 2024

(24-1403)

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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

<b>1. Notifying Member:</b> <u>REPUBLIC OF KOREA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Ministry of Food and Drug Safety <b>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:</b> Documents are available from the Ministry of Food and Drug Safety website ( <a href="http://www.mfds.go.kr">www.mfds.go.kr</a> ). Also available from: International Cooperation Office Ministry of Food and Drug Safety (MFDS) 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: <a href="mailto:intmfds@korea.kr">intmfds@korea.kr</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical Devices
<b>5. Title, number of pages and language(s) of the notified document:</b> Proposed amendments to the "Regulation on medical device group and class by group"; (32 page(s), in Korean)
<b>6. Description of content:</b> The proposed amendments to the "Regulation on medical device group and class by group" is as follows: 1) Establishment of the technology levels of autonomous driving electric wheelchair - Establishment of new standards to create a basis for classifying autonomous driving electric wheelchairs, taking into account their place of use and technical functionalities such as location determination, map formation, route creation, etc. 2) Establishment of new items - Establishment of 42 new items for medical devices to categorize those developed within the industry and formalize temporarily designated items 3) Adjustment of the class of medical devices

<p>- The class of 8 items was adjusted considering international harmonization and equity with other medical devices.</p> <p>4) Change in item name (including English name) and definition.</p> <p>- Two item names or definitions were changed based on item subdivision and considerations regarding clinical use environments.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety</p>
<p><b>8. Relevant documents:</b></p> <p>MFDS NOTIFICATION No. 2024-75, 7 February 2024</p>
<p><b>9. Proposed date of adoption:</b> To be determined</p> <p><b>Proposed date of entry into force:</b> To be determined</p>
<p><b>10. Final date for comments:</b> 60 days from notification</p>
<p><b>11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p>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 5315 Fax: (+82) 43 870 5682  E-mail: <a href="mailto:tbt@kats.go.kr">tbt@kats.go.kr</a> Website: <a href="http://www.knowtbt.kr">http://www.knowtbt.kr</a>  <a href="https://members.wto.org/crnattachments/2024/TBT/KOR/24_01539_00_x.pdf">https://members.wto.org/crnattachments/2024/TBT/KOR/24_01539_00_x.pdf</a></p>