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 Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Chengju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+85) 43 719-1550 Email: [wtokfda@korea.kr](mailto:wtokfda@korea.kr) Website: [www.mfds.go.kr](http://www.mfds.go.kr) |
| **3.** | **Notified under Article 2.9.2 [****],** **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 "Regulation on medical device group and class by group" (51 page(s), in Korean) |
| **6.** | **Description of content:** The Republic of Korea is proposing to amend the "Regulation on medical device group and class by group". The main changes proposed are:   1) 'Respirator, medical' as medical device was newly classified  2) The number of software as medical devices were expanded from 8 to 90 considering clinical field |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Promoting the health and safety of medical professionals and improving the management of medical devices; Protection of human health or safety |
| **8.** | **Relevant documents:**   * Ministry of Food and Drug Safety Public Notice No. 2020-373 (28 August 2020) |
| **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 Point Technical Barriers to Trade (TBT) Division Korean Agency for Technology and Standards (KATS) 93 Isu-ro Maengdong-myeon Eumseong-gun Chungchungbuk-do  27737 +(82) 43 870 5525 +(82) 43 870 5682 (Fax) [tbt@korea.kr](mailto:tbt@korea.kr) <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_5645_00_x.pdf> |