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:**  Documents are available from the Ministry Food and Drug safety website ([www.mfds.go.kr](http://www.mfds.go.kr)).  Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea 28159 Tel: (+82) 43 719-1564  Fax: (+82) 43-719-1550 Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **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:** Amendments to the "Medical Devices Act" (27 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is amending the "Medical Devices Act" as stated below:   1. The amendments have clarified the ground for the revocation of designation of an institution as a training institution for medical devices quality managers. 2. Items that are granted "conditional marketing approval" would be allowed to obtain "approval for change" in case of any changes in relevant information. 3. Quality managers would no longer be entitled to serve as quality managers if they have not completed the training on latest standards and specifications of medical devices, quality control and safety control as required by the Medical Devices Act. 4. Prior review of advertisements that the government used to be responsible for would be conducted by an independent panel. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The amendments aim to address the limitations found in operation of the Act. |
| **8.** | **Relevant documents:**   * MFDS NOTIFICATION No. 2019-398, 21 August 2019 |
| **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:**  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@korea.kr](mailto:tbt@korea.kr)  Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2019/TBT/KOR/19_4902_00_x.pdf> |