



7 April 2016

(16-1947)

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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 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 (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, 363-700 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: wtokfda@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: Amendment of "Regulation on standard specification of medical devices" (1687 pages, available in Korean) |
| 6. | Description of content: <ul style="list-style-type: none">• Harmonized standard specification of medical device with IEC (International Electro-technical Commission), ISO (International Organization for Standardization) international standard• Objects of enactment and revision are total 49 standard specifications<ul style="list-style-type: none">• Medical devices that are powered by electricity: 10 standards' enactments, 23 standards' revisions• Medical devices, for example, medical supplies, dental materials, that are not powered by electricity: 8 standards' enactments, 8 standards' revisions• In case of medical electrical devices, standard specification is to be harmonized with IEC 60601 3ed. particular standards |
| 7. | Objective and rationale, including the nature of urgent problems where applicable: Through partial revision of particular standard, secure safety, effectiveness and quality of medical device for protection public health |
| 8. | Relevant documents: Ministry of Food and Drug Safety Advance Notice No. 2016-96 (18 March 2016) |

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| 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 date of 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: WTO 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 |