

# WORLD TRADE ORGANIZATION

G/TBT/Notif.00/275  
23 June 2000

(00-2552)

## Committee on Technical Barriers to Trade

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	<b>Member to Agreement notifying:</b> <u>REPUBLIC OF KOREA</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Korea Food and Drug Administration <b>Agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical Devices
5.	<b>Title, number of pages and language(s) of the notified document:</b> Public Notification of Draft Enactment of Particular Requirement for Safety of Medical Devices (306 pages)
6.	<b>Description of content:</b> Additionally establishes the particular requirement for safety of 29 dental materials and of 13 medical devices including electrocardiograph, and matches the particular requirement with the international standards such as IEC or ISO.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> This amendment is to provide applicants for approval with clear standards, increase transparency and promptness of approval process, and achieve proper quality control.
8.	<b>Relevant documents:</b> Particular requirement of IEC 601 and particular requirement of ISO for dental materials.
9.	<b>Proposed date of adoption:</b> } <b>Proposed date of entry into force:</b> } August 2000
10.	<b>Final date for comments:</b> 25 July 2000
11.	<b>Texts available from: National enquiry point [ ] or address, e-mail and telefax number of the other body:</b>  Medical Device Division Korea Food and Drug Administration #5 Nokbun-dong, Eunpyung-ku, Seoul Republic of Korea, 122-020  Tel: +82.2 380 16.69 Fax: +82.2 388 63.94