

# WORLD TRADE ORGANIZATION

G/TBT/N/KOR/2  
28 February 2001

(01-0989)

## 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 – KFDA <b>Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of 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 (362 pages, in Korean)
6.	<b>Description of content:</b> To specify a particular requirement for safety of medical devices
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> In order to harmonize Particular Requirement for Safety of Medical Devices in Korea with ISO and IEC
8.	<b>Relevant documents:</b> KFDAC Notification number 2001-17 Particular requirement for IEC 601
9.	<b>Proposed date of adoption:</b> } April 2001 <b>Proposed date of entry into force:</b> }
10.	<b>Final date for comments:</b> 31 March 2001
11.	<b>Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b>  Medical Device Division Drug Safety Bureau Korea Food and Drug Administration #5, Nokbun-dong, Eunpyung-ku Seoul 122-704 Republic of Korea  Tel: +822-380-1699 Fax: +822-351-6394