



4 December 2013

(13-6620)

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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

1. Notifying Member: <u>VIET NAM</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: The Ministry of Health Department of Science and Training 138A Giang Vo Street Ba Dinh District Ha Noi, Viet Nam Tel: (84-4) 62732273 Fax: (84-4) 38464051 E-mail: byt@moh.gov.vn 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: The Ministry of Health Department of Medical Equipments and Constructions. 138A Giang Vo Street Ba Dinh District Ha Noi, Viet Nam Tel: (84-4) 62732279 ext 1609 Fax: (84-4) 62732279 . Email: vuttbctyt@gmail.com
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: Decree on Medical devices (44 pages, in Vietnamese).
6. Description of content: This decree specifies the requirements for manufacture, sale, services, information and advertising medical devices. It also prescribes the provisions for management of quality and organization system of medical devices as well as technical persons in medical devices manufacturing units.
7. Objective and rationale, including the nature of urgent problems where applicable: Human health and safety
8. Relevant documents: -

9.	Proposed date of adoption:	1 January 2014
	Proposed date of entry into force:	1 July 2014
10.	Final date for comments: 60 days from the date of notification.	
11.	Text available from: National enquiry point [X], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: The Ministry of Health Department of Medical Equipments and Constructions. 138A Giang Vo Street Ba Dinh District Ha Noi, Viet Nam Tel.: (84-4) 62732279 ext 1609 Fax: (84-4) 62732279 Email: vuttbctyt@gmail.com Or can download at: http://tbtvn.org/Ti%20liu%20upload%20cho%20QCKT/Tai%20lieu%20tham%20khao/QC%20KT%202013%20Y%20Te.doc	