



20 May 2016

(16-2769)

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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: Ministry of Health Department of Medical Equipment and Construction 138A Giang Vo Str., Ba Dinh Dist., Ha Noi City, Viet Nam Tel (84-4) 62732273 Fax: (84-4) 38464051 Email: byt@moh.gov.vn Website: www.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:
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): High Frequency Surgical Equipment (ICS: 11.040)
5. Title, number of pages and language(s) of the notified document: National technical regulation on the basic safety of high frequency surgical equipment (12 pages, in Vietnamese)
6. Description of content: This regulation applies to agencies, organizations and individuals that manufacture, export, import and use the High Frequency Surgical Equipment for medical purposes in the territory of Vietnam. The regulation defines safety requirement of high frequency surgical equipment in medical purpose. It does not apply to equipment which have rated output power less than 50W.
7. Objective and rationale, including the nature of urgent problems where applicable: Medical devices have direct impact on the health of patients, therefore the most concerned issue is the safety of the device. On 6 December 2011, the Ministry of Health promulgated Circular No.44/2011/TT-BYT on the list of products and goods likely to be unsafe subject to the management assigned to the Ministry of Health. In this Circular, high frequency surgical equipment is listed in products and goods Group No. 2 Equipment of direct intervention on the patient. In addition, high frequency surgical equipment are now being imported into Vietnam and more widely used in the medical facilities. Therefore, technical standards defining safety criteria for high frequency surgical equipment should be developed to ensure the quality thereof during manufacturing, importing and use.

8. Relevant documents:

TCVN 7303-2-2:2006 (IEC 60601-2-2:1998) Medical Electrical Equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment.

IEC 60601-2-2:2009 Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

TCVN 6196-1:2008 (ISO 15223-1:2007/Amd 1:2008) Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied –Part 1: General requirements.

TCVN 7303-1:2009 (IEC 60601-1:2005) Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.

9. Proposed date of adoption: 2 July 2016

Proposed date of entry into force: 5 September 2016

10. Final date for comments: 60 days after the 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:**

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Department of Medical Equipment and Construction
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Or can be downloaded at:

<http://tbt.gov.vn/Ti%20liu%20upload%20cho%20QCKT/QCKT/QCKT%20dao%20mo%20dien.rar>