



23 May 2016

(16-2778)

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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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| <b>1. Notifying Member:</b> <u>VIET NAM</u><br><b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>   |
| <b>2. Agency responsible:</b><br>Ministry of Health<br>Department of Medical Equipment and Facilities<br>138A Giang Vo Str., Ba Dinh Dist., Ha Noi City, Viet Nam<br>Tel (84-4) 62732273<br>Fax: (84-4) 38464051<br>Email: <a href="mailto:byt@moh.gov.vn">byt@moh.gov.vn</a><br>Website: <a href="http://www.moh.gov.vn">www.moh.gov.vn</a><br><br><b>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:</b>  |
| <b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>  |
| <b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Rigid Endoscopic Equipment (ICS:11.040)   |
| <b>5. Title, number of pages and language(s) of the notified document:</b> National technical regulation on the basic safety of Rigid Endoscopic Equipment (11 pages, in Vietnamese)  |
| <b>6. Description of content:</b> This regulation applies to agencies, organizations and individuals that produce, export, import and use the endoscopic equipment for medical purposes in the territory of Vietnam. This regulation defines safety requirements of the endoscopic equipment and the enclosed portion of endoscopic equipment used together or separately for a medical purpose.  |
| <b>7. Objective and rationale, including the nature of urgent problems where applicable:</b><br>Medical devices have direct impact on the health of patients, therefore the most concerned issue is the safety of the device. On December 06, 2011, 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, rigid endoscopic equipment is in the group of goods likely to become unsafe. Currently, hard endoscopic equipment is being imported widely and used in medical facilities. Therefore, technical standards defining safety criteria for Rigid Endoscopic Equipment should be developed to help ensure the quality thereof during the examination and treatment. |

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| <b>8.</b>  | <p><b>Relevant documents:</b> <i>TCVN 7303-2-18:2006 (IEC 60601-2-18:1996)</i> Medical electrical equipment - Part 2-2: Particular requirements safety Specification for endoscopic equipment.</p> <p><i>IEC 60601-2-18:2009</i> Medical Electrical Equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment</p> <p><i>TCVN 7303-2-2:2006 (IEC 60601-2-2:1998)</i> Medical Electrical Equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment.</p> <p><i>TCVN 6196-1:2008 (ISO 15223-1:2007/Amd 1:2008)</i> Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied –Part 1: General requirements.</p> <p><i>TCVN 7303-1:2009 (IEC 60601-1:2005)</i> Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.</p> |
| <b>9.</b>  | <p><b>Proposed date of adoption:</b> 2 July 2016</p> <p><b>Proposed date of entry into force:</b> 5 September 2016</p>  |
| <b>10.</b> | <p><b>Final date for comments:</b> 60 days after the date of notification</p>   |
| <b>11.</b> | <p><b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p>Ministry of Health<br/> Department of Medical Equipment and Construction<br/> 138A Giang Vo Str., Ba Dinh Dist., Ha Noi City, Viet Nam<br/> Tel (84-4) 62732273<br/> Fax: (84-4) 38464051<br/> Email: <a href="mailto:byt@moh.gov.vn">byt@moh.gov.vn</a><br/> Website: <a href="http://www.moh.gov.vn">www.moh.gov.vn</a></p> <p>Or can be downloaded at:</p> <p><a href="http://tbt.gov.vn/Ti%20liu%20upload%20cho%20QCKT/QCKT/QCKT%20noi%20soi.rar">http://tbt.gov.vn/Ti%20liu%20upload%20cho%20QCKT/QCKT/QCKT%20noi%20soi.rar</a></p>  |