



20 May 2016

(16-2771)

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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 Facilities 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): Infant Incubator (ICS:11.040)
5. Title, number of pages and language(s) of the notified document: National technical regulation on the basic safety of Infant Incubator (20 pages, in Vietnamese)
6. Description of content: This regulation applies to agencies, organizations and individuals that produce, export, import and use Infant Incubators for medical purposes in the territory of Viet Nam. This regulation defines safety requirements and limits on the accuracy of some parameters of infant incubators used for medical purposes. This regulation does not apply to mobile incubator used to move infants.
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, 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, infant incubator, which is now being imported widely and used in medical facilities, is in the list of potentially unsafe commodities. This device directly relates to the health of children because it provides environmental essential conditions to ensure the health of children. Therefore, technical standards defining safety criteria for Infant Incubator should be developed to help ensure the quality thereof during manufacturing, importing and using.

8.	Relevant documents: <i>TCVN 7303-2-19:2006 (IEC 60601-2-19:1990)</i> Medical electrical equipment - Part 2-19: Particular requirements for the safety of baby incubators. <i>IEC 60601-2-19:2009</i> Medical Electrical Equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators. <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. <i>TCVN 7303-1:2009 (IEC 60601-1:2005)</i> Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
9.	Proposed date of adoption: 20 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: 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 Or can be downloaded at: http://tbt.gov.vn/Ti%20liu%20upload%20cho%20QCKT/QCKT/QCKT%20Long%20ap%20tre.rar