Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** RUSSIAN FEDERATION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Eurasian Economic Commission **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**: Eurasian Economic Commission Department for Technical Regulation and Accreditation Tel: +7(495)669-24-00 Fax: +7(495)669-24-15 E-mail: dept_techregulation@eecommission.org Website: www.eurasiancommission.org
3.	**Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [X], 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:** Draft decision of The Board of the Eurasian Economic Union "On the rules of registration and of the safety, quality, and efficiency inspection of medical devices" (76 pages, in Russian).
6.	**Description of content:** Establishment of procedures of registration and evaluation of safety, quality, and efficiency of medical devices, of the procedures of modification the registration dossiers of a medical device, of the issue of registration certificate duplicates, and of the procedures of denial of registration, suspension and repeal of registration certificate for medical device.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human health or Safety
8.	**Relevant documents:** Draft decision of The Board of the Eurasian Economic Union "On the rules of registration and of the safety, quality, and efficiency inspection of medical devices" https://docs.eaeunion.org/docs/ru-ru/0149253/clco_30122015_171_doc Agreement on common principles and rules of medical devices circulation in the Eurasian Economic Union. http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/konsultComitet/Documents/1%20Sogl%20MI.pdf
9.	**Proposed date of adoption:** 5 July 2016 **Proposed date of entry into force:** 1 January 2017

10.	**Final date for comments:** 5 June 2016
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Eurasian Economic Commission Department for Technical Regulation and Accreditation Tel: +7(495)669-24-00 Fax: +7(495)669-24-15 E-mail: dept_techregulation@eecommission.org Website: www.eurasiancommission.org