



11 May 2016

(16-2604)

Page: 1/2

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>RUSSIAN FEDERATION</u> 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 [X], 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): Pharmaceutical products and 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 establishment of the common requirements for safety and efficiency of medical devices, for their labelling requirements and operational documentation for them" (54 pages, in Russian).
6.	Description of content: Establishing of requirements for safety and efficiency of medical devices and of the requirements for their labelling requirements and operational documentation for them.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of Human health or Safety; Prevention of deceptive practices and consumer protection
8.	Relevant documents: Draft decision of The Board of the Eurasian Economic Union "On the establishment of the common requirements for safety and efficiency of medical devices, for their labelling requirements and operational documentation for them" https://docs.eaeunion.org/docs/ru-ru/0149235/clco_30122015_165_att Agreement on common principles and rules of pharmaceutical products circulation in the Eurasian Economic Union. http://www.eurasiancommission.org/ru/act/tehnreg/deptexreg/konsultComitet/Documents/1%20Sogl%20LS.pdf Agreement on common principles and rules of medical devices circulation in the Eurasian Economic Union. http://www.eurasiancommission.org/ru/act/tehnreg/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@ecommission.org

Website: www.eurasiancommission.org