



21 August 2025

(25-5228)

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>KYRGYZ REPUBLIC</u> If applicable, name of local government involved (Articles 3.2 and 7.2): The Kyrgyz Republic
2. Agency responsible: Eurasian Economic Commission
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [X], 5.7.1 [], 3.2 [], 7.2 [], Other:
4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Cotton wool, gauze, bandages and similar articles (for example, bandages, Band-Aids, poultices), impregnated or coated with pharmaceutical substances or packaged in forms or packages for retail sale, intended for use in medicine, surgery, dentistry or veterinary medicine (HS 3005); Devices and instruments used in medicine, surgery, dentistry or veterinary medicine, including scintigraphic equipment, other electro-medical equipment and vision testers (HS 9018); Equipment based on the use of X-ray, alpha, beta or gamma radiation, intended or not intended for medical, surgical, dental or veterinary use, including X-ray or radiotherapy equipment, X-ray tubes and other X - ray generators, high-voltage generators, shields and control panels, screens, tables, chairs and similar products for examination or treatment (HS 9022); Medical, surgical, dental or veterinary furniture (for example, operating tables, examination tables, hospital beds with mechanical devices, dental chairs); barber chairs and similar chairs with devices for rotating and simultaneously for tilting and lifting; parts of the above-mentioned products (HS Code 9402).
5. Details of notified document(s) (title, number of pages and languages, means of access): Draft amendments to the Requirements for the implementation, maintenance and evaluation of the quality management system of medical devices, depending on the potential risk of their use (2 pages, in Russian); (2 page(s), in Russian) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2025/TBT/KGZ/25_05435_00_x.pdf 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@eurasiancommission.org Website: www.eurasiancommission.org https://docs.eaeunion.org/ru-ru https://regulation.eaeunion.org/orv/3144/
6. Description of content: The draft amendments to the Requirements for the implementation, maintenance and evaluation of the quality management system of medical devices, depending on the potential risk of their use, apply to medical devices put into circulation in the territory of the Eurasian Economic Union and provide for the following: the possibility, in certain situations, of confirming the compliance of the production conditions of the sterilization site with the established requirements without the

inspection organization visiting the sterilization site, which will avoid repeating individual procedures when evaluating the quality management system in order to rationalize the resources of manufacturers of medical devices and inspecting organizations.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: Draft amendments to the Requirements for the implementation, maintenance and evaluation of the quality management system of medical devices, depending on the potential risk of their use https://regulation.eaeunion.org/orv/3144/ Decision of the Council of the Eurasian Economic Commission No. 106 of November 10, 2017
9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10. Provision of comments Final date for comments: 3 October 2025 [] 60 days from notification Contact details of agency or authority designated to handle comments regarding the notification: 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@eurasiancommission.org Website: www.eurasiancommission.org https://docs.eaeunion.org/ru-ru