NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Russian Federation  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  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](mailto:dept_techregulation@eecommission.org)  Web-site: [www.eurasiancommission.org](http://www.eurasiancommission.org),  <https://docs.eaeunion.org/ru-ru>  **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:**  Russian Scientific and Technical Centre for Information on Standardization, Metrology and Conformity Assessment (Standartinform, National enquiry point for the TBT Agreement) Tel: +7(495) 531-26-59 E-mail: [info@gostinfo.ru](mailto:info@gostinfo.ru) Website: [www.gostinfo.ru](http://www.gostinfo.ru) |
| **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):** Wadding, gauze, bandages and similar products (bandaging material, adhesive plasters,poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes (HS 3005); Instruments and appliances used in medical, surgical, dental or veterinary sciences,including scintigraphic apparatus, other electro-medical apparatus and sight testing instruments (HS 9018); X-ray, alpha, beta, gamma radiation apparatus; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examinationor treatment tables, chairs and the like (HS 9022); Furniture; medical, surgical, dental or veterinary (e.g. operating tables, hospital beds, dentists' chairs) barbers' chairs; parts (HS 9402). |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft amendments to the Rules for conducting studies (tests) for evaluation of biological action of medical products (18 page(s), in Russian) |
| **6.** | **Description of content:** The Draft amendments to the Rules for conducting studies (tests) for evaluation of biological action of medical products to medical devices issued for circulation in the territory of the Eurasian Economic Union and provide for the following: - clarification of the concepts; - determining the grounds for excluding testing laboratories (centers) from the unified register of authorized organizations that have the right to conduct research (testing) of medical devices for the purpose of their registration; - clarification of the form of the Protocol of studies (tests) for evaluation of biological action of medical products. |
| **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 Rules for conducting studies (tests) for evaluation of biological action of medical products to medical devices: <https://docs.eaeunion.org/ria/ru-ru/0104121/ria_20072020> * Decision No.38 of the Council of the Eurasian Economic Commission of May 16, 2016 <http://www.eurasiancommission.org/en/act/texnreg/deptexreg/LS1/Documents/Rules%20for%20Studies%20%28Tests%29%20for%20Evaluation%20of%20Biological%20Action_38.pdf> |
| **9.** | **Proposed date of adoption:** to be determined  **Proposed date of entry into force:** to be determined |
| **10.** | **Final date for comments:** 60 days from notification |
| **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](mailto:dept_techregulation@eecommission.org)  Web-site: [www.eurasiancommission.org](http://www.eurasiancommission.org),  <https://docs.eaeunion.org/ru-ru>  <http://www.eurasiancommission.org/en/act/texnreg/deptexreg/LS1/Documents/Rules%20for%20Studies%20%28Tests%29%20for%20Evaluation%20of%20Biological%20Action_38.pdf> <https://docs.eaeunion.org/ria/ru-ru/0104121/ria_20072020> |