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)  **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 Center 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)  Web-site: [www.gostinfo.ru](http://www.gostinfo.ru) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **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 articles (for example, dressings, 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 code(s): 3005); Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments. (HS code(s): 9018); Apparatus based on the use of X-rays or of alpha, beta or gamma radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like. (HS code(s): 9022); Medical, surgical, dental or veterinary furniture (for example, operating tables, examination tables, hospital beds with mechanical fittings, dentists' chairs); barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements; parts of the foregoing articles. (HS code(s): 9402) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft amendments to the Rules of classification of medical devices depending on the potential risk of use; (39 page(s), in Russian) |
| **6.** | **Description of content:** The Draft amendments to the Rules of classification of medical devices depending on the potential risk of use apply to medical devices and provide for the following:clarification of the concepts; clarification of classification criteria for medical devices for in vitro diagnostics; establishment of criteria and conditions for the classification of software that is a medical device; clarification of classification of medical devices. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Protection of human health or safety |
| **8.** | **Relevant documents:**   * Draft amendments to the Rules of classification of medical devices depending on the potential risk of use <https://docs.eaeunion.org/ria/ru-ru/0105470/ria_29062022> * Decision № 173 of the Board of the Eurasian Economic Commission of December 22, 2015 <https://docs.eaeunion.org/docs/ru-ru/0149288/clcd_30122015_173> |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 4 October 2022 |
| **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-maii: [dept\_techregulation@eecommission.org](mailto:dept_techregulation@eecommission.org)  Web-site: [www.eurasiancommission.org](http://www.eurasiancommission.org) |