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 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 (dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or in forms or packings for retail sale, for medical, surgical or veterinary use (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, examination or 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 registration and examination of safety, quality and effectiveness of medical devices (104 page(s), in Russian) |
| **6.** | **Description of content:** The Draft amendments to the Rules for registration and examination of safety, quality and effectiveness of medical devices apply to medical devices issued for circulation in the territory of the Eurasian economic union and provide for the following:  - clarification of terms and definitions; - clarification of the mechanism for implementing the procedure for approval by States of the recognition of the expert opinion of the reference state; - determination of cases when changes are made to the registration dossier of medical devices in the notification procedure; - clarification of the procedure for canceling the validity (cancellation) of the registration certificate of a medical device. |
| **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 registration and examination of safety, quality and effectiveness of medical devices: <https://docs.eaeunion.org/ria/ru-ru/0103911/ria_18022020> * Decision N° 46 of the Board of the Eurasian Economic Commission of 12 February 2016: <https://docs.eaeunion.org/docs/ru-ru/01410768/cncd_12072016_46> |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 20 April 2020 |
| **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>  <https://docs.eaeunion.org/ria/ru-ru/0103911/ria_18022020>  https://docs.eaeunion.orq/docs/ru-ru/01410768/cncd\_12072016\_46 |