IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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The Scheme of State Registration of Medical Devices (because of COVID-19) in the Russian Federation

Russian Government order **No. 1416 dated 27.12.2012** "Adoption of rules for state registration of medical devices"
(as revised in the Russian Government order **No. 299 Dated 18.03.2020**)

Russian Government order **No. 430 dated 03.04.2020** "About features of the circulation of medical devices, including state registration of a series (batch) of a medical device"

Single-use medical devices registered in the country of origin are not subject to registration in Russian Federation

Russian Government order **No. 1826 dated 13.11.2020** “About features of the circulation of medical devices, including state registration of a series (batch) of a medical device”

Came into force on 23 November 2020

Preparation of documents

Operational documentation of medical device
Photos of medical device
Documents confirming that the series (batch) of the medical device belongs to the applicant on legal grounds
Technical tests according to the standard program
Toxicological tests according to the standard program
Clinical trials according to the standard program
All documents must be certified by the applicant

Registration of medical devices

Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration of a series (batch) of medical devices

Refusal in state registration

Validity of the registration certificate – 01.01.2022

Russian Government order No. 1906 dated 24.11.2020 "On amendments to the Rules of State Registration of Medical devices"

Entered into force on 05.12.2020

- **An accelerated procedure for bringing new software as medical device to the market, including software with the use of artificial intelligence technologies, has been introduced by introducing a one-stage procedure for their state registration**

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The order of the Ministry of Health of the Russian Federation No. 661n dated 30.06.2020 "On approval of the Procedure for the Import of medical devices into the territory of the Russian Federation for the purpose of state registration "

Entered into force on 01.01.2021

- **The procedure for importing medical devices into the territory of the Russian Federation for the purpose of state registration, including for the purpose of making changes to the documents contained in the registration dossier for a medical device, has been established.**
- **It is determined that a permit for the import of medical devices is not required for software that is a medical device.**
- **A permit for the import of a medical device is issued in electronic form.**

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The order of the Ministry of Health of the Russian Federation No. 1236n dated 20.11.2020 "On amendments to the requirements for the content of the technical and operational documentation of the manufacturer (manufacturer) of a medical device, approved by Order of the Ministry of Health of the Russian Federation No. 11n dated 19.01.2017"

Entered into force on 01.01.2021

- **The requirements for the technical and operational documentation of the manufacturer (manufacturer) for software that is a medical device, including software with the use of artificial intelligence technologies, are established. These requirements are harmonized with the provisions of the acts of the Eurasian Economic Union and the IMDRF acts**

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The order of the Ministry of Health of the Russian Federation No. 980n dated 15.09.2020 "On approval of the Procedure for monitoring of medical device safety"

The order of the Ministry of Health of the Russian Federation No. 1113n dated 19.10.2020 "On the approval of the Procedure for reporting by the subjects of circulation of medical devices on all cases of detection of side effects not specified in the instructions for use or operating instructions of the medical device, on adverse reactions during its use, on the features of interaction of medical devices with each other, on the facts and circumstances that pose a threat to the life and health of citizens and medical workers during the use and operation of the medical device"

Entered into force on 01.01.2021

- **The Orders establish the procedure for monitoring of medical device safety harmonized with the IMDRF principles.**

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Russian Government order No. 1440 dated 15.09.2020 "On approval of the Rules for the Destruction of Seized Counterfeit Medical Devices, Substandard Medical Devices and Counterfeit Medical Devices"

Entered into force on 01.01.2021

- **The procedure for the destruction of seized counterfeit, substandard and counterfeit medical devices is defined**
- **The procedure for the owner's actions to destroy the seized medical devices is regulated**

Circulation of Medical Devices in Eurasian Economic Union

4 medical devices are registered in accordance with the rules for registration of medical devices of the EEU

Amendments have been prepared to the Agreement of EEU, under which the validity of national registration certificates is extended, from January 1, 2022, the primary registration of medical devices is carried out only under the legislation of the Eurasian Economic Union

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Thank you for your attention!