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. 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**)

Came into force on 19 March 2020

Registration of medical devices

Technical and operational documentation of medical device
Photos of medical device
Power of attorney for an authorized representative of an manufacturer
All documents must be certified in the country of origin in the prescribed manner

Not more than 150 days

Confirmation of registration of medical devices

In-country Testing of medical devices at Federal State Budgetary Institution "All-Russian Scientific-research and Test Institute for Medical Engineering" of Roszdravnadzor:
- ✓Technical tests
- ✓Toxicological test

In country Clinical trials of medical devices at Russian Authorized Hospitals

The review of documents

Elimination of violations (if necessary)

Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration

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”

Came into force on 06 April 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 – 01.01.2021

The order of the Ministry of Health of the Russian Federation No. 206n dated 20.03.2020 “About approval of the procedure of organization and carrying out of examination of quality, efficacy and safety of medical devices"

Entered into force on 02.08.2020

- **Procedure of organization and carrying out of expertise of quality, efficiency and safety of medical devices at the state registration of medical devices and in case of making changes in dossier;**

- **Procedure of organization and carrying out of expertise of dossier of medical devices in case if this product is not medical device accordance with legal laws**

Update of the order of the Ministry of Health of the Russian Federation No. 4n dated 06.06.2012 “About approval of nomenclature classification of medical devices"

Entered into force on 21.08.2020

- **Classification of software as medical device depending on the potential risk of its use;**
- **Criteria of classification: type of information and condition of application;**
- **The document based on IMDRF principles of SaMD**

The pilot project "Medical device Labeling"

Based on Unique Device Identification System (UDI) and IMDRF principles

<u>Types of medical devices selected for pilot project:</u>

- **Coronary stents;**
- **Computer tomograph;**
- **Diapers;**
- **Hearing-aid**

The pilot project "Patient registry"

Based on IMDRF principles

Types of medical direction selected for pilot project:

- **Cardiosurgery;**
- **Orthopedics;**
- **Plastic surgery**

Circulation of Medical Devices in Eurasian Economic Union

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

The first Inspection of Quality Management System of medical devices was carried out in accordance with the rules for registration of medical devices of the EEU (which is harmonized with IMDRF principles)

The 22nd annual conference "State regulation of medicines and medical devices – PharmMedObrashenie-2020"

the 29th – 30th of October 2020
Moscow

The Conference traditionally brings together more than 1000 interested experts from medical and pharmaceutical industries, representatives of federal and regional legislative and executive authorities of the Russian Federation, foreign regulatory authorities, scientific-research and public organizations, professional associations, wholesale and retail organizations and manufacturers of medical products

Thank you for your attention!

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