IMDRF International Medical Device Regulators Forum

NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION

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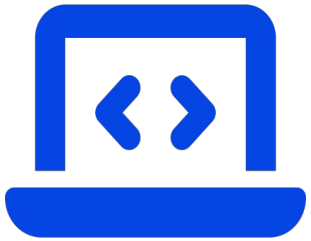
State registration of medical devices

Russian Government order № 1684 dated 30.11.2024 «Adoption of rules for state registration of medical devices»

Came into force on 1 March 2025



Provide services in electronic format

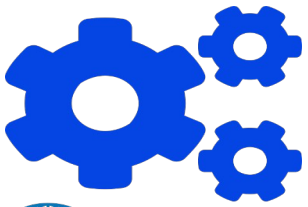
medical device registration services in accordance with the legislation of the Russian Federation are being converted to an electronic format (switching to the registry model)

Alternative procedures

possibility to choose one of the "alternative" state registration procedures for medical devices of domestic manufacturing

Own proofs

establishing whether the manufacturer can use it own evidence materials



Features of making changes to the software

features making changes to the documents contained in registration dossier on software with using artificial intelligence technologies

State registration of medical devices

Russian Government order № 552 dated 01.04.2022 «On approval of the specifics of circulation of medical devices» (as revised in the Russian Government order **No. 240 Dated 28.02.2025**)

Provide services in electronic format

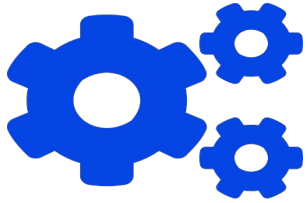
medical device registration services in accordance with the legislation of the Russian Federation are being converted to an electronic format (switching to the registry model)

Simplification and reduction

Possibility to present a "shortened" list of documents and simplified procedure for conducting tests (studies), also possibility provide in certain cases evidence materials from manufacturer instead of tests and studies

«Deferred» registration

for medical devices with a low degree of potential risk of their use (with the exception of medical devices, issued by in a sterile form) and included in a specific list, provides for a "deferred" registration procedure



Features making changes

features of making changes to the documents contained in the registration dossier for a medical device of domestic manufacturing

Inspection of the manufacturing of medical devices

Russian Government order № 136 dated 09.02.2022

Came into force on 1 September 2022

Manufacturers of medical devices need to:

- develop risk management requirements at all stages of the life cycle of medical devices
- define a sequence of processes
- establish criteria and methods that are necessary for ensuring effectiveness
- provide monitoring, analysis and measuring of the processes

If the manufacturer has implemented the GOST ISO 13485-2017 inspection is limited with assessment of verifying compliance with the requirements related to the design, development, manufacturing and output control processes of a medical device and to the processes related to application and use of medical device (monitoring postmarketing services).

Inspection of the manufacturing of medical devices

Russian Government order № 135 dated 09.09.2022
(as revised in the Russian Government order **№ 2517 Dated 29.12.2022**)

Came into force on 1 September 2022

Inspection of the manufacturing of medical devices is carried out in the following cases:

- manufacture of medical devices which need state registration with requiring expertis of quality, efficiency and safety of medical device
- manufacture of medical devices that manufactured for individual patient and which are subjects to special requirements of medical professionals

Inspection objectives:

- Assessment of quality, safety and effectiveness of medical devices
- checking the operation of the quality management system
- confirmation of manufacturing compliance with standards ISO 13485-2017
- state registration of medical equipment and access to the market

Nomenclature classification of medical devices

Update of the order of the Ministry of Health of the Russian Federation № 4n dated 06.06.2012 «About approval of nomenclature classification of medical devices»

Systematization and structuring medical devices

- planning equipment in medical facilities
- accounting adverse events related to medical devices
- binding medical devices to standards and recommendations for healthcare

Assignment by classification criteria

- area of application
- invasiveness
- sterility
- frequency of use
- design and constractional features

Classification of adverse events based on IMDRF classification

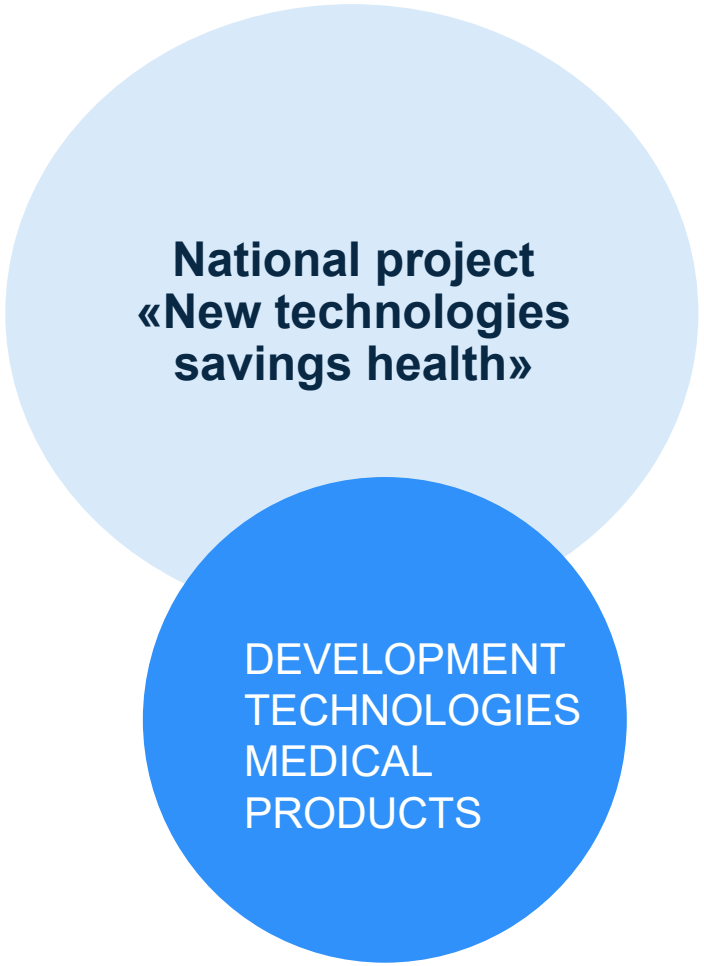
Roszdravnadzor order № 4513 dated 20.05.2021

Medical devices located in the request form on the territory of the Russian Federation, are subject to security monitoring in order to identify and prevention of adverse events

The classification system includes 24 types to be considered tracking unfavorable conditions events

- different types of technical malfunctions medical devices;
- an individual intolerance for materials;
- violations in labeling of medical devices;
- incorrect installing and configuring a medical device;
- not following the recommendations of the manufacturer during medical device use

National projects in the Russian Federation



Activities and expected key results:

1. conducting clinical trials of at least 38 medical devices with artificial intelligence technology
2. introduction of medical devices based on technology bio-prints
3. increase in the share of Russian-manufactured medical devices from 31.4% to 40%
4. manufacturing of more than 3,400 medical devices products
5. support for more than 50 projects, including startups, by development of new medical devices
6. provision with raw materials and components for russian manufacturers

General market of medical devices in Russia within the framework of the Eurasian Economic Union

Changes to the Rules classification of medical devices in depending on the potential risk, approved by the Decision of the Board of the Eurasian Economic Commission from 22.12.2015 № 173

on recommendations adopted IMDRF (GHTF/SG1/N77:2012 Principles of Medical Devices Classification)

Abouttdelny Section – " Classification of software as amedical device»

- 4 classes are defined for software medical devices potential user application risk factors: 1, 2a, 2b and 3 - for low, medium, high and high risk
- if the software as medical device does not uses artificial intelligence technologies, then the class of potential risk is determined based on the clinical scenario (condition) of use, the type of information provided and its impact on medical decision-making solutions

- Also document added appendix, which contains information and examples when establishing risk class, depending on intended use of a software-based medical device

General market of medical devices in Russia within the framework of the Eurasian Economic Union

Changes to the Rules conducting clinical and clinical laboratory tests (studies) of medical devices in within the framework of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission from 12.02.2016 № 29

on recommendations adopted by IMDRF (GHTF/SG5 / N3: 2010 Clinical Investigations; GHTF/SG5/N8:2012 Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices)

1. report on clinical evidence of safety and efficacy of the medical device should be approved with a specialist in the field of medical use
2. specialties for acceptances for clinical data received for another product (equivalence should be presented)
3. defined clear requirements for conducting clinical trials and diagnostic studies in vitro, including justification of the effectiveness and safety of medical devices
4. forms and documents to get a permissions for conducting clinical or clinical laboratory tests (studies) and requirements to medical organizations (clinical sites)

Development prospects general medical device market in within the framework of the Eurasian Economic Union

1. Action plan (roadmap) for ensuring the transition to implementation of registration of medical devices in accordance with the Registration Rules and expert examinations of the safety, quality and effectiveness of medical devices approved by the Decision of the Council of the Eurasian Economic Commission of 12.02.2016 № 46

2. Project Decree of the Eurasian Intergovernmental Council "On the Concept of further development of the common market of medical devices within the Framework of the Eurasian Economic Union».

3. Amendments to the Agreement on Common Principles and Rules of Circulation of Medical Devices (Medical Devices and Medical Equipment) within the framework of the Eurasian Economic Union from 23.12.2014

- extension of the transition period from national registration to registration within the framework of the Eurasian Economic Union
- development of a procedure for bringing national registration dossiers for medical devices in line with the requirements of international treaties and acts that constitute the legislation of the Eurasian Economic Union

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Thank you for your attention!

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