



IMDRF International Medical Device
Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026



Changes in Russian regulation of medical device circulation

Ministry of Health of the Russian Federation



National registration

Decree of the Government of the Russian Federation no. 1684 of 30 November 2024 on the approval of the rules for state registration of medical devices



Validity period:

Medical device registration

until 31.12.2027

Amendments to the registration dossier

until 31.12.2028



Electronic services

The state service for state registration is provided electronically (registry model)

The common market within the EAEU

Agreement on common principles and rules for the circulation of medical devices (medical products and medical equipment) in the framework of the Eurasian Economic Union of 23 December 2014



Decision no. 46 of 12 February 2016 on Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products



Unified requirements

Establishment of common safety and effectiveness requirements for medical devices within the EAEU

REGISTERED



> 41 thous.

REGISTRATION CERTIFICATES

of these 38 % DOMESTIC MANUFACTURERS





On medical device registration

- **Procedure for conformity assessment of medical devices in the form of technical tests, toxicological studies, and clinical trials for the purpose of state registration of medical devices** (effective from 1 September 2026)
- **Procedure for organization and conduct of expert evaluation of the quality, effectiveness, and safety of medical devices** (effective from 1 March 2027)

Systematic updates to ensure alignment with advanced international practices, taking into account new versions of the forum's guidance documents and the experience of member states



On monitoring the safety of medical devices

- **Procedure for monitoring the safety of medical devices** (effective September 2026)
- **Procedure for reporting by medical device market operators of all cases of adverse events at all stages of circulation of the relevant medical device in the territory of the Russian federation and other states** (effective 1 September 2026)

Systematic updates to ensure alignment with advanced international practices, taking into account new versions of the forum's guidance documents and the experience of member states



Decree of the government of the Russian Federation no. 1829 of 19 November 2025 on amendments to the decree of the government of the Russian Federation no. 1066 of 30 June 2021 on federal state control (surveillance) over the circulation of medical devices” (together with the ‘regulation on federal state control (surveillance) over the circulation of medical devices’)

Key changes

1. Medical device operators are classified according to risk category:

- **High risk;**
- Significant risk (inspected once every 4 years)
- Medium risk (inspected once every 6 years)
- Moderate-low risk (inspected once every 6 years)
- Low risk

2. **Planned oversight activities** inspections for facilities classified as **high-risk**, are conducted with the following frequency:

- On-site inspection— once every 2 years
- Sample purchase (market check) – once every 2 years
- Documentary review— once every 2 years



High-risk organizations include those engaged in:

- Manufacture of in vitro diagnostic medical devices and implantable medical devices of risk class III;
- Conducting clinical trials of medical devices classified as risk class 2b or III.

The use of the “Inspector” mobile application is mandatory for all inspection and preventive activities

“Inspector” mobile application

The “Inspector” mobile application (MA) is software employed by supervisory authorities and regulated parties on a computing device for the execution of inspection and preventive measures

Inspection history

Checklists

Geolocation monitoring

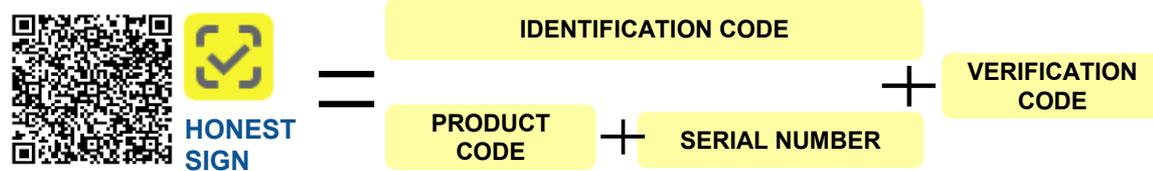
Online verification

Video recording of inspection



13 categories subject to labeling

- Orthopedic shoes and devices
- Air purifiers
- Coronary stents
- Hearing aids
- Diapers, nappies, sanitary pads
- Computed tomography scanners
- Medical gloves
- Wheelchairs
- Canes, crutches, supports, handrails
- Urine and fecal collection bags
- Anti-decubitus mattresses and cushions
- Prosthesis parts; functional units and segments
- Chairs with sanitary equipment



Statistics on the operation of the labeling system



More than **83 900***
total market participants



MORE THAN **1 460 ***
MANUFACTURERS



MORE THAN **17 150 ***
WHOLESALEERS



MORE THAN **3 430 ***
IMPORTERS



MORE THAN **71 590 ***
RETAIL

NUMBER OF LABELING CODES ISSUED

More than **202 613 880 *** units have been introduced into circulation

More than **54 328 740 *** units have been withdrawn from circulation

*There is a steady increase both in the number of participants and in the issuance of labeling codes

Medical device labeling experiment

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The EXPERIMENT involves 9 categories

- Condoms
- Syringes
- Test tubes
- Infusion systems
- Wipes, including reusable
- Equipment for ozone, oxygen, and aerosol therapy, ventilators and other respiratory therapy devices
- Neonatal incubators
- Medical masks
- Implants for plastic surgery and cosmetology (fillers, cosmetic threads)

Extension of the EXPERIMENT to 7 categories

- Blood glucose monitoring system (glucometers)
- Test strips for glucose measurement
- Blood pressure monitors (sphygmomanometers / tonometers)
- Rapid diagnostic tests (RDTs / point-of-care tests)
- Reagent kits (in vitro reagents)
- Suturing materials
- Endoprostheses

Statistics on the operation of the labeling system



More than 76 000*
total market participants



MORE THAN 500 *
MANUFACTURERS



MORE THAN 9 400 *
WHOLESALEERS



MORE THAN 1 700 *
IMPORTERS

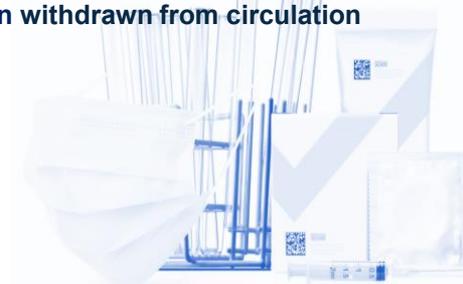


MORE THAN 64 500 *
RETAIL

NUMBER OF LABELING CODES ISSUED

More than 208 700 * units have been introduced into circulation

More than 540 * units have been withdrawn from circulation



HSA
Health Sciences Authority



IMDRF

International Medical Device
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Healthcare development strategy of the Russian Federation until 2030

29th IMDRF 2026

Presidential Decree No. 896, December 8, 2025

Key priorities for healthcare development include:

- Promoting domestic production of medicines and medical devices, along with the necessary raw materials and components

By 2030, the strategy aims to achieve:

- > **40 %** share of medical devices produced within Russia in the total supply required by the healthcare system
- > **19.5 %** share of implantable medical devices produced domestically in the total supply required by the healthcare system
- ~ **80 %** level of technological independence in the healthcare sector



National project “new health preservation technologies” – medical devices component

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GOAL OF THE NATIONAL PROJECT

Achieve a high level of technological sovereignty by 2030 in the field of medical technologies, and in the production of medicines and medical devices

AIMED AT ACHIEVING THE NATIONAL DEVELOPMENT GOAL:

Ensuring technological independence and creating new markets in the area of citizen health preservation

FEDERAL PROJECTS INCLUDED IN THE NATIONAL PROJECT

- 1 Management of medical science
- 2 Technologies for the development of medical devices, pharmaceuticals, and next-generation platforms
- 3 Biomedical and cognitive technologies of the future
- 4 Regenerative biomedicine, preventive medicine technologies, and support for active healthy longevity
- 5 Development of production for the most in-demand medicines and medical devices

RESULTS OF 2025 UNDER THE NATIONAL PROJECT

- Implementation of investment projects for the development of medicines and medical devices
- Advancement of scientific research in the interests of medicine and healthcare

33 Medical devices registered include the most in-demand products intended for the diagnosis of socially significant diseases, such as

- Hormone level testing (e.g., growth hormone)
- Detection of immune response to infectious diseases
- Various medical imaging equipment
- Rehabilitation devices



Thank You!

