IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

New aspects in medical devices regulation in the Russian Federation

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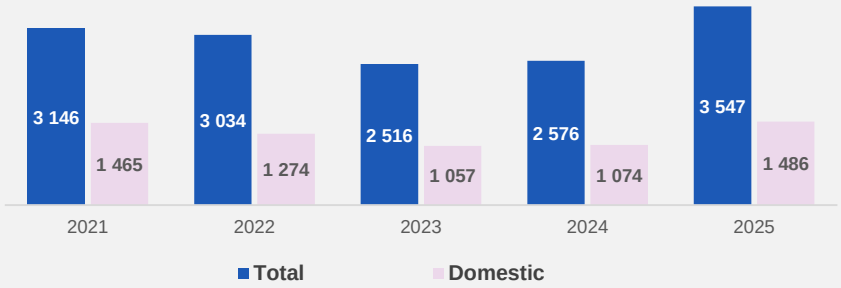
Medical Devices Market in the Russian Federation

REGISTERED MEDICAL DEVICES IN 2025 under the national procedure

Total	Russia
3 547	1 486

TRENDS IN THE REGISTRATION OF MEDICAL DEVICES

> 41 th.
REGISTRATION CERTIFICATES
Of these, **38%** are DOMESTICALLY MANUFACTURED



TOTAL NUMBER OF MEDICAL DEVICES REGISTERED IN THE RUSSIAN FEDERATION, BY COUNTRIES WITH WELL-DEVELOPED REGULATORY SYSTEMS

AUSTRALIA 44	KOREA 1 310
BRASIL 121	RUSSIA 16 893
UK 665	SINGAPORE 77
EU 9 396	USA 4 136
CANADA 78	SWITZERLAND 853
CHINA 4 879	JAPAN 1 026

Legislative Amendments Implemented in the Russian Federation

01 Registration

Decree of the Government of the Russian Federation No. 974 of August 3, 2026, "On Amending the Russian Government Decree No. 1684 of November 30, 2024"

Extension of the deadline for updating authorization documents for foreign medical device representatives until September 1, 2027

- **Manufacturers have been granted additional time to bring the information about the authorized representative into compliance with the established requirements**

02 Import regulations

Decree of the Government of the Russian Federation No. 557 of May 16, 2026, "On Approval of the Rules for Importing Specific Medical Devices in the Russian Federation, as Defined in Clauses 1, 2, and 5 of Part 5 of Article 38 of the Federal Law 'On the Fundamentals of Public Health Protection in the Russian Federation' (with the exception of medical devices specified in subparagraphs "a," "c," and "d" of paragraph 11 of Article 4 of the Agreement on Uniform Principles and Rules for the Circulation of Medical Devices (Medical Products and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014)"

The procedure for importing specific unregistered medical devices into the Russian Federation has been clarified and digitized (electronic document management)

- **importation of certain categories of medical devices into Russia on a notification basis without registration**
- **the list of documents required to notify Roszdravnadzor has been expanded**

New Regulations on the Distribution of Medical Devices

01 Conformity Assessment

Order of the Russian Ministry of Health No. 421n dated May 13, 2026 «On the Approval of the Procedure for Conducting Conformity Assessments of Medical Devices Through Technical Testing, Toxicological Studies, and Clinical Trials for the Purpose of State Registration of Medical Devices»

- **Clinical trials**
  additional cases in which clinical trials involving human subjects are conducted

- **Revision of procedures**
  specifies the timeframes for interaction between the applicant, testing laboratories, and medical organizations

Effective September 1, 2026

02 Post-Market Surveillance Rules

Order of the Russian Ministry of Health No. 540n dated May 26, 2026 «On the Approval of the Procedure for Monitoring the Safety of Medical Devices, with the Exception of Medical Devices Registered in Accordance with International Treaties and Legal Acts Constituting the Law of the Eurasian Economic Union»

- **Types of evidence:** spontaneous adverse event reports, automated data from AI-based medical devices, post-market clinical follow-up (PMCF) reports, and information from manufacturers and importers

- **Increasing the role of responsible parties**
  market participants must designate a person responsible for collecting information

- **Digitization**
  - All adverse event reports are submitted through the AIS «Roszdravnadzor» information system
  - For AI MD – automatic submission of error data has been introduced

Effective September 1, 2026

03 Reporting Forms and Data Requirements

Order of the Ministry of Health of Russia No. 541n dated May 26, 2026 «On the Approval of the Procedure for Reporting All Cases of Adverse Events Identified at All Stages of the Distribution of the Relevant Medical Device within the Territory of the Russian Federation and the Territories of Other States»

- **Updated Submission Format**

- **Deadlines and application specifics**
  deadline for submitting PMCF is February 1. Applications must be submitted via the Roszdravnadzor AIS

- **Information specifics**
  the information scope to be included in the report and in the post-marketing clinical follow-up (PMCF) report has been expanded

Effective September 1, 2026

Changes in the Legislation of the Russian Federation and the Eurasian Economic Union

The Agreement on Uniform Principles and Rules for the Circulation of Medical Devices (medical products and medical equipment) within the Eurasian Economic Union signed on December 23, 2014

✓ Approved by Order No. 23 of the Council of the Eurasian Economic Commission dated May 23, 2025, and signed by the member states of the Union on **December 29, 2025**

extension of the transition period until December 31, 2028

National regulation

Extension of National Registration Procedures for Medical Devices

Decree of the Government of the Russian Federation No. 1684, dated November 30, 2024 (Rules for State Registration)

up to 31.12.2028

Decree of the Government of the Russian Federation No. 552 of April 1, 2022, (Specifics of State Registration)

up to 31.12.2028

The Agreement on Uniform Principles and Rules for the Circulation of Medical Devices (medical products and medical equipment) within the Eurasian Economic Union signed on December 23, 2014

✓ Approved by Order No. 25 of the Council of the Eurasian Economic Commission dated August 1, 2025, and signed by the member states of the Union on **February 9, 2026**

expansion of the list of medical devices not subject to registration

National regulation

Expansion of the list of medical devices that are not subject to registration under national law

a draft federal law «On Amending Article 38 of the Federal Law «On the Fundamentals of Public Health Protection in the Russian Federation»

REISSUANCE of Resolution No. 1590 of the Government of the Russian Federation dated September 22, 2021
(rules for issuing import permits for medical devices intended for the life-saving treatment of specific patients)

AMENDMENTS to Resolution No. 557 of the Government of the Russian Federation dated May 16, 2026
(rules for importing specific unregistered medical devices)

Changes in the Legislation of the Eurasian Economic Union

01 Requirements for implementing QMS

Decision of the EEC Council dated April 27, 2026 No. 43 "On Amendments to the Requirements for the Implementation, Maintenance, and Evaluation of the Quality Management System for Medical Devices Depending on the Potential Risk of Their Use"

- **introduces a simplified procedure for auditing organizations that perform sterilization of medical devices, compared to other critical suppliers**

02 Recommendations for conducting an inspection

Recommendation of the EEC Board dated 07.04.2026 No. 6 "On Methodological Recommendations for Conducting Inspections of Medical Device Manufacturing"

- **formulates general approaches to conducting regulatory audits based on the guidelines IMDRF/MDSAP AU P0002.008**

03 List of standards

Recommendation of the EEC Board dated July 28, 2026 No. 19 " On Amending the List of Standards for Voluntary Compliance with General Safety and Performance Requirements for Medical Devices, Their Labeling and Operating Documentation"

- **updates the list of recognized standards that provide a presumption of conformity with the General Requirements for the "Essential Principles of Safety and Performance of Medical Devices"**

Mandatory labeling of medical devices

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

HONEST SIGN =

IDENTIFICATION CODE

PRODUCT CODE + SERIAL NUMBER + VERIFICATION CODE

Statistics on the operation of the labeling system

More than 115 379* total market participants

MORE THAN 1 817 * MANUFACTURERS

MORE THAN 22 305* WHOLESALERS

MORE THAN 4 144* IMPORTERS

MORE THAN 87 113* RETAILERS

NUMBER OF LABELING CODES ISSUED

More than 333 757 269* units have been released

More than 110 826 490* units have been withdrawn

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

Medical device labeling experiment

The EXPERIMENT involves 13 categories

- Syringes
- Infusion systems
- Wipes
- Test tubes
- 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)
- 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)

Statistics on the operation of the labeling system

More than 92 312*
total market participants

MORE THAN 633 *
MANUFACTURERS

MORE THAN 12 171*
WHOLESALERS

MORE THAN 1 902 *
IMPORTERS

MORE THAN 77 606*
RETAILERS

NUMBER OF LABELING CODES ISSUED

More than 6 600 743* units have been released

More than 38 517 * units have been withdrawn

Thank You!