IMDRF International Medical Device Regulators Forum

CHANGES IN MEDICAL DEVICE REGULATION IN THE RUSSIAN FEDERATION

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Enhancing regulatory acts within Russian legislation

01

Federal Law of 31.07.2025 No. 304-FZ

«On amendments to certain legislative acts of the Russian Federation»

amendments introduced to Part 1 of Article 2 of Federal Law No. 323-FZ of 21.11.2011

- **the registration certificate** for a medical device is an entry in the State Register of Medical Devices and organizations (individual entrepreneurs), **confirming the state registration** of the device

Effective from 01.03.2026

02

Government Decree of the Russian Federation of 13.08.2025 No. 1206

«On amendments to the Government Decree of the Russian Federation of 30.11.2024 No. 1684»

- establishing unified requirements for the content of technical and operational documentation developed by manufacturers
- **extending the deadline** for updating information about the authorized representative of a medical device manufacturer **until 01.09.2026**

Entered into force on 15.08.2025

Enhancing regulatory acts within Russian legislation

01

Order of the Ministry of Health of Russia dated 11.04.2025 No. 181n

Entered into force on 01.09.2025

«On approval of requirements for the content of technical and operational documentation of medical device manufacturers»

- establishing unified requirements for technical and operational documentation

02

Order of the Ministry of Health of Russia dated 29.04.2025 No. 257n

Entered into force on 01.09.2025

«On approval of the list of medical devices classified as measuring instruments within the framework of state regulation of measurement uniformity, and the procedure for testing them for type approval»

- approval of the list of medical devices classified as measuring instruments and the procedure for their testing

03

Order of the Ministry of Health of Russia dated 24.06.2025 No. 364n

Entered into force on 17.08.2025

«On amendment to subparagraph 4.13 of paragraph 4 of the nomenclature classification of medical devices by risk class, approved by Order of the Ministry of Health of Russia No. 4n of 06.06.2012»

- clarification of the classification of antiseptic wipes for hand treatment of medical personnel, in line with EAEU acts and IMDRF recommendations

Prospects for the development of the common market for medical devices within the Eurasian Economic Union

01

Decision of the Eurasian Intergovernmental Council “On the Concept of Further Development of the Common Market for Medical Devices within the EAEU”

Signed on 15.08.2025

this strategic program document includes:

- general approaches to developing unified rules for medical device circulation, taking IMDRF recommendations into account
- main results of the functioning of the common medical device market
- prospective directions for regulatory development
- creation of a unified information space within the EAEU for medical device circulation

02

Amendments to the Agreement on the Unified Principles and Rules for Circulation of Medical Devices (23.12.2014)

- the draft provides for changes to the deadlines for submitting applications for examination, registration, re-registration of medical devices, and amendments to registration documents in accordance with EAEU member state legislation

extension of medical device registration under national rules until 01.01.2028

Development of acts of the Eurasian Economic Union

Amendments

1. **Decision of the EAEU Council of 12.02.2016 No. 46**
«On the Rules for Registration and Examination of the Safety, Quality, and Effectiveness of Medical Devices»
Draft Decision of the EAEU Council “On amendments to the Rules for Registration and Examination of the Safety, Quality, and Effectiveness of Medical Devices”

— approved at the EAEU Council meeting on 08.07.2025

- clarification of the terminology used in the Registration Rules, including removal of the term “adverse event” in line with terminology from the Rules on Post-Market Surveillance of Safety, Quality, and Effectiveness of Medical Devices (EEC Board Decision No. 174 of 22.12.2015);
- clarification of registration procedures when a new type of medical device must be included in the Global Medical Device Nomenclature and the EAEU nomenclature;
- adjustment of the list of documents required for registration of Class 1 and 2a medical devices, as well as in vitro diagnostic devices (Annex No. 4 to the Registration Rules).

Development

1. **Methodological recommendations on inspection procedures for medical device manufacturing in accordance with EAEU rules**

- establishing and applying unified approaches to medical device manufacturing inspections in accordance with the “Requirements for the implementation, maintenance, and assessment of medical device quality management systems depending on potential risk,” approved by EAEU Council Decision No. 106 of 10.11.2017.

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Mandatory identification system for medical devices

13 categories subject to implementation

2023

- Orthopedic footwear and devices
- Air purifiers
- Coronary stents
- Hearing aids
- Diapers, nappies, pads
- CT scanners
- Wheelchairs

2024

- Canes, crutches, supports, handrails
- Urine and fecal collectors
- Anti-decubitus mattresses and cushions
- Prosthetic components and functional parts
- Commode chairs with sanitary equipment

2025

- Medical gloves

9 categories under pilot project

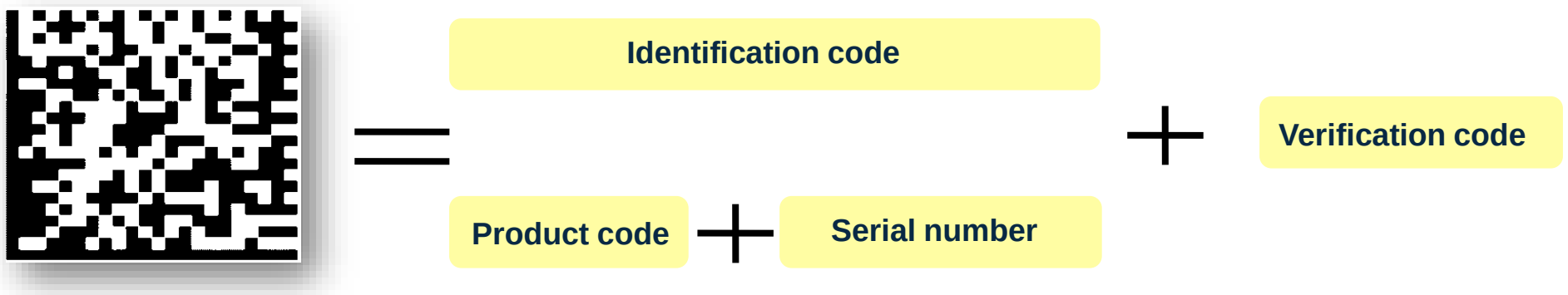
- Condoms
- Syringes
- Test tubes
- Infusion systems
- Wipes, including reusable
- Equipment for ozone, oxygen, and aerosol therapy, ventilators and other respiratory therapy devices
- Neonatal incubators
- Medical masks
- Implants for plastic surgery and cosmetology (fillers, cosmetic threads)

from 01.09.2024 to 28.02.2026

What is identification code

Identification code – a unique identifier for each product unit, generated by the system operator using cryptographic algorithms and placed on the label of medical device.

- Ensures full traceability of each product unit from entry into circulation to withdrawal.
- After the introduction of mandatory labeling, unlabeled products will not be able to cross the customs border of the Russian Federation.
- Identification codes for imported products must be applied either at the manufacturing site or at a customs warehouse.



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What market participants need to do (manufacturer/importer)

Steps to connect to the system

1. Obtain an advanced qualified electronic signature for the head of the organization or individual entrepreneur.
2. Register in the “Honest SIGN” identification system using the QES
3. Add the “Medical devices” product group in the personal account
4. Select a technical solution;
   Importers must additionally choose a labeling site (customs warehouse, logistics terminal, or foreign manufacturing site)
5. Review the experience of other participants and study the details of medical device labeling in the Honest Community

helpful links

Honest SIGN – the national labeling system

Technology partners

Virtual learning space

Labeling webinars

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Statistics on the operation of the identification system

Total number of market participants

~72 468 *

Identification codes issued

placed on the market **~124 907 507 ***

withdrawn from the market ~26 116 586 *

Manufacturers

~1 206 *

Importers

~2 885 *

Wholesalers

~12 449 *

Retail

~55 928 *

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

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ALL-RUSSIAN FORUM WITH INTERNATIONAL PARTICIPATION "CIRCULATION OF MEDICAL DEVICES "NOVAMED"

>1000	IN-PERSON PARTICIPANTS	>300	ONLINE PARTICIPANTS	>170	SPEAKERS	>120	PUBLICATIONS IN THE MEDIA	30	EXHIBITORS
89	SUBJECTS OF RUSSIA	12	COUNTRIES	19	INFOPARTNERS	20	SESSIONS	17	PARTNERS

LIST OF ISSUES TO BE DISCUSSED

- ✓ Specifics of medical device registration under national procedures and EAEU regulations
- ✓ Government oversight of medical device circulation in the Russian Federation
- ✓ Regulation and standardization in the medical device sector
- ✓ Product launch on the Russian market
- ✓ Inspection of medical device manufacturing
- ✓ Challenges and development prospects of testing laboratories (centers)
- ✓ Maintenance and repair of medical equipment

Participants 2024:

ALSO IN THE FORUM PROGRAM:

- ✓ *BRICS Meeting on "Medical Device Nomenclature Worldwide: Current Status and Prospects"*

Discussion on the use of existing national nomenclature classification systems in BRICS countries and the prospects for developing an international nomenclature based on current national lists.

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Thank you for your attention!

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