

**Соглашение о единых принципах и правилах обращения медицинских изделий
(изделий медицинского назначения и медицинской техники) в рамках Евразийского
экономического союза от 23 декабря 2014 года**

**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**

Member states of the Eurasian Economic Union (hereinafter the member states),
based on of the Treaty on Eurasian Economic Union dated 29th of May, 2014,
recognizing the expediency of a coordinated policy in the field of medical devices (medical
products and medical equipment) (hereinafter medical devices),
considering their mutual interest in ensuring the safety, quality and efficacy of medical devices
for human life and health, environmental protection, properties of legal entities and individuals,
prevention of actions misleading consumers (users) of medical devices,
recognizing that medical devices are socially significant products,
to create a common market of medical devices within the Eurasian Economic Union
(hereinafter the Union),
seeking to improve the competitiveness of medical devices produced within the Union,
seeking to remove restrictions in mutual trade,
have agreed as follows:

Article 1

Scope of the Agreement

1. This Agreement establishes common principles and rules for the circulation of medical devices within the Union in order to form a common market of medical devices.
2. This Agreement shall apply to legal relations related to the circulation of medical devices intended for circulation within the Union, as well as medical devices in circulation within the Union.
3. Regulation of circulation of medical devices within the Union shall carry out in accordance with the Treaty on the Eurasian Economic Union of 29 May 2014, current agreement, other international agreements that are the components of the Union law, decisions of the Commission, legislation of the member states.

Article 2

Definitions

For purposes of this Agreement, the following terms shall have the indicated meanings:

“release of medical devices” – any compensated or uncompensated transfer of medical devices, which is carried out for the first time and makes them available for distribution and (or) application, except for the transmission of medical devices for research (tests) to their subsequent implementation and application.

“medical devices”- any instruments, apparatus, appliances, equipment, materials and other products, which are used for medical purposes alone or in combination with each other as well as with the accessories required for use of these products for intended purposes (including special software), intended by manufactures for conducting preventive measures, diagnosis and treatment, medical rehabilitation and monitoring of the human body, conducting medical research, rehabilitation, replacement and alterations of anatomical structure or physiological functions of organism, preventing or terminating of pregnancy and functionality, which cannot be realized by pharmacological, immunological, genetic or metabolic effects on the human body, however, can be supported by drugs.

“medical devices circulation” – designing, developing, prototyping, conducting technical inspections, investigations (tests) to assess the biological action, clinical trials, examination of safety, quality and efficacy of medical products, registration, production (manufacturing), storage, transportation, sale, assembling, commissioning, application (exploitation), maintenance, repair and disposal of medical devices.

Article 3

Conducting a coordinated policy in the field of circulation of medical devices

1. Member states shall create a common market of medical devices within the Union in accordance with the principles set out in Article 31 of the Treaty on the Eurasian Economic Union on May 29, 2014.
2. Member states shall conduct a coordinated policy in the field of medical devices by means of:
 - a) taking measures necessary for the harmonization of legislation of member states in the field of medical devices circulation;
 - b) establishing common safety and efficacy requirements of medical products within the Union;
 - c) establishing single rules for the medical devices circulation in accordance with the recommendations of the International Medical Device Regulators Forum (IMDRF);
 - d) defining single approaches to create a system of quality assurance of medical devices;
 - e) harmonizing nomenclature of medical devices used in the member states, with Global Medical Device Nomenclature;
 - f) harmonizing the legislation of member states in the sphere of control (supervision) of the medical devices circulation.
3. For the purpose of implementing this Agreement, the member states shall define the body (bodies) of government (administration), authorized to carry out and (or) coordinate activities in

the field of medical devices circulation in the territory of member states (hereinafter – the authorized body) and to inform the other member states and the Eurasian Economic Commission (hereinafter- the Commission).

4. The Commission carries out coordination of activities aimed at harmonizing the legislation of member states in the field of medical devices circulation.

5. The harmonization of the legislation of member states in the field of medical devices circulation is based on international standards, taking into account decisions of the Commission in the field of medical devices circulation.

6. Authorized bodies shall cooperate in the field of medical devices circulation, including through the organization and coordination of scientific research, scientific and practical conferences, seminars and other activities.

Authorized bodies shall carry out activities for the exchange of experience and the organization of joint training of specialists in the field of medical devices circulation.

Authorized bodies or organizations, acting on their behalf, of the member states shall carry out, with the participation of representatives of the Commission, consultations aimed at coordinating the positions of the member states on medical devices circulation matters.

Article 4

Registration of medical devices

1. The provisions of this Article shall apply to medical devices released into circulation within the Union from the date of entry into force of this Agreement.

2. Medical devices, released into circulation within the Union, are subject to registration in the manner prescribed by the Commission.

The authorized bodies carry out registration of medical devices.

Conducting safety, quality and efficacy examination of medical devices, for the purpose of registration, is carried out by expert organizations determined by the governmental bodies of the member states in the field of healthcare, to be approved by the Commission.

3. Upon implementation of registration, the same requirements shall be imposed on the medical devices manufactured within the Union and imported into the customs territory of the Union from third countries.

4. To register medical devices, technical testing and investigation (testing) to assess the biological activities, clinical trials, tests for approval of types of measuring tools (with respect to medical devices related to measuring instruments, the list of which is approved by the Commission) and the safety, quality and efficacy examination of medical devices shall be carried out.

Rules for the classification of medical devices depending on the potential risk of application, the rules for conducting nomenclature of medical devices, general safety and efficacy requirements of medical devices, requirements for in-line documentation of medical devices, rules for conducting research (tests) of medical devices, rules for registration of medical devices (including requirements for the registration dossier, applications for registration, the grounds and the order of suspension or revocation (cancellation) of the registration certificates of medical device), the rules for conducting safety, quality and efficacy examination of medical devices, shall be approved by the Commission.

5. Authorized bodies determine the list of institutions, organizations and enterprises, including medical institutions and organizations entitled to carry out investigation (testing) of medical devices for purposes of their registration (hereinafter- the authorized organizations).

The Commission shall establish requirements for the authorized organizations and the order of assessments of compliance thereof with these requirements.

6. The document confirming the fact of registration of a medical device is the registration certificate of medical device, which is effective within the Union.

The Commission shall establish the form of the registration certificate and the rules for its completion.

The registration certificate is of indefinite duration.

7. Member states create conditions for ensuring compliances of methods and modalities of conducting investigations (testing) and comparability of examination results through the application of common safety and efficacy requirements of medical devices and common requirements for the authorized organizations.

8. The authorized bodies shall mutually recognize the outcomes of investigations (testing) and examination during the implementation of procedures of registration of medical devices, provided that they are made in accordance with the requirements and rules established by the Commission.

9. Settlement of disputes, arising out among the authorized bodies upon the registration of medical devices, shall be carried out in accordance with the order established by the Commission.

10. The decisions of the authorized bodies on refusal of issuance of a registration certificate of medical device can be appealed by the medical device manufacturer or his competent representative before the court of member states in accordance with the legislation of member states.

11. Medical devices that are not subject to the registration within the framework of the Union:
- a) imported by individuals to the customs territory of the Union and intended for personal use;
 - b) made in the territory of member state on individual orders of patients solely for personal use, which is subject to special requirements in accordance with the purpose issued by a medical professional.
 - c) imported to the customs territory of the Union for use by employees of diplomatic missions and consular offices.
 - d) imported to the customs territory of the Union to provide medical assistance to the passengers and crew members of vehicles, train crew and drivers of vehicles arrived at the territory of the Union.
 - e) imported to the customs territory of the Union to provide medical assistance to the participants of international cultural and sporting activities and to the participants of international expedition, as well as to conduct exhibitions.
 - f) imported to the customs territory of the Union to conduct investigation (testing), including for scientific purposes.
 - g) imported to the customs territory of the Union as humanitarian aid in cases determined by the legislation of the member states.

Article 5

Release of the medical devices in circulation within the Union

1. It is the responsibility of manufacturer or his authorized representative to release medical devices in circulation within the Union.
2. Release of the medical devices in circulation shall be prohibited if :
 - a) there is an official notification of the authorized body, manufacturer and (or) his authorized representative stating that the circulation of the medical devices was suspended, or it was withdrawn from circulation, or it was withdrawn by the manufacturer;
 - b) serviceable life (expiration date) of medical device has expired;
 - c) medical device is not registered in accordance with the established order (except for the medical devices, which are not subject to registration according to paragraph 11 of Article 4 of this Agreement).

Article 6

Production of medical devices

1. The manufacturer of medical device intended for circulation within the Union, shall ensure implementation and maintenance of the quality management system of medical devices. The Commission establishes implementation, maintenance and assessment requirements for the quality management system of medical devices depending on the potential risks of their use.

2. The manufacturer shall establish and maintain in an actual state the system of collection and analysis of data on the use of medical devices, tracking and identification of side effects of medical devices in use.

The manufacturer shall send reports to the authorized bodies prepared on the basis of clinical experiences of separate types of high-end potential risk of application medical devices in the order established by the Commission.

In the case of non-compliance of medical devices with the general safety and efficacy requirements of medical devices or receiving information about facts and circumstances that pose a threat to human life and health, the authorized body shall notify the authorized bodies of other member states within 5 days and take measures to prevent the circulation of such medical devices on the territory of the state.

3. In the case of termination of production of medical devices, the manufacturer or his authorized representative shall provide relevant information to the authorized body, which issued the registration certificate of medical devices, within 30 calendar days from the date of decision to terminate production of medical devices.

Article 7 Labelling of medical devices

1. Medical devices, which have passed the registration procedure and the compliance confirmation with the general safety and efficacy requirements of medical devices, the requirements for implementation and maintenance of the quality management system of medical devices established within the framework of the Union, are subject to mandatory labelling of a special mark before releasing to circulation within the Union (hereinafter – the special circulation mark).

2. It is the responsibility of manufacturer or his authorized representative for the unreasonable labelling of medical devices with the special circulation mark.

3. If the authorized body finds out that the labelling of medical devices with the special circulation mark is unreasonably used by any manufacturer or his authorized representative, he/she shall inform the authorized bodies of other member states and the Commission about this violation, and shall take necessary measures to withdraw such medical devices from circulation in the territory of state and shall bring the perpetrators to justice.

4. The Commission establishes the labeling requirements of medical devices, the image of the special circulation mark and the provision of the special circulation mark.

5. With respect to the medical devices, the labelling with a single circulation mark of goods does not apply on the market of the Union.

Article 8

Controlling the circulation of medical devices and monitoring the safety, quality and efficacy of medical devices

1. Controlling the circulation of medical devices is carried out with respect to legal entities and individuals registered as individual entrepreneurs engaged in the activities in the field of medical devices circulation within the Union, in accordance with the legislation of member states.

2. The Commission establishes the rules for conducting safety, quality and efficacy monitoring of medical devices.

3. In the case of detection of medical devices circulation within the Union that pose a threat to life and (or) human health, of substandard, counterfeit and falsified medical devices, the authorized body shall notify the authorized bodies of other member states and send relevant information to the Commission within 5 days after the establishment of such facts, as well as entitled to take measures to suspend or to prohibit the use of these medical devices and to withdraw them from circulation.

4. If it is revealed that the safety, quality and efficacy of medical devices are affected, the authorized body shall inform the manufacturer of medical devices or his authorized representative, and entitled to request additional information about the medical devices.

5. The authorized body entitled to:

conduct additional safety, quality and efficacy examinations of medical devices through considering the identified negative outcomes of its use in cases envisaged by the legislation of member states;

suspend the issued registration certificates of medical devices;

revoke (cancel) the issued registration certificates of medical devices;

Grounds and procedure of suspension or revocation (cancellation) of the registration certificate of the medical devices are determined by the rules of registration of medical devices, which is approved by the Commission.

The authorized body shall immediately inform the other member states' authorized bodies, manufacturer or his authorized representatives about the suspension or revocation (cancellation) of the registration certificate of medical devices, as well as the notification of the need for conducting additional examination of medical devices.

Article 9

Information system in the field of medical devices circulation

1. To ensure safety, quality and efficacy conditions of medical devices within the Union, the Commission forms and conducts information system in the field of circulation of medical devices (hereinafter- information system), which is part of the integrated information system of the Union, including:

- a) a common register of medical devices registered within the Union;
- b) a common register of the authorized organizations;
- c) a common information database for monitoring safety, quality and efficacy of medical devices.

2. The Commission establishes the procedure of formation and maintenance of information system.

The authorized bodies shall present to the Commission the necessary information for the formation of information system.

3. Data included in the information system will be installed on the official website of the Commission's information and telecommunication network "Internet".

Article 10

Confidentiality of information

1. The authorized bodies and the Commission shall take the necessary measures to protect the received and transmitted confidential information, including personal data within the framework of current Agreement.

2. To transfer the confidential information received from the authorized body and (or) the Commission to third parties, it is necessary to have a prior consent of the party who provided the information.

3. Information and data contained in the registration certificate of medical devices cannot be classified as confidential information.

Article 11

Transition period

Documents, confirming the state registration of medical devices, and issued by the authorized bodies before the entry into force of this Agreement, operate on the territory of member states before the end of their validity, but not later than December 31, 2021.

Article 12

Dispute settlement

Disputes related to interpretation and (or) implementation of current Agreement shall be settled in accordance with the provisions of Article 112 of the Treaty on the Eurasian Economic Union of May 29, 2014.

Article 13

Modification of Agreement

Changes can be made to this Agreement by the mutual consent of member states in the form of a separate protocol, which shall be an integral part of this Agreement.

Article 14

Entry into force of Agreement

This Agreement shall enter into force from the date when the depositary receive the last written notification of fulfillment of internal procedures by member states necessary for its entry into force, but not earlier than January 1, 2016.

This Agreement is an international treaty concluded within the framework of the Union, and it is part of the Union law.

Done in Moscow on 23 December 2014, signed in a single copy in Russian language.

The original of this Agreement shall be deposited at the Eurasian Economic Commission, which, as the depositary of this Agreement shall send each member state a certified copy of this Agreement.