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;

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 st0 TD2nthe lfiel

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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, whigi

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

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.