

**THE EURASIAN ECONOMIC COMMISSION**

**THE COUNCIL**

**DECISION**

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| February 12, 2016 | **No. 30** | Moscow |



**On approving the Procedure for Establishing and Maintaining an Information System in the Field of Medical Device Circulation**

In accordance with Paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Article 9 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, Paragraph 112 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 “On Implementing the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union”, the Eurasian Economic Commission's Council **decided to:**

1. Approve the attached Procedure for Establishing and Maintaining an Information System in the Field of Medical Device Circulation.

2. This Decision shall come into effect after 10 calendar days have elapsed from the effective date of the Protocol signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, but not earlier than after 10 calendar days have elapsed from the date of the official publication of this Decision.

**Members of the Eurasian Economic Commission’s Council:**

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| **For the Republic of Armenia** | **For the Republic of Belarus** | **For the Republic of Kazakhstan** | **For the Kyrgyz Republic** | **For the Russian Federation** |
| **V. Gabrielyan** | **V. Matyushevsky** | **B. Sagintaev** | **O. Pankratov** | **I. Shuvalov** |

APPROVED BY

Decision No. 30 of the Eurasian Economic Commission's Council dated February 12, 2016

**PROCEDURE**

**for Establishing and Maintaining an Information System in the Field of Medical Device Circulation**

I. General Provisions

1. This Procedure is developed in accordance with Paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, and Article 9 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014.

2. The information system in the field of medical device circulation (hereinafter, the “information system”) is intended to create conditions for ensuring the circulation of safe, high-quality and effective medical devices within the Eurasian Economic Union (hereinafter, the “Union”).

3. The information system is part of the Union's integrated information system (hereinafter, the “integrated system”) and includes the following information resources:

a) a unified register of medical devices registered within the Union;

b) a unified register of authorized organizations entitled to conduct research (testing) of medical devices for the purpose of their registration;

c) a common information database for monitoring the safety, quality and efficiency of medical devices.

4. General information resources of the information system are formed on the basis of information exchange between the Union Member States and the Eurasian Economic Commission (hereinafter, respectively, the “Member States” and the “Commission”).

5. For the purpose of this Procedure, the following terms are used in the following meanings:

“Reference Member State” means a Member State chosen by the applicant, the competent authority (expert organization) of which performs marketing authorization and expert examination;

“Competent authority” means a public authority of a Member State authorized to carry out and/or coordinate the activities in the field of medical device circulation in the territory of this Member State;

“Expert organization” means a legal entity of a Member State to which the competent authority has delegated certain functions in the field of medical device circulation, and granted the right to access the information contained in the information system.

6. Using the integrated system means, the competent authority will:

a) provide the Commission with information necessary for establishing and maintaining the information system;

b) keep up to date the information submitted by it for inclusion in the general information resources of the information system;

c) exchange information with the competent authorities of other Member States concerned regarding the implementation of the procedures established by the Rules for Registration and Examination of the Safety, Quality and Efficiency of Medical Devices (hereinafter, the “Rules for Registration of Medical Devices”).

7. The Commission publishes the information of the open part of the information system on the Union's information portal in the information and telecommunications network “Internet” (hereinafter, respectively, the “Union's information portal” and the “Internet”).

8. Information exchange between the competent authorities (expert organizations), as well as between the competent authorities (expert organizations) and the Commission in the process of establishing maintaining and using common information resources, will be ensured through common processes within the Union by means of the integrated system.

9. The process documents regulating the information exchange through common processes by means of the integrated system, including the requirements for formats and structures of electronic documents and information used for such exchange, are developed and approved by the Commission.

10. The information of general information resources subject to publication may be accessed by stakeholders through the Union's information portal free of charge.

11. The integrated system for information exchange between the competent authorities (expert organizations) of other Member States and the Commission will be used by the competent authority (expert organization) for the following purposes:

a) receiving and transferring information about any facts and circumstances posing a threat to the life or health of people when using a medical product;

b) identifying, during the implementation of measures for controlling the circulation of medical devices and monitoring the safety, quality and efficiency of medical devices, any nonconformities of medical devices with the general requirements for the safety and efficiency of medical devices or any unreasonable use by a manufacturer or its authorized representative of the marking of a medical device with a special sign of medical device circulation on the Union market, as well as revealing the facts of circulation of substandard, counterfeit or falsified medical devices in the territory of a Member State;

c) implementing measures to suspend and/or prohibit the use of (withdraw from circulation) a medical device or measures to notify the medical device manufacturer or its authorized representative of the need for additional examination of a medical device;

d) initiating the procedure for cancelling (withdrawing or revoking) the marketing authorization for a medical device;

e) other cases related to the regulation of the circulation of medical devices within the Union.

II. Establishing and maintaining a unified register of medical devices registered within the Union

12. The unified register of medical devices registered within the Union (hereinafter in this section and section III, the “unified register”) contains information about medical devices circulating within the Union.

13. The unified register is established and maintained by the Commission on the basis of information provided by competent authorities by means of the integrated system.

14. The unified register contains the following information:

a) medical device description;

b) names of modifications of the medical device (if any);

c) names of components for the medical device (if any);

d) names of accessories for the medical device (if any);

e) names of consumables for the medical device (if any);

f) date of registration of the medical device;

g) medical device marketing authorization number;

h) name of the reference Member State;

i) names of the Member States concerned where the circulation of the medical device is allowed in accordance with its marketing authorization (hereinafter, the “Member States concerned”);

j) the status of the medical device marketing authorization (valid, suspended, canceled,

revoked, withdrawn or the medical device manufacture is discontinued);

k) the date of change in the status of the medical device marketing authorization (indicated where necessary);

l) the date of making changes to the medical device marketing authorization application (hereinafter, the “marketing authorization application”);

m) code and name of the medical device type in accordance with the nomenclature of medical devices used in the Union;

n) the class of potential risk of using the medical device in accordance with the classification of medical devices used in the Union, depending on the potential risk of use;

o) the organizational and legal form of the medical device manufacturer, full and abbreviated (if any) names of the legal entity, location (last name, first name, patronymic (if any), place of residence of the individual registered as an individual entrepreneur), postal address, telephone and fax numbers, e-mail address and Internet website (if any);

p) the organizational and legal form of the authorized representative of the medical device manufacturer, full and abbreviated (if any) names of the legal entity, location (last name, first name, patronymic (if any), place of residence of the individual registered as an individual entrepreneur), postal address, telephone and fax numbers, e-mail addresses and Internet website (if any);

q) location and postal address(es) of the manufacturing site(s);

r) instructions for use of the medical device (in an electronic form);

s) image of the medical device labeling (in an electronic form);

t) information about the issue of a duplicate marketing authorization for the medical device.

III. Information exchange between the competent authorities (expert organizations) in the course of establishing and maintaining a unified register

15. Information about medical devices for which the registration procedure is conducted, as well as materials of marketing authorization applications, except for instructions for use of registered medical devices and images of their labeling, are classified as confidential information, are published in the information systems of competent authorities (expert organizations) and are only available to other competent authorities (expert organizations) concerned.

Competent authorities (expert organizations) may access the information contained in the information system of another competent authority (expert organization) by accessing the information systems of competent authorities (expert organizations) by means of the integrated system.

16. After accepting an application for marketing authorization or an application for making changes to the marketing authorization application, the competent authority of a reference Member State assigns an identification number to this application.

The identification number of the application is indicated in an alphanumeric form and consists of a 2-digit alpha code of the reference state, the serial number and the acceptance date of the application for marketing authorization or the application for making changes to the marketing authorization application (in the dd.mm.yyyy format).

17. Within the scope of medical device registration procedure, the competent authorities (expert organizations) are given access to the following documents and information by means of the integrated system:

a) identification number of the application for registration;

b) application for registration (in an electronic form);

c) marketing authorization application;

d) expert opinions prepared in accordance with the Rules for Registration of Medical Devices, including research (testing) protocols;

e) requests for additional information to be provided by the applicant and responses to them;

f) requests, comments and proposals of the competent authorities (expert organizations) of the Member States concerned sent to the competent authority (expert organization) of the reference Member State, and responses to them;

g) documents (including reports) on the inspections of medical device manufacturing carried out in the course of expert work;

h) information on the stages of consideration of the marketing authorization application.

18. When making changes to the marketing authorization application, the competent authorities exchange the following information and documents by means of the integrated system:

a) identification number of the application for making changes to the marketing authorization application;

b) the application for making changes to the marketing authorization application;

c) a set of documents in accordance with the Rules for Registration of Medical Devices;

d) requests, comments and proposals of the competent authorities bodies (expert organizations) of the Member States concerned sent to the competent authority (expert organization) of the reference Member State, and responses to them;

e) information on the stages of consideration of the application for making changes to the marketing authorization application.

19. To ensure that all relevant competent authorities (expert organizations) of the Member States concerned receive recognition of the information necessary for the exchange of information in a timely manner as part of the procedures for registering medical devices and making changes to marketing authorization applications, the competent authority of the reference Member State provides the Commission with information about the identification numbers of applications for marketing authorization of medical devices and applications for making changes to marketing authorization applications by means of the integrated system.

20. The applicant interacts with the competent authority (expert organization) within the scope of the procedures for registering a medical device or making changes to the marketing authorization application using the resources of the information system of the competent authority body (expert organization) of the reference Member State.

21. If a decision is made to register a medical device, the competent authority of the reference Member State will within 1 working day:

a) receive, by means of the integrated system, the serial number of the marketing authorization certificate of the medical device in the unified register;

b) enter the information in the unified register in accordance with Paragraph 14 of this Procedure;

c) notify, by means of the integrated system, the competent authorities (expert organizations) of the Member States concerned about the registration of the medical device and the entry of information about it and relevant documents into the unified register.

22. In the event of a change in the status of the marketing authorization certificate of a medical device, the competent authority (expert organization) of the reference Member State notifies this to the competent authorities (expert organizations) of the Member States concerned by means of the integrated system.

IV. Establishing and maintaining a unified register of authorized organizations entitled to conduct research (testing) of medical devices for the purpose of their registration

23. The unified register of authorized organizations entitled to conduct research (testing) of medical devices for the purpose of their registration (hereinafter, the “register of authorized organizations”) contains information about the institutions, organizations and enterprises, including medical institutions and organizations, in accordance with the lists of such institutions, organizations and enterprises, determined by the competent authorities.

24. The register of authorized organizations is established and maintained by the Commission on the basis of information provided by competent authorities by means of the integrated system.

25. The register of authorized organizations contains:

a) a list of institutions, organizations and enterprises (hereinafter, the “list of testing laboratories (centers)”) that are entitled to:

conduct technical testing of medical devices and studies (testing) to assess the biological effect of medical devices certified in the prescribed manner;

conduct testing to approve the type of measuring instruments duly certified or duly authorized by the Member State's legislation in the field of ensuring the uniformity of measurements (with respect to medical devices classified as measuring instruments, the list of which is approved by the Commission);

b) a list of medical organizations that have the right to carry out clinical and/or clinical and laboratory research (testing) of medical devices to assess their safety and clinical efficacy (hereinafter, the “list of medical organizations”).

26. The list of testing laboratories (centers) contains the following information:

a) the organizational and legal form, full and abbreviated (if any) names of the testing laboratory (center);

b) the number of the accreditation certificate or authorization document;

c) the date of issue of the accreditation certificate;

d) the expiration date of the accreditation certificate;

e) the validity status of the accreditation certificate or authorization document;

f) the location (address) of the testing laboratory (center), telephone and fax numbers, e-mail addresses and Internet website (if any);

g) the last name, first name, patronymic (if any) and contact details of the head of the testing laboratory (center);

h) a description of the scope of accreditation or authorization document.

27. The list of medical organizations contains the following information:

a) the organizational and legal form, full and abbreviated (if any) names of the medical organization;

b) the location (address) of the medical organization, telephone and fax numbers, e-mail address and Internet website (if any);

c) the last name, first name, patronymic (if any) and contact details of the head of the medical organization;

d) the types of activity of the medical organization;

e) the details of the administrative document, on the basis of which the medical organization is allowed to conduct clinical and/or clinical and laboratory studies (testing) of medical devices.

V. Establishing and maintaining a common information database for monitoring the safety, quality and efficiency of medical devices

28. The common information database for monitoring the safety, quality and efficiency of medical devices (hereinafter, the “database”) contains information about adverse events (incidents) associated with medical devices and corrective actions for ensuring the medical device safety.

29. The database is established and maintained by the Commission on the basis of information submitted by competent authorities in an electronic form by means of the integrated system.

30. The database contains the following information:

a) the name of the medical device and the factory (serial) number and/or batch number;

b) the details of the marketing authorization certificate of the medical device (date, number, validity period, name of the competent authority body of the reference Member State);

d) the code and name of the medical device type in accordance with the nomenclature of medical devices used in the Union;

e) the class of potential risk of using the medical device in accordance with the classification of medical devices used in the Union, depending on the potential risk of use;

f) the organizational and legal form of the medical device manufacturer or its authorized representative, full and abbreviated (if any) names of the legal entity, location (last name, first name, patronymic (if any), place of residence of the individual registered as an individual entrepreneur), postal address, telephone and fax numbers, e-mail addresses and Internet website (if any);

h) information about adverse events (incidents): the date of the adverse event (incident), a description of the adverse event (incident), the number of the adverse event (incident) report of the medical organization — user (if applicable), the date the manufacturer received information about the adverse event (incident), the number of patients involved (if known), the number of medical devices involved (if known), the current location of the medical device (if known), the user of the medical device at the time of the adverse event (incident), the use of the medical device;

j) information on corrective actions:

in the initial report — general information and the reason for corrective actions, description and rationale of actions, recommendations for suppliers (distributors) and users;

in the subsequent report — general information and the reason for corrective actions, description and rationale for actions, recommendations for suppliers (distributors) and users, the process of implementing corrective actions, the deadline for corrective actions;

in the final report — general information and the reason for corrective actions, description and rationale for actions, recommendations for suppliers (distributors) and users, the process of implementing corrective actions, the deadline for corrective actions;

k) information on the results of the investigation of the adverse event (incident): the results of the analysis carried out by the medical device manufacturer, the assessment of the adverse event (incident) (codes and terms of levels 1 and 2 in accordance with the rules for monitoring the safety, quality and efficiency of medical devices), the actions taken and the period of their implementation, the manufacturer’s final comments, the manufacturer’s awareness of similar adverse events (incidents) associated with this type of medical device, with a similar cause of an adverse event (incident) and their number, with an indication of the countries and numbers of adverse events (incidents) and the country of distribution of medical devices;

l) information obtained as part of the report on the safety and clinical efficacy of medical devices of potential risk class 3, as well as medical devices of potential risk class 2b implanted in the human body: a list of identified residual risks associated with a medical device, goals, objectives and post-marketing clinical monitoring scheme, clinical data obtained during the reporting period (with assessments of clinical data for the reporting period and for the entire period of clinical monitoring), a conclusion on the need (or no need) to adjust the clinical monitoring plan, a conclusion on the need (or no need) for corrective actions for ensuring the safety of the medical device and a description of corrective actions, a conclusion (justification) on the clinical safety and efficiency of the medical device, and a conclusion on the need (or no need) to extend the clinical monitoring cycle;

m) a copy of the manufacturer's notification about the safety of the medical device in the form established by the Rules for Monitoring the Safety, Quality and Efficiency of Medical Devices.

31. The information contained in subparagraphs “h”–“m” of Paragraph 30 of this Procedure refers to the restricted part, is not subject to publication and is only available to competent authorities (expert organizations).