/Logotype/

EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

February 12, 2016 **No. 46** city of Moscow

On Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraphs 2 and 4 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraph 92 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 in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union", the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products (hereinafter referred to as the Rules).

2. To establish that:

a) during the transition period until December 31, 2021:

registration of a medical product at the choice of the manufacturer of a medical product (its authorized representative) can be carried out in accordance with the Rules or in accordance with the legislation of a Member State of the Eurasian Economic Union (hereinafter referred to as Member States);

medical products registered in accordance with the legislation of a Member State are circulated in the territory of this Member State;

b) documents confirming the registration of medical products and issued by the authorized public health authority of the Member State in accordance with the legislation of this Member State are valid until the end of their validity, but not later than December 31, 2021.

3. Member States before December 31, 2016 should:

a) approve the amount of charges (duties) or other mandatory payments provided for by the Rules, taking into account the complexity of the procedures and scope of performing works in the reference state and states concerned, including during:

medical product registration;

examination of safety, quality and efficacy of the medical product;

introduction of changes into the medical product registration dossier;

issuance of duplicates of registration certificates;

b) determine bodies (organizations) responsible for registration, introduction of changes into the registration dossier and other procedures related to the registration of medical products provided for by the Rules, and to inform the Eurasian Economic Commission about this.

4. This Decision shall enter into force 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 Common Principles and Rules for Circulation of Medical Products (Medical Devices 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 Council of the Eurasian Economic Commission:

For the Republic of Armenia	For the Republic of Belarus	For the Republic of Kazakhstan	For the Kyrgyz Republic	For the Russian Federation
Seal: *Eurasian Economic Commission.* *For documents*	Seal: *Eurasian Economic Commission.* *For documents*	Seal: *Eurasian Economic Commission.* *For documents*	Seal: *Eurasian Economic Commission.* *For documents*	Seal: *Eurasian Economic Commission.* *For documents*
V. Gabrielyan	**V. Matyushevskiy**	**B. Sagintaev**	**O. Pankratov**	**I. Shuvalov**

APPROVED
by Decision No. 46 of the Council of
the Eurasian Economic Commission
dated February 12, 2016

Rules for Registration and Examination of Safety, Quality and Efficacy of Medical Products

1. General provisions

1. These Rules are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 2 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and establish the procedure for the registration and examination of safety, quality and efficacy of medical products (hereinafter referred to as the registration and examination of a medical product), introduction of changes into the registration dossier of a medical product, issuance of duplicates of registration certificates, as well as refusal to register a medical product, suspension and cancellation (withdrawal) of the registration certificate of a medical product within the Eurasian Economic Union (hereinafter referred to as the Union).

The requirements of these Rules do not apply to medical products, the need for which arises in emergency situations or for the diagnosis of new, natural-focal or especially dangerous infectious diseases, treatment of which is regulated by the legislation of Member States.

2. During the transition period, at the choice of the manufacturer of medical products (his authorized representative), examination and registration of medical products is carried out in accordance with the legislation of the Member State of the Union (hereinafter referred to as the Member State) or with these Rules.

3. The concepts used in these Rules have the following meanings:

“safety of medical products” - absence of unacceptable risk associated with causing of harm to life, human health, environment;

“validation” - a confirmation by presenting objective evidence of fulfillment of requirements intended for a specific use or application;

“software validation” - a process of confirmation of software suitability for handling of specific applied problems;

“verification” - confirmation based on presentation of objective evidence of fulfillment of established requirements;

“software verification” – a process of confirmation of software compliance with the established requirements (including with the relevant technical specifications, specifications, industry standards);

“state concerned” - a Member State, the authorized authority (expert organization) of which carries out the procedure for the approval of the expert opinion of the reference state;

“unified register of medical products, registered within the Eurasian Economic Union” - an electronic database of medical products registered and authorized for medical use in the territory of the Union;

“applicant” - a manufacturer who is a resident of a Member State or its authorized representative;

“identification and marking of the operating system” - analysis of information on the operating system used in software development with the purpose of evaluation of the possibilities to protect software from unauthorized access;

“medical product quality” – a degree of conformance of a combination of properties and characteristics of a medical product to the purposes of its intended use;

“classification of a medical product depending on the potential risk of use” –assigning to or identification of one of the classes of potential risk of medical use of a medical product;

“medical product accessory” - a product that is not a medical product or medical product accessory, including blocks, parts, components of the product, materials, spare parts designed by the manufacturer of the medical product for use as part of a medical product or in combination with a medical product;

“medical products for in vitro diagnostic” - any instruments, apparatus, devices, equipment, materials, reagents, calibrators, control materials and other products used for medical purposes separately or in combination with each other, as well as with accessories necessary for use of the specified products (including special software) and designed by the manufacturer for use in in vitro studies of human biological material samples to obtain information on physiological or pathological condition, congenital pathology, predisposition to a particular clinical condition or disease, compatibility of tissues with a potential recipient, prediction of reactions to therapeutic effects, selection of therapeutic agents and (or) treatment monitoring;

“medical product modification” - a medical product version having design features common with a main medical product developed on the basis of the main product for the purpose of its improvement, expansion or specialization of use for medical purposes;

“multicenter software study” - simultaneous testing of software in the context of its planned use at several external experimental sites (outside the enterprise - the developer of such software);

“set (kit) of medical products” - combination of medical products having a single purpose and marking with the indication of the list of the specified medical products;

“accessory” - a product that is not a medical product designed by the manufacturer for joint use with one or more medical products for use in accordance with their purpose;

“medical product manufacturer” - a juridical person or natural person registered as an individual entrepreneur responsible for the development and manufacture of a medical product that makes it available for use on its own behalf, regardless of whether the medical product was designed and (or) manufactured by that person or by another person (s) on its behalf, and responsible for the safety, quality and effectiveness of the medical product;

“manufacturing site” - a territorially separate complex designed for performance of the entire process of a medical product manufacture or its specific stages;

“consumable material for medical products” – products and materials consumable when using medical products that provide manipulations in accordance with the functional purpose of the medical product;

“registration dossier” - a set of documents and materials of the established structure submitted by the applicant when registering a medical product, introducing changes to the registration certificate, as well as copies of decisions taken by the authorized authority (expert organization) with respect to a particular medical product;

“registration number” - a code symbol assigned to medical products when they are registered, under which they are entered in the unified register of medical products registered within the Union and kept unchanged when a medical product is circulated within the Union;

“registration certificate” - a document of a unified form that confirms a fact of medical product registration;

“medical product registration” - a procedure for the issuance of an authorization for the medical use of a medical product within the Union by an authorized authority;

“reference state” - a Member State chosen by the applicant, the authorized authority of which registers the medical product;

“authorized representative of the manufacturer” - a juridical person or natural person registered as an individual entrepreneur who is a resident of a Member State and authorized in accordance with a Power of Attorney of a manufacturer of a medical product to represent its

interests and be responsible for medical product circulation within the Union and fulfillment of mandatory requirements, imposed to medical products.

4. Registration and examination of a medical product are mandatory conditions for its release for circulation within the Union and are carried out by the authorized authority of the reference state. At the same time, the same requirements are imposed for medical products manufactured in the territory of the Union and imported into the customs territory of the Union from third countries.

5. Prior to submission of an application for registration and examination of a medical product to the authorized authority of the reference state, the applicant collect evidence of safety and efficacy of the medical product and prepare the relevant registration dossier.

6. In order to prepare the registration dossier, the applicant:

a) receives preliminary consultations of the expert organization on the registration and examination of a medical product (if necessary);

b) conducts technical testing, studies (tests) to assess biological action of the medical product, studies for the approval of the type of measuring instruments (with respect to medical products classified as measuring instruments, the list of which is approved by the Commission) to confirm compliance with general requirements to safety and efficacy of medical products, requirements for their marking and operational documentation for them in the institutions and organizations selected by the applicant and which have a right to conduct such study for the purposes of registration of medical products and which are included in the unified register of authorized organizations of the Union (hereinafter referred to as authorized organization);

c) conducts clinical trials (studies) in accordance with the rules for the conducting of clinical trials (studies) of medical products in the authorized organizations selected by the applicant or puts clinical data into the registration dossier.

7. In order to register a medical product, an expert organization, determined by the authorized authority of a Member State (hereinafter referred to as the expert organization), examined the medical product.

8. The medical product manufacturer ensures the implementation and maintenance of the quality management system of this product in accordance with the requirements for the introduction, maintenance and evaluation of the quality management system of medical products depending on the potential risk of use approved by the Eurasian Economic Commission (hereinafter referred to as the Commission)

9. When registering and examining medical products, the authorized authorities mutually recognize the results of technical testing, studies (tests) in order to evaluate the biological action of these medical products, clinical trials, study for the approval of the type of measuring instruments (with respect to medical products related to measuring instruments in the public regulation to ensure uniformity of measurements, the list of which is approved by the Commission), provided that they are carried out in accordance with the requirements and rights established by the Commission.

10. The reference state registers the medical product based on the results of medical product examination and approval of the expert opinion by the states concerned.

11. A document confirming medical product registration is a registration certificate, a form and rules for filling of which are defined in accordance with Annex No. 1.

The registration certificate is issued for an indefinite period of time and remains in force within the Union.

12. The registered medical product should comply with the general requirements for the safety and efficacy of medical products, requirements for their marking and operational documentation for them, approved by the Commission. The manufacturer of the medical product (his authorized representative) is responsible for compliance of medical products with the specified general requirements.

13. Costs for registration and examination of the medical product are borne by the applicant in accordance with the legislation of the Member State.

14. When simultaneously filling for registration several medical product modifications related to one type of medical product in accordance with the nomenclature of medical products manufactured by the same manufacturer used in the Union, which have different changes in the configuration and (or) technical parameters that do not affect the principle of operation and functional purpose, relating to one class of potential risk of use, the applicant submits 1 application and 1 registration dossier. In case if the submitted modifications refer to different types of medical product in accordance with the specified nomenclature, each modification is registered separately with the provision of a separate registration dossier.

15. In case if a medical product registered in accordance with these Rules is declared for registration in the Member States which are not indicated by the applicant earlier as states concerned, as well as in the states that have acceded to the Union, the registration procedure is carried out on the basis of an expert opinion of the authorized authority (expert organization) of the reference state. In this case, the authorized authority of the reference state issues a registration certificate with indication of all states concerned.

II. Procedures for registration and examination of the medical product

16. To register the medical product, the applicant selects a reference state and a state concerned.

17. The applicant submits the following documents to the authorized authority (expert organization) of the reference state:

a) application for examination and registration of the medical product (on paper and (or) electronic media) in the form according to Annexes 2 and 3 (hereinafter referred to as the application);

b) a registration dossier on an electronic medium containing documents according to the list in accordance with Annex No. 4. If the legislation of a Member State does not provide for the possibility of issuance of these documents in electronic form, the authorized authority (expert organization) of the reference state has the right to request such documents (their copies) on paper. At the same time, documents submitted in a foreign language should have authentic translation into Russian certified in the manner established by the legislation of the Member State;

c) copies of documents confirming payment for examination and registration of the medical product in the reference state.

18. Within 5 working days from the date of receipt of the application and registration dossier the authorized authority (expert organization) of the reference state verifies completeness and reliability of the information contained in them, takes a decision to start the procedure for registration and examination of the medical product and places the application and registration dossier in its information system. Information on medical products subject to the examination and registration procedure and documents contained in the registration dossier, except for instructions for use of the medical product and medical product marking, belong to confidential information and are available only to interested authorized authorities (expert organizations) of Member States.

If the application is submitted in violation of the requirements set forth in these Rules, inaccurate information is indicated in the application or the registration dossier is submitted not in full, within 5 working days from the date of receipt of such application and registration dossier the authorized authority (expert organization) of the reference state notifies the applicant of the need to eliminate identified violations and (or) submission of missing documents within a period not exceeding 30 working days from the date of placement of the corresponding documents in the information system of the authorized authority (expert organization) of the reference state, by delivery of the notice to the applicant personally against the receipt, or by sending a notice electronically through telecommunication channels or in the form of a digitally signed electronic document.

Within 3 working days from the date of submission of the application and registration dossier corresponding to the requirements of these Rules, the authorized authority (expert organization) of the reference state takes a decision to start the procedure for examination and registration of the medical product.

19. The authorized authorities (expert organizations) of the states concerned are entitled to familiarize themselves with the progress of expert works in the reference state, including the correspondence of the applicant and the authorized authority (expert organization) on the removal of comments and with the documents submitted by the applicant in the process of examination and registration of medical products.

20. The applicant is responsible for the reliability of the registration dossier submitted to the authorized authority (expert organization).

21. If necessary, the authorized authority (expert organization) involves experts, persons who do not work in the authorized authority (expert organization), if their expertise is necessary for the examination.

Representatives of the authorized organizations who conducted technical testing, studies (tests) to assess biological action and clinical trials of the medical product submitted for examination, cannot be involved in the examination.

When conducting the examination, the expert in any way cannot be dependent on the authority or person who appointed this examination, medical product manufacturer, his authorized representative or other persons interested in the results of the examination.

If the expert knows the circumstances that prevent him to be involved in the examination or that prevent him to follow principles of its conduct, he should inform the head of the authorized authority (expert organization) of the reference state about this.

22. The authorized authority (expert organization) of the reference state examines the medical product and draws up an expert opinion in accordance with Annex No. 5 within a period not exceeding 60 working days from the date of its decision to start the procedure for registration and examination of the medical product.

Conclusions contained in the expert opinion should be unambiguous and understandable.

If the conclusions of the expert opinion regarding the possibility of the medical product registration in a reference state are positive, the authorized authority of the reference state within 5 working days from the date of the expert opinion notifies the applicant of the need to provide copies of documents on payment for examination and registration in the states concerned not exceeding 10 working days from the date of placement of the relevant notice in the information system of the authorized authority (expert organization) or from the date of receipt of the notice by the applicant personally against receipt, by registered mail with delivery confirmation, in electronic form via telecommunication channels or in the form of a digitally signed electronic document.

23. The authorized authority (expert organization) or organization determined by the authorized authority (expert organization) of the reference state inspects manufacture of medical products in accordance with the requirements established by the Commission. Inspection of the manufacture of medical products is carried out before the preparation of an expert opinion. The term of organization and inspection is not included in the general term of the examination and shall not exceed 90 working days in total.

24. Medical product examination includes:

a) analysis of documents and materials determining safety, efficacy and quality of the medical product, including consumables and accessories to the medical product;

b) analysis of data on the development and manufacture of the medical product (process flowcharts, main stages of production, packaging, testing and procedure for the release of the final product);

c) analysis of the standards to which the medical product corresponds;

d) analysis of the technical testing protocols (regarding the completeness and competence of the testing laboratory), as well as recognition of test results based on this analysis;

e) analysis of reports on the results of inspection of the medical product manufacture;

f) analysis of reports on the evaluation of the biological action of the medical product (in terms of the completeness and quality of the study performed, for compliance with the rules for studies (tests) of the biological action of medical products approved by the Commission), as well as recognition of test results based on this analysis;

g) analysis and evaluation of the clinical data contained in the report on clinical evidence of the medical product efficacy and safety, including compliance of clinical trials with the rules of performance of clinical trials of medical product approved by the Commission, completeness of the study performed, reliability of the results, comparison of clinical data with available analogues and recognition of test results on the basis of this analysis;

h) risk analysis (with indication of identified risks, generalized data on validation and verification of tests, laboratory tests confirming the feasibility of implementation of scientific and technical ideas in the final product, scientific literature data on the analogues);

i) an assessment of the applicant's compliance with the class of potential risk of medical product use in accordance with the rules for medical product classification depending on the potential risk of use approved by the Commission;

j) analysis of the correctness of determination of medical product nomenclature according to the nomenclature of medical products used in the Union;

k) analysis of safety and efficacy of a drug product being a part of a medical product, its effect on the medical product functionality, compatibility of the drug product with the medical product (with the exception of medical products for in vitro diagnostics). The drug product should be registered and approved for use in the stet of manufacture of the drug product;

l) analysis of the medical product biological safety on the basis of analysis of all materials of animal or human origin included in the medical product, as well as information on the selection of sources (donors), material selection, processing, storage, testing, validation of testing procedures, and handling of tissues, cells, substances of animal or human origin, cultures of microorganisms and viruses;

m)analysis of the procedure and methods of sterilization of a medical product, materials justifying the method of sterilization, proposed quality control methods and determination of sterilizing agent residues using a chemical sterilization method;

n) study of software validity based on analysis of data on its verification and validation, including information on its development and testing in the enterprise and in multicenter study, data on identification and labeling of the operating system;

o) analysis of the medical product stability report, justification of the claimed shelf life;

p) analysis of the data collection plan on the medical product safety and efficacy at the after-sale stage;

q) analysis of marketing information (if the medical product has been circulated on the market for more than 2 years) (if any);

r) analysis of information provided by the manufacturer on the presence or absence of reports of accidents and medical product recalls from the market, about undesirable events and (or) accidents involving the medical product use, notices of the medical product safety, approach to addressing these problems and their solutions by the manufacturers in each of these cases, description of the corrective actions taken in response to these cases, as well as ratio of the level of sales and the number of accidents and medical product recall from circulation;

s) analysis of the information provided by the manufacturer on the medical product conformity to the general requirements for the safety and efficacy of medical products, requirements for their marking and operational documentation for them;

t) evaluation of the user's manual (instruction for medical use) and operational documentation;

u) evaluation of medical product marking;

v) analysis of documents confirming the results of medical product tests for the purpose of approval of the type of measuring instruments (regarding medical products classified as measuring instruments, the list of which is approved by the Commission).

25. When examining a medical product in case of insufficiency for preparation of an expert opinion for the materials and information contained in the application for registration and documents of the registration dossier, the authorized authority (expert organization) sends the relevant request to the applicant specifying the nature of remarks and way of their elimination (hereinafter referred to as the request). The request is sent once and can be handed over to the applicant personally against receipt, sent by registered mail with delivery confirmation or transmitted electronically via telecommunication channels or in the form of a digitally signed electronic document.

The applicant must submit a response to the request within a period not exceeding 60 working days from the date of receipt of the request. In the event of failure to submit a response in due time, the authorized authority (expert organization) takes a decision on the basis of documents being at its disposal.

26. The period from the date of sending the request to the date of receipt of the response to the request by the authorized authority (expert organization) is not taken into account when calculating the term of the medical product examination.

27. The grounds on which the authorized authority (expert organization) refuses to register the medical product are:

a) failure to confirm quality, and (or) efficacy, and (or) safety of the medical product by the relevant materials and information contained in the registration dossier;

b) excess of the risk of harm to the health of citizens and medical workers due to the use of the medical product over the efficacy of its use;

c) failure to eliminate detected violations and (or) failure to submit documents upon request.

28. If necessary, the authorized authorities (expert organizations) of the states concerned can send their comments and proposals using means of the integrated system of the Union to the authorized authority (expert organization) of the reference state before the expert opinion is issued by this authorized authority (expert organization).

When approving the expert opinion, the authorized authorities (expert organizations) of the Member States can interact with each other to resolve emerging issues.

29. After execution of the expert opinion, the authorized authority (expert organization) of the reference state places an expert opinion in its information system. The authorized authorities (expert organizations) of the states concerned within a period not exceeding 30 calendar days from the date of placement of the expert opinion by the authorized authority (expert organization) of the reference state, sends to the authorized authority (expert organization) confirmation of the approval (non-approval) of the expert opinion (with justification) in the form according to Annex No. 6 using means of the integrated system of the Union, including the correctness of the user's manual (instructions for medical use) translation, marking of the medical product in the official languages in accordance with the requirements of the legislation of the Member States.

In case of failure of states concerned to acknowledge confirmation of approval (non-approval) of the expert opinion within 30 calendar days from the date of placement of the expert opinion by the authorized authority (expert organization) of the reference state, the expert opinion is considered approved.

Within 10 working days after approval of the expert opinion by the states concerned, the authorized body of the reference state decides to register the medical product and places information on the medical product, the user's manual (instruction for medical use) and the image of the approved marking of the medical product in the unified register of medical products registered within the Union.

30. The authorized authority of the reference state, within 10 working days from the date of the decision on medical product registration, executes a registration certificate and annex to it, or

notifies the applicant of the refusal to register the medical product personally against receipt, sends a notice by registered mail with delivery confirmation, or transfers it in the electronic form via telecommunication channels or in the form of a digitally signed electronic document.

III. Procedure for expert opinion approval

31. When approving an expert opinion, the states concerned evaluate the expert opinion of the reference state for completeness and sufficiency of data confirming medical product safety, quality and efficacy.

32. Expert opinion approval is the basis for making a decision on the medical product registration.

33. The basis for non-approval of the expert opinion of the reference state is availability of evidence that medical product efficacy and (or) safety is not confirmed by the information provided in the registration dossier or that the risk of harm to the health of citizens and medical personnel due to the medical product use exceeds efficacy of its use.

34. In the absence of consensus on the approval of the expert opinion, the disputes are settled by applying of the authorized authority of the reference state to the advisory committee on medical products attached to the Commission Board (referred to as the advisory committee).

The authorized authority (expert organization) of the reference state sends an application to the advisory committee on the authorized authority (expert organization) form on the need to consider disputes with indication of general information on the subject of disputes and information on the results of negotiations and consultations. Any materials justifying the position of the authorized authority (expert organization) of the reference state on the subject of disputes can be attached to the application.

Once the application and attached materials from the authorized authority (expert organization) of the reference state are received, the advisory committee requests from the authorized authorities (expert organizations) of the states concerned the materials confirming their position on the subject of disputes.

Once the materials from authorized authorities (expert organizations) are received, the advisory committee sends notices of a meeting on dispute settlement to the authorized authorities (expert organizations).

The Advisory Committee ensures the organization and arrangement of a meeting on dispute settlement. Representatives of the authorized authorities (expert organizations) of the reference state and states concerned take part in the meeting.

At the end of the meeting, a decision is adopted that is of advisory nature.

The term for the settlement of disputes regarding the approval of the expert report should not exceed 30 working days from the date of submission of the relevant application by the authorized authority (expert organization) of the reference state to the advisory committee.

35. Non-approval of the expert opinion of the reference state in one of the states concerned is the basis for refusal to use the medical product in the territory of that state.

IV. Examination of changes introduced to the registration dossier

36. Examination of changes introduced to the registration dossier is carried out by the authorized authority (expert organization) of the reference state and includes an assessment of fullness, completeness and correctness of documents execution, impact of the introduced changes on medical product safety, quality and efficacy.

37. The manufacturer initiates within 2 months from the date of introduction of changes into the documents of the registration dossier submitted as part of medical product registration, by submitting the relevant application to the authorized authority (expert organization) of the reference state in accordance with Annex No. 7 (in this section - the application) with attachment of documents confirming changes under the list according to Annex No. 8.

38. The application and documents confirming the changes are placed by the authorized authority (expert organization) of the reference state in its information system and are available only to the concerned authorized authorities (expert organizations) of the Member States.

39. The authorized authorities (expert organizations) of the states concerned within 30 working days from the date of placement of the application and documents confirming the changes by the authorized authorities (expert organization) of the reference state in their information system can send their comments and proposals to the authorized authority (expert organization) of the reference state using means of the integrated system of the Union, prior to the preparation of the expert opinion by this authority (organization) on the form in accordance with Annex No. 9.

Within 5 working days from the date of receipt of the application and documents confirming the changes, the authorized authority (expert organization) of the reference state conducts an audit of completeness and reliability of the information contained therein.

If the application is made in violation of the requirements established by these Rules and (or) the application contains inaccurate information or documents confirming the changes, are not fully provided by the applicant, the authorized authority (expert organization) of the reference state no later than 30 working days from the date of receipt of such application and documents notifies the applicant of the need to eliminate the violations detected and (or) present the missing documents by delivery of a notice to the applicant personally against receipt, or by sending a notice by registered mail with delivery confirmation, or transmission in electronic form via telecommunication channels or in the form of a digitally signed electronic document.

Within 3 working days from the date of submission of the application and properly executed documents confirming the changes, the authorized authority (expert organization) of the reference state decides to start the procedure for introduction of changes into the registration dossier.

40. The applicant submits a response to the request of the authorized authority (expert organization) within a period not exceeding 60 calendar days from the date of receipt of this request. In case of failure to respond in the specified period, the authorized authority (expert organization) takes a decision on the basis of the documents being at its disposal.

41. The time period from the date of sending the request by the authorized authority (expert organization) until the date of receipt of a response to the request is not taken into account in calculating the term for medical product examination.

42. Changes to the registration dossier are made on the basis of the results of the examination of these changes within a period not exceeding 30 working days from the date of submission of the application and properly executed documents confirming the changes.

43. The basis for the authorized authority (expert organization) to prepare an expert opinion on the impossibility of introduction of changes into the registration dossier is:

a) inaccuracy of the submitted information justifying the introduction of changes;

b) lack of information confirming the invariability of the medical product functional purpose and (or) the principle in connection with the changes introduced;

c) non-elimination of detected violations and (or) non-submission of missing documents.

44. The expert opinion and user's manual (instruction for medical use), the image of the medical product marking in Russian are placed by the authorized authority (expert organization) of the reference state in its information system and are available only to the concerned authorized authorities (expert organizations) of the Member States.

45. The states concerned within 10 working days from the date of placement of the expert opinion in the information system by the authorized authority(expert organization) of the reference state are entitled to send comments and proposals (with justification) to the authorized authority (expert organization) of the reference state.

46. If the changes introduced relate to the information contained in the registration certificate, the authorized authority of the reference state issues a new registration certificate preserving the previous number (with the date of relevant changes introduction).

47. The authorized authority of the reference state within 10 working days from the date of adoption of the relevant decision:

a) executes a registration certificate;

b) places information on introduction of changes into the registration dossier in the order established by the Commission in the unified register of medical products registered within the Union, as well as scanned copies of documents that have been amended;

c) notifies the applicant of the refusal to introduce changes the registration dossier by delivery of notice personally against receipt, or by transmission in electronic form via telecommunication channels or in the form of a digitally signed electronic document.

V. Procedure for suspension or cancellation (withdrawal) of the registration certificate

48. The registration certificate is suspended by the authorized authority of the reference state in the following cases:

a) based on the results of monitoring of medical product safety, quality and efficacy during the post-marketing period – when identifying a potential serious public health risk;

b) based on the results of the state control over the circulation of medical products – with the availability of information on facts and circumstances that endanger the life and health of citizens and medical workers when using and operating medical products.

49. The decision to suspend the validity of the registration certificate (indicating the reasons, date and period of suspension) is taken by the authorized authority of the reference state in accordance with the legislation of this Member State.

50. The period of suspension of the registration certificate validity cannot exceed 6 months; at the same time, sale and use of such medical products within the Union are not allowed.

The authorized authority of the reference state immediately informs the authorized authorities of the states concerned, the manufacturer or its authorized representative and the Commission about the suspension of the validity of the registration certificate and enters the relevant information into a unified register of medical products registered within the Union.

51. During the period established by the authorized authority of the reference state, the applicant should eliminate the circumstances that caused the suspension of registration certificate, notify the authorized authority (with attachment of supporting documents) about this in writing. Based on the results of the examination of the documents submitted by the applicant, the authorized authority of the reference state takes a decision to renew or cancel (withdraw) the registration certificate (indicating the date of renewal, cancellation (withdrawal) of the registration certificate).

52. The authorized authority of the reference state notifies the applicant about the renewal of the validity of the registration certificate within 5 working days from the date of adoption of such decision personally against the receipt or sends a notice by registered mail with delivery confirmation or transfers electronically via telecommunication channels or in digitally signed electronic document.

The decision to renew the validity of the registration certificate is taken in accordance with the legislation of the reference state and comes into force from the date of its adoption.

53. If the applicant failed to eliminate circumstances that caused the suspension of the registration certificate, the authorized authority of the reference state takes a decision to cancel (withdraw) it (with justification).

The authorized authority of the reference state immediately notifies the applicant of the cancellation (withdrawal) of the registration certificate by sending a notice to the applicant personally against the receipt or sending a notice by registered mail with delivery confirmation or by transmission in the electronic form via telecommunication channels or in the form of a digitally signed electronic document, and enters relevant information into the unified register of medical products registered within the Union.

The decision on the cancellation (withdrawal) of the registration certificate is taken by the authorized authority of the reference state also in the event that the manufacturer or his authorized representative submits an application for the cancellation of the registration certificate in accordance with Annex No. 10.

54. The grounds for the decision of the authorized authority of the reference state to cancel (withdraw) the registration certificate are:

a) the statement of the manufacturer or his authorized representative about the (withdrawal) of the registration certificate;

b) identification of cases of submission of false information that could not be established at medical product registration by the applicant;

c) a final judgment of the court of the Member State;

d) submission of information on facts and circumstances that endanger life and health of citizens and medical workers when using and operating a medical product by the authorized authority of the Member State, based on the results of the state control over the circulation of medical products;

e) loss of medical status of the medical product in connection with the introduction of changes into the acts constituting the right of the Union.

VI. Procedure for issuing a duplicate registration certificate

55. In case of loss (damage) of the registration certificate, the applicant is entitled to apply to the authorized authority of the reference state with an application to issue a duplicate of the registration certificate in accordance with Annex No. 11.

56. In case of damage of the registration certificate, a damaged registration certificate is attached to the application to issue its duplicate.

57. Within 7 working days from the date of receipt of the application to issue a duplicate registration certificate, the authorized authority of the reference state draws up a duplicate registration certificate on the form of the registration certificate and issues it to the applicant or sends it by registered mail with a delivery confirmation.

Seal:
Eurasian Economic Commission. For documents

ANNEX No. 1
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of a medical product registration certificate and rules of its execution

I. Form of a medical product registration certificate

Emblem of the Eurasian Economic Union (1)

EURASIAN ECONOMIC UNION (2)

_____
(full name of the authorized authority of the reference state) (3)

REGISTRATION CERTIFICATE (4)
MI-XX-No._____ (5)

In accordance with_____ (6)
(number and date of the order of the authorized authority of the reference state)
this registration certificate is issued:_____
_____ (7)
(full name and country of the manufacturer, including location (address) a juridical person)
_____ (8)
(full names of manufacturing sites, including location (address) of a juridical person)
_____ (9)
(name of the authorized representative of the manufacturer in territories of Member States of the Eurasian Economic Union, including location (address) of a juridical person)

to certify that_____ (10)
(full name of a medical product)
class of potential risk of medical product use:_____ (11)

type of the medical product in accordance with the nomenclature of medical products, used in the European Economic Union_____ (12)

registered and allowed to put into circulation within the Eurasian Economic Union_____ (13)
(full name of the Member State of the Eurasian Economic Union)

List of components, accessories and consumables to the medical product modification is provided in the Annex to this registration certificate on ___ sheets (14)

The Annex is an integral part of this registration certificate (15)
The validity period of the registration certificate: perpetual (16)
Date of registration: _____ "___" 20____ (17)
Date of changes: _____ "___" 20____ (18)

_____
(full name of the Head (authorized person) of the authorized authority)

_____ L. S. (19)
(signature)

No._____ (20)

Annex to registration certificate
MI-XX No._____ (1)

Item No.	Name of components of the medical product
1.	Main blocks (parts) of the medical product
2.	Accessories (if any)
3.	Consumables (if any)
4.	Components (if any)

(2)

_____
(full name of the Head (authorized person) of the authorized authority)

_____ L. S. (3)
(signature)

_____ "____" 20_____

II. Rules for execution of the medical product registration certificate

1. The registration certificate is to be filled by the authorized authority of the Member State of the Eurasian Economic Union registering the medical product in Russian using electronic printing devices and in the event that there is an appropriate requirement in the legislation of the reference state in the state language of that state.

2. The registration certificate in the Russian language and state language of the state concerned is filled on different sides of the registration certificate.

3. The registration certificate refers to the strict accountable documents, the forms are produced typographically.

If necessary, the name of the manufacturer, its location (address of a juridical person), actual address (other than the name of the state) and product information (type, brand, model, article, etc.) can be indicated using letters of the Latin alphabet.

4. All fields of the registration certificate should be filled in (in the original of the registration certificate there is no field numeration).

5. The registration certificate contains:

a) in field 1 - the emblem of the Eurasian Economic Union;

b) in field 2 - an inscription made in 1 line:

“EURASIAN ECONOMIC UNION”;

c) in field 3 – full name of the authorized authority of the reference state;

d) in field 4 – an inscription made in one line “Registration Certificate”;

e) in field 5 - registration number of the registration certificate and date of its issue.

The registration number of the registration certificate is formed in the following order:

MI-X X-XXXXXX
1 2 3 4

where:

element 1 – medical product;

element 2 - 2-digit letter code of the reference state in accordance with the classificatory of the countries of the world;

element 3 - 2-digit letter code of the states concerned in accordance with the classificatory of the countries of the world (codes of all states concerned, confirmed the approval of the expert opinion of the reference state, are indicated);

element 4 - 6-digit sequential number of the registration certificate, assigned by the authorized authority of the reference state (it is assigned automatically form the unified register of medical products, registered within the Eurasian Economic Union);

f) in field 6 - number and date of the order of the authorized authority of the reference state;

g) in field 7 - full name and country of the manufacturer, location (address of the legal entity), actual address - for the legal entity and its branches that produce products, or surname, name, patronymic (if any), place of residence - for a natural person registered as an individual entrepreneur;

h) in field 8 – names of the manufacturing sites that manufacture the medical product, location (address of a juridical person), actual address - for a juridical person and its branches that manufacture the products, or surname, name, patronymic (if any), place of residence - for a natural person registered as an individual entrepreneur;

i) in field 9 – a name of the authorized representative of the manufacturer in the territory of the Member State, its location (address of a juridical person), actual address - for a juridical person and its branches that manufacture products, or surname, name, patronymic (if any), place of residence - for a natural person registered as an individual entrepreneur;

j) in field 10 – full name of the medical product, which should confirm to the name, indicated in the expert opinion of the authorized authority of the reference state, trade name of

the medical product (if any), medical product data, provided its identification (type, brand, model, article, etc.);

k) in field 11 – class of potential risk of medical product use, confirmed during the examination of the medical product in the reference state;

l) in field 12 – medical product type in accordance with the nomenclature of medical products used in the Eurasian Economic Union;

m) in field 13 – name of the reference state and state concerned;

n) in field 14 – number of sheets of the Annex to the registration certificate (filled in, if the Annex is available);

o) in field 17 – date of registration of the medical product, which is indicated verbally and digitally: date – two Arabic numerals (in quotes), month – in a word, year – four Arabic numerals (with indication of abbreviated notation of the year "y");

p) in field 18 – date of introduction of changes into the registration certificate, which is indicated verbally and digitally: date – two Arabic numerals (in quotes), month – in a word, year – four Arabic numerals (with indication of abbreviated notation of the year "y"). This field is filled in when introducing changes to the registration dossier with the issue of a new registration certificate with a previous number;

q) in field 19 – title, signature, surname, name, patronymic (if any) of the Head (authorized person) of the authorized authority, issued the certificate, affixed with a seal of this authorized authority. It is prohibited to use facsimile instead of the signature;

r) in field 20 – typographic number, series and sequential number of the registration certificate form, which is placed during its manufacture.

5. If there are components of the medical product, including main blocks (parts) of the medical product, accessories, components and consumables to the medical product, an Annex to the registration certificate is filled in, which is an integral part of the registration certificate. Each sheet of the Annex should be numbered. In the Annex to the registration certificate the following is indicated:

a) in field 1 – registration number of the registration certificate and date of its issue;

b) in field 2 – list of components of the medical product, which are included main blocks (parts) of the medical product, components, accessories and consumables to the medical product, indication of the model (if any);

c) in field 3 – title, signature, surname, name and patronymic (if any) of the Head (authorized person) of the authorized authority, issued the certificate, affixed with a seal of this authorized authority. It is prohibited to use facsimile instead of the signature.

6. When filling in the registration certificate and (or) the Annex thereto it is prohibited to indicate data, which are not provided for by these rules, as well as use of abbreviated words (except for general words) and text correction.

7. In case of loss or damage of the registration certificate, the authorized authority of the reference state issues a duplicate of this registration certificate. At the same time, in the right upper corner of the registration certificate, the following notations are marked: "Duplicate was issued on _____ "___" 20___" and "The original of the registration certificate is declared invalid".

ANNEX No. 2
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of the application for the medical product examination

To the authorized authority (expert organization)
of the Member State of the Eurasian Economic Union

_____
(name of the reference state)

_____
(name of the state concerned)

APPLICATION
for the medical product examination

_____
(full or abbreviated (if any), including corporate name of the organization on behalf of which the registration is carried out (manufacturer (manufacturer's authorized representative), legal organizational form of a juridical person)

hereby requests to examine the medical product as _____
(reference state, state concerned – indicate the necessary)

1.	Name of the medical product	
2.	Medical product designation	
3.	Scope of application of the medical product	
4.	Class of potential risk of the medical product use	
5.	Code of medical product type (according to the nomenclature of medical products used in the Union)	
6.	The medical product contains the drug product (mark the necessary)	○ Yes ○ No

7.	Component parts of the medical product			
No.	Name	Model	Manufacturer	Country
	1) Main block (if any)			
	2) Components (if any)			
	3) Consumables (if any)			
	4) Accessories (if any)			
8.	Period of storage / warranty operating life			
9.	Storage conditions			
10.	Registration in the manufacturing country and other countries			
1.	Name of the country	Registration certificate No. (if any)	Date of issue	Validity period
2.				
…				
11.	Manufacture	fully at this manufacturing site partly at this manufacturing site fully at another manufacturing site		

12.	Manufacturing data						
No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
13.	Data on manufacturing site(s)						
No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
14.	Data on the authorized representative (if any)						
No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
15.	Data on the document confirming a payment for the medical product examination						

I guarantee the authenticity and identity of the information contained in the registration dossier and the application.	
Date of application submission	
Full name of the Head of the manufacturer (authorized representative)	
Signature, seal of the manufacturer (authorized representative)	

ANNEX No. 3
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of the application for the medical product registration

To the authorized authority of the Member State of the Eurasian Economic Union

_____
(name of the reference state)

_____
(name of the state concerned)

APPLICATION
for the medical product registration

_____
(full or abbreviated (if any), including corporate name of the organization on behalf of which the registration is carried out (manufacturer (manufacturer's authorized representative), legal organizational form of a juridical person)

hereby requests to register the medical product as _____
(reference state, state concerned – indicate the necessary)

1.	Name of the medical product	
2.	Medical product designation	
3.	Scope of application of the medical product	
4.	Class of potential risk of the medical product use	
5.	Code of medical product type (according to the nomenclature of medical products used in the Union)	
6.	The medical product contains the drug product (mark the necessary)	○ Yes ○ No
7.	List of components	
8.	Data on the manufacturer	

No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
9.	Data on manufacturing site(s)						
No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
10.	Data on the authorized representative (if any)						

No.	name, country	number, date and term of the authorization document	legal address	actual address	telephone and fax, e-mail (if any)	full name and title of the Head	full name and title of the contact person
11.	Data on the document confirming a payment of the state fee for the medical product registration						
I guarantee the authenticity and identity of the information contained in the registration dossier and the application.							
Date of application submission							
Full name of the Head of the manufacturer (authorized representative)							
Signature, seal of the manufacturer (authorized representative)							

ANNEX No. 4
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

LIST
of documents, necessary for the medical product registration
and form of the certificate for the medical product

Item No.	Document name	Class of the medical product				Medical product for in vitro diagnostics (independent on the class of the potential risk of use)	Note
		1	2a	2b	3		
1.	Application	+	+	+	+	+	according to forms provided for by Annex No. 2 and 3 to the Rules
2.	Power of Attorney from the manufacturer for the right to represent interests during registration (if necessary)	+	+	+	+	+	in accordance with international norms of certification or norms of certification, established in accordance with the legislation of the Member State of the Eurasian Economic Union (hereinafter referred to as the Member State)
3.	Copy of the authorization document for the right to manufacture in the country of manufacture with the Annex (if any)	+	+	+	+	+	in accordance with international norms of certification or norms of certification, established in accordance with the legislation of the Member State
4.	Copies of the certificates for the quality management system of the medical product manufacturer (ISO 13485 of the relevant regional or national standard of the Member State) (if any)	+	+	+	+	+	in accordance with international norms of certification or norms of certification, established in accordance with the legislation of the Member State
5.	Declaration of conformity to the requirements of safety and efficacy of the medical product or equivalent document (if	+	+	+	+	+	

Item No.	Document name	Class of the medical product				Medical product for in vitro diagnostics (independent on the class of the potential risk of use)	Note
		1	2a	2b	3		
	any)						
6.	Copy of the registration certificate (free sale certificate, export certificate (except for medical products manufactured in the territory of the Member State for the first time)), issued in the manufacturer's country (if any) with presentation of translation into Russian.	+	+	+	+	+	in accordance with international norms of certification or norms of certification, established in accordance with the legislation of the Member State
7.	Copy of the document which certifies the registration in other countries (if any)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
8.	Certificate for the medical product with description of scope of application, designation, brief description of the medical product, design variant and components (according to the form)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
9.	Data on marking and package (full color package and label designs, marking text in Russian and state languages of the Member States	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
10.	Information on design and manufacture: process flowcharts, main manufacturing stages, package, tests and procedure for the final product release	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
11.	Information on the manufacturer: name, type of activity, legal address, form of ownership, management, list of departments and affiliates with indication of their status and powers	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
12.	Marketing information (history if the product has been circulated in the	-	-	+	+	+ (except for class 1 and 2a)	it is certified by the manufacturer (his authorized

Item No.	Document name	Class of the medical product				Medical product for in vitro diagnostics (independent on the class of the potential risk of use)	Note
		1	2a	2b	3		
	market for more than 2 years) (if any)						representative)
13.	Notices of accidents and recalls (information is not provided for newly developed and designed medical products): list of undesirable events, related to the product use, and indication of the time period, during which such events occurred if there are too many undesirable events, brief reviews on each of event type and indicate total number of the events of each type, on which reports were provided list of recalls of the medical products from the market and (or) advisory notices and description of the approach to consideration of these problems and their solution by manufacturers in each of such case description of the analysis and (or) corrective actions, taken in reaction for the specified cases	+	+	+	+	+ (except for class 1)	it is certified by the manufacturer (his authorized representative)
14.	List of standards to which the medical product confirms	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
15.	Information on medical product compliance with general requirements for medical product safety and efficacy, requirements for their marking and operational documentation on them (hereinafter referred to as the general requirements)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
16.	Document, which establishes requirements for technical characteristics of the	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)

Item No.	Document name	Class of the medical product				Medical product for in vitro diagnostics (independent on the class of the potential risk of use)	Note
		1	2a	2b	3		
	medical product						
17.	Protocols of technical testing, performed in order to prove compliance with general requirements	+	+	+	+	+ (except for reagents and reagent kits)	
18.	Protocols of studies (tests) to evaluate biological action of the medical product, performed in order to prove compliance with general requirements	+	+	+	+	-	
19.	Protocol of clinical evidence of medical product biological action	+	+	+	+	+ (except for class 1)	it is certified by the manufacturer (his authorized representative)
20.	Risk analysis report	-	+	+	+	+ (except for class 1)	it is certified by the manufacturer (his authorized representative)
21.	Data on drug products contained in the medical product (drug product composition, quantity, data on compatibility of the drug product with the medical product, registration of the drug product in the manufacturing country)	+	+	+	+	-	it is certified by the manufacturer (his authorized representative)
22.	Data on biological safety (if any)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
23.	Data on sterilization procedure, including information on process validation, results of the testing on microorganisms (degree of biological load), pyrogenicity, sterility (if necessary) with indication of test methods and data on package validation (for sterile products)	+	+	+	+	+ (except for class 1)	it is certified by the manufacturer (his authorized representative)
24.	Information on special software (if any): manufacturer's data on software validation)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
25.	Stability study protocol	+	+	+	+	+	it is certified by the

Item No.	Document name	Class of the medical product				Medical product for in vitro diagnostics (independent on the class of the potential risk of use)	Note
		1	2a	2b	3		
	with authentic translation of study results and conclusions for the products, having shelf life, into Russian						manufacturer (his authorized representative)
26.	Operational document or instruction of use of the medical product on state languages of states concerned (if necessary) and in Russian	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
27.	Service maintenance manual (related to components of the medical product) in case of absence of data in operational documentation (if any)	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
28.	Manufacture inspection report	+	+	+	+	+	
29.	Plan of collection and analysis of data on medical product safety and efficacy at after-sales stage	+	+	+	+	+	it is certified by the manufacturer (his authorized representative)
30.	Documents confirming results of medical product study in order to approve measuring instrument type (with respect to medical products classified as measuring instruments, the list of which is approved by the Commission) (if any)	+	+	+	+	+	

(form)

Medical product certificate

<table>
<tr><th rowspan="2">Name</th><th rowspan="2">Manufacturer (country)</th><th colspan="4">Completeness</th><th rowspan="2">Scope of application, designation</th><th rowspan="2">Brief characteristic of the medical product</th></tr>
<tr><td>name of components</td><td>model</td><td>manufacturer</td><td>country</td></tr>
<tr><td rowspan="5"></td><td rowspan="5"></td><td>1. Main blocks (parts) of the medical product</td><td></td><td></td><td></td><td rowspan="5"></td><td rowspan="5"></td></tr>
<tr><td>2. Accessories (if any)</td><td></td><td></td><td></td></tr>
<tr><td>3. Consumables (if any)</td><td></td><td></td><td></td></tr>
<tr><td>4. Components (if any)</td><td></td><td></td><td></td></tr>
</table>

ANNEX No. 5
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

EXPERT OPINION
on evaluation of safety, efficacy and quality of medical product during registration

1. Medical product specification:

a) name;

b) manufacturer, country;

c) manufacturing site, country;

d) scope of application and designation;

e) type of medical product in accordance with the nomenclature of the medical product, used in the Eurasian Economic Union:

f) class of potential risk of medical product use;

g) description of components and consumables;

h) description or list of modifications of the medical product;

i) medical product composition;

j) materials of which the medical product made;

k) main technical characteristics

2. Data on quality management system certification (if any):

Quality management system of the manufacturer is certified for compliance with requirements:

_____

(list of certificates with description of identification data: numbers, dates of issue, validity term, certification body name)

3. Development and manufacture:

a) evaluation of design and manufacturing data provided by the applicant, including an analysis of the manufacturing inspection report (if any);

b) opinion on the conformity of the development, technological process and quality control to the manufacture of safe and quality products.

4. Standards applied by manufacturers of medical products, including for materials for manufacturing, components, consumables, test methods, standards used in technical testing, biological action studies (tests), clinical trials of a medical product.

5. The justified conclusion on the compliance of the standards used with the general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation for them (hereinafter referred to as general requirements).

6. A document establishing requirements for technical characteristics of a medical product:

a) analysis of the document for compliance with general requirements;

b) an opinion on the compliance of the medical product technical characteristics with general requirements.

7. Assessment of technical testing and studies (tests) to assess biological action:

a) analysis of the protocols of technical testing and studies (tests) in order to evaluate the biological effect in terms of completeness and reliability of studies in comparison with the requirements of the manufacturer's specifications or technical conditions (if any);

b) an opinion on the completeness and reliability of technical testing and studies (tests) conducted to assess the biological action.

8. Analysis of the results of clinical trials (studies) or clinical data:

a) analysis of compliance of clinical trials (studies) with the rules for clinical trials (studies) of medical products approved by the Commission, completeness and reliability of results of performed studies;

b) an opinion on the compliance of clinical trials (studies) with the rules for performance of clinical trials (studies) approved by the Commission, completeness and reliability of their results, validity of conclusions;

c) analysis of the report on clinical evidence of efficacy and safety of the medical product

9. Risk analysis: an opinion on the completeness and reliability of the performed risk analysis.

10. Medical products which contain drug products: an opinion on safety and efficacy of a medical product containing a drug product, drug product effect on the functionality of a medical product and compatibility of a drug product with a medical product.

11. Biological safety of a medical product: an opinion on the biological safety of a medical product on the basis of the analysis of the list of all materials of animal or human origin, as well as nanoparticles, genetically modified organisms and other newly developed materials included in the product, information on the selection of sources (donors), material selection, processing, storage, testing, validation of testing procedures and handling of tissues, cells, substances of animal or human origin, microorganisms and viruses.

12. Sterilization: sterilization procedure analysis based on the study of the development of methods of medical product and material sterilization that justify sterilization methods, proposed quality control methods and determination of sterilizing agent residues when using the sterilization method.

13. Medical products that include special software: opinion on the validity of special software based on analysis of data on its verification and validation, including information on its development, testing within the enterprise and in clinical multicenter study, data of operating system identification and marking.

14. Analysis and opinion according to the data on the medical product stability.

15. Analysis of a plan for the collection and analysis of data on the medical product safety and efficacy at the after-sales stage.

16. Information analysis and opinion on the medical product marketing (history provided the product has been circulated on the market for more than 2 years) (if any).

17. Analysis of reports of accidents and reviews of undesirable events (accidents) involving medical product use, analysis of cases of withdrawal of medical products from circulation and (or) explanatory notices, written evidence on elimination of circumstances of medical product withdrawal from circulation, description of corrective actions taken by the manufacturer in response to these cases, the ratio of sales level to the number of accidents and reviews (information is not provided for newly developed and designed medical products).

18. Analysis of the information provided by the manufacturer on the conformity of the medical product to general requirements:

a) opinion on the correctness of determination of requirements relating to this medical product, completeness and reliability of evidence of compliance with general requirements.

19. Analysis of reports on manufacturing inspection (if any).

20. Analysis of documents confirming results of tests of medical products in order to establish a type of measuring instruments (for medical products classified as measuring instruments, the list of which is approved by the Commission) (if necessary).

21. General conclusion on the confirmation (non-confirmation) of the medical product safety, quality and efficacy, recommendation on the possibility (impossibility) of medical product registration.

22. Full name, position, academic degree (title) (if any), signature of experts who conducted the examination.

23. Date of the report.

24. Signature of the head of the expert organization.

25. Expert organization seal.

ANNEX No. 6
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of the opinion on confirmation of the approval (non-approval)
of the expert opinion according to the results medical product
safety, efficacy and quality examination of the Member State
of the Eurasian Economic Union, which registers the medical product

_____
(name of the authorized authority (expert organization) of the state concerned)

APPROVED
(Head of the authorized authority (expert
organization), full name, signature, seal)
_____ "___", 20___

OPINION
on confirmation of the approval (non-approval)
of the expert opinion according to the results medical product
safety, efficacy and quality examination of the Member State
of the Eurasian Economic Union, which registers the medical product

No. _____ dated _____ "____", 20____

1. Name of the authorized authority (expert organization) of the Member State of the Eurasian Economic Union, which registers the medical product (hereinafter referred to as the reference state)	
2. Date of placement of the expert opinion in the information system of the authorized authority (expert organization) of the reference state	
3. Expert opinion No.	
4. Medical product name (with indication of accessories necessary for medical product intended use)	
5. Medical product manufacturer (full and abbreviated name, organizational and legal form of a juridical person, location, address)	
6. Authorized representative of the manufacturer (full and abbreviated name, organizational and legal form of a juridical person, location, address) (if any)	
7. Applicant	
8. Data on experts (full names, specialty, science degree (academic title) (if any, place of work and position)	
9. Analysis of the expert opinion provided for by the authorized authority (expert organization) of the reference state according to the results of medical product safety, efficacy and quality for completeness, examination document quality, volume evaluation and completeness of studies and tests	
11. Results of examination (conclusions on separate aspects of the expert opinion are indicated)	
12. Conclusion (indicate a general conclusion and in case of negative opinion – with rationale)	
Date of submission of the opinion on the approval (non-approval) of the expert opinion of the reference state according to the results of medical product safety, efficacy and quality examination	

I have been warned on the responsibility for the correctness of data, specified in the opinion on confirmation of approval (non-approval) of the expert conclusion of the reference state according to the results of medical product safety, efficacy and quality examination. _____ _____ (full name of the expert) (signature)

ANNEX No. 7
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of the application for introduction of changes into the medical product registration dossier

To the authorized authority
of the Member State
of the Eurasian Economic Union

_____
(name of the reference state)

_____
(name of the state concerned)

APPLICATION
for introduction of changes into the medical product registration dossier

_____
(full and abbreviated name (if any), including corporate one, names of the organization on behalf of which changes are introduced (manufacturer (authorized representative of the manufacturer), organizational and legal form of a juridical person)

1. Medical product name	
2. Medical product manufacturer	
3. Country of medical product manufacture	
4. Authorized representative of the manufacturer (if any)	
5. Class of potential risk of medical product use	
5. Code of medical product type (according to the nomenclature of medical products applied in the Union)	

hereby requests to introduce changes into the medical product registration dossier in connection with the following changes:

Changes introduced into the registration dossier		
1.	Change of data on the applicant, including data on the reorganization of the juridical person, on change of its surname, name and residence address of the individual entrepreneur	
	Version prior to change introduction	Changes introduced
2.	Change of medical product name	
	Version prior to change introduction	Changes introduced
3.	Change of accessories and (or) components and (or) consumables	
	Version prior to change introduction	Changes introduced
4.	Change of indications for use, scope of application, contraindications, adverse effects;	
	Version prior to change introduction	Changes introduced
5.	Change of data on medical product manufacturer	
	Version prior to change introduction	Changes introduced
6.	Change of technical and (or) operational documentation of the medical product	
	Version prior to change introduction	Changes introduced

The introduction of changes into the registration dossier does not entail any change in properties and characteristics that affect safety, quality and efficacy of the medical product.

_____

(manufacturer of the medical product (its authorized representative))

I guarantee the reliability of the information provided.

I guarantee the retention of the declared safety and efficacy characteristics of the medical product during the entire service life, under conditions of operation, transportation and storage of the medical product in accordance with the manufacturer’s requirements.

Date of application submission

Full name and position of Head of the
manufacturer (authorized representative)

Signature, seal of the manufacturer
(authorized representative)

_____

ANNEX No. 8
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

LIST
of changes, introduced to the medical product registration dossier during the term of the registration dossier and which do not require new registration

Name of changed data	Conditions	Data and documents necessary to introduce changes
1. Data on the applicant, including data on reorganization of a juridical person, on change of its name or surname, name, residence address of and individual entrepreneur	introduction of changes into the registration dossier does not have effect on efficacy and safety of the medical product in accordance with the General requirements for safety and efficacy of the medical product. Requirements for their marking and operational documentation on	copy of the document confirming powers of the authorized representative of the manufacturer registration dossier number documents confirming changes record statement
2. Medical product name	motivated justification of the need to change the medical product name that does not affect the functional and technical characteristics	application for changes according to the form provided for in Annex No. 7 to the Rules document*, certifying the medical product registration in the manufacturing country (declaration of conformity, registration certificate, free sale certificate, certificate for export, etc.), as amended a copy of the registration certificate issued in the form provided for by Annex No. 1 to the Rules a letter of the manufacturer containing a reasoned justification for the need to change the medical product name that does not affect functional and technical characteristics of the medical product draft instructions for use (user manual) of the medical

Name of changed data	Conditions	Data and documents necessary to introduce changes
		product marking design a document establishing requirements for technical characteristics of the medical product to which the medical product conforms, which in brought in line with a new medical product name the manufacturer's operational documentation for the medical product, including the instruction manual (operation manual) of the medical product, which is brought in line with a new medical product name photographic images of a general view of a medical product together with accessories necessary for medical product intended use (size of not less than 18x24 cm) record statement
3. Accessories, components and (or) consumables	absence of impact on medical product functional characteristics	application for introduction of changes in the form, provided for by Annex No. 7 to the Rules copy of the registration certificate, executed in the unified form, provided for by Annex No. 1 to the Rules a letter of the manufacturer, containing a reasoned justification of the need for change of components with indication of a new list of components, confirming absence of impact on functional characteristics of the medical product

Name of changed data	Conditions	Data and documents necessary to introduce changes
		draft instruction for use (user's manual) of the medical product in the state language of the Member State of the Eurasian Economic Union and in Russian updated specification specifying the list of components and consumables according to the approved form record statement in case of addition of a component being a medical product, samples of such component (in case of a sterile component, the entire set of such samples is provided) and regulatory documentation for it
4. Indications for use, scope of application, contraindications, adverse effects	safety of medical product use should be retained and confirmed by data of studies, clinical safety and quality	application for introduction of changes according to the form, provided for by Annex No. 7 to the Rules copy of the registration certificated executed according to the form provided for by Annex No. 1 to the Rules letter of the manufacturer, containing reasoned justification of the need to change indications for use of the medical product draft instructions for use (user's manual) of the medical product previously approved instruction for use (user's manual) of the medical product

Name of changed data	Conditions	Data and documents necessary to introduce changes
		full-color designs of packages, labels, stickers (if necessary) (on electronic media CD in JPEG format) results of clinical (medical) study reflecting changes introduced record statement
5. Data on the medical product manufacturer	there are no changes in the manufacturing process or specifications, including test methods	application for introduction of changes according to the form, provided for by Annex No. 7 to the Rules document*, certifying medical product registration in the country of the manufacturer (registration certificate, free sale certificate, certificate for export, etc.) as amended document*, confirming introduction of changes (with indication of date of change introduction) document*, confirming compliance of manufacturing conditions to national and / or international standards (GMP, ISO, EN) document*, confirming compliance of the medical product with national or international standards, class of potential risk (declaration of conformity, certificate of conformity) copy of the registration certificate according to the form provided for by Annex No. 1 to the Rules letter of the manufacturer, certifying that manufacturing

Name of changed data	Conditions	Data and documents necessary to introduce changes
		process and finished product safety and quality control remain unchanged with indication of date of change introduction draft instructions for use (user's manual) of the medical product marking design record statement
6. Manufacturer's specification or technical conditions (if any) to which the medical product correspond and (or) operational documentation of the medical product	there are no changes in the manufacturing process or specifications, including test methods	application for introduction of changes according to the form, provided for by Annex No. 7 to the Rules copy of the registration certificate according to the form provided for by Annex No. 1 to the Rules justification letter of the changes introduced data of stability (for the medical product) of not less than batches (report justifying medical product shelf life) (if necessary) draft instruction for use (user's manual) of the medical product (if necessary) full color designs of packages, labels, stickers (if necessary) regulatory documentation with changes introduced, regulated quality of the finished product, certificate of analysis and procedure for finished product control (if necessary) protocol of technical testing or studies (tests) in order to assess biological action taken

Name of changed data	Conditions	Data and documents necessary to introduce changes
		into account the changes, introduced to the regulatory documentation (if necessary) record statement

* Documents are provided with the mandatory authentic notarized translation into Russian.

ANNEX No. 9
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

EXPERT OPINION
on possibility (impossibility) to introduce changes into the medical product registration dossier

1. Medical product name
2. Manufacturer, country
3. Manufacturing site. Country
4. Scope of application and designation.
5. Type of the medical product in accordance with the medical product nomenclature, used in the Eurasian Economic Union.
6. Class of the potential risk of the medical product use.
7. Registration certificate number.
8. Date of issue of the registration certificate.
9. Changes introduced.

Type of the change introduced	Data, entered into the dossier during registration	Changes introduced	Justification of the applicant for change introduction
1. Change of the name of the manufacturer, places (place) of manufacture for the entire manufacturing process and/or its part			
2. Change of the medical product name			
3. Change of list of accessories, components and (or) consumables			
4. Change of indications for use, scope of application, contraindications, adverse effects			
5. Change of data on the medical product manufacturer			
6. Change in the manufacturer's specifications or technical conditions (if any), to which the medical product correspond, and (or) operational documentation of the medical product			

10. Analysis and evaluation of data, justifying introduction of changes.
11. Analysis of risks when introducing changes (opinion on possible risks when introducing changes).
12. Opinion on recommendation or rejection of the recommendation for registration of changes introduced.
13. Full name, position, academic degree (title) (if any), signature of experts who conducted the examination.
14. Date of the report.
15. Signature of Head of the expert organization.
16. Expert organization seal.

ANNEX No. 10
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of the application for cancellation (withdrawal)
of the medical product registration certificate

(*on the organization's letterhead)*
To the authorized authority of the reference state

APPLICATION
for the cancellation (withdrawal) of the medical product
registration certificate

_____
(full and abbreviated (if any) name of the applicant, including corporate name, organizational and legal form of a juridical person)

Asks to cancel the validity of the registration certificate (withdraw a registration certificate) of the medical product

_____
(name of the medical product (with indication of accessories necessary for intended use of the medical product))

_____
(date of medical product registration and registration certificate number)

in connection with_____
(indicate a reason)

_____
(full name of Head of the medical product manufacturer (his authorized representative))

_____ "____", 20____ L. S. _____
(signature)

ANNEX No. 11
to the Rules for Registration and Examination of
Safety, Quality and Efficacy of Medical Products

FORM
of application for issue of duplicate registration certificate
for the medical product

(on the organization's letterhead)
To the authorized authority of the reference state

APPLICATION
for issue of duplicate registration certificate
for the medical product

1. Name of the medical product (with indication of accessories, necessary for intended use of the medical product – in the form of the Annex to the application, affixed with the seal and signature of the Head)

I. With respect to the medical product manufacturer

2. Organization and legal form and full name of a juridical person

3. Abbreviated name of a juridical person (if any)

4. Corporate name of a juridical person (if any)

5. Location (address) of a juridical person

6. Telephone number

7. E-mail of a juridical person (if any)

8. Taxpayer identification number

II. With respect to the authorized representative of the manufacturer

9. Organizational and legal form and full name of a juridical person

10. Abbreviated name of a juridical person (if any)

11. Corporate name of a juridical person (if any)

12. Location (address) of a juridical person

13. Telephone number

14. e-mail of a juridical person (if any)	
15. Taxpayer identification number	
16. Place of medical product manufacture	
17. Designation of the medical product, established by the manufacturer	
18. Type of the medical product in accordance with the medical product nomenclature applied in the Eurasian Economic Union	
19. Class o the medical product in accordance with rules medical product classification depending on the potential risk of use	
20. Way of obtaining information related to the procedure of medical product registration	
21. Way of obtaining medical product registration certificate	personally in hard copy send by registered mail with delivery confirmation in hard copy in the form of electronic document other
22. Reason for issuing the duplicate	
23. Data on payment of the state fee (indicate on the applicant's initiative): date and number of bank order	

_____

(full name of the head of the medical product manufacturer (his authorized representative))

_____ "___", 20_____ L. S. _____

(signature)