THE EURASIAN ECONOMIC COMMISSION
THE COUNCIL

D E C I S I O N

December 24, 2021 **No. 144** Nur-Sultan

On amending the Rules for Marketing Authorization and Expert Examination of Security, Quality and Efficiency of Medical Devices

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 the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the framework of the Eurasian Economic Union dated December 23, 2014, Paragraph 92 of Annex 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, the Eurasian Economic Commission's Council **d e c i d e d :**

1. To amend the Rules for Marketing Authorization and Expert Examination of Security, Quality, and Efficiency of Medical Devices approved by Decision No. 46 of the Eurasian Economic Commission's Council dated February 12, 2016, as attached.

2. This Decision shall come into effect after 180 calendar days have elapsed from the date of its official publication.

Members of the Eurasian Economic Commission's Council:

For the Republic of Armenia	For the Republic of Belarus	For the Republic of Kazakhstan	For the Kyrgyz Republic	For the Russian Federation

ANNEX

to Decision No. 26 of the Council
of the Eurasian Economic Commission
dated December 24, 2021

AMENDMENTS
to the Rules for Marketing Authorization and Expert Examination of Security, Quality, and Efficiency of Medical Devices

The Rules for Marketing Authorization and Expert Examination of Security, Quality, and Efficiency of Medical Devices shall read as follows:

"APPROVED

by Decision No. 46 of the Eurasian
Economic Commission's Council,
dated February 12, 2016
(as amended by Decision No. 26 of the
Eurasian
Economic Commission's Council
dated December 24, 2021)

RULES
for Marketing Authorization and Expert Examination of Security, Quality,
and Efficiency of Medical Devices

I. General Provisions

1. These Rules have been 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 the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the framework of the Eurasian Economic Union dated December 23, 2014, and establish the sequence of the procedures for marketing authorization and expert examination of the safety, quality and efficiency of medical devices (hereinafter referred to as expertise), approval of an expert report, settlement of disagreements regarding the approval of an expert report, amendments to the marketing authorization application (including by way of a notice), issuance of a duplicate of marketing authorization for a medical device, approval of an expert report on a registered medical device, as well as suspension and/or cancellation of the validity (invalidation) of the marketing authorization for a medical device within the framework of the Eurasian Economic Union (hereinafter referred to as the Union).

These Rules shall not apply to medical devices, which become required in emergency situations or for the diagnostics of new, natural focal, or especially dangerous infectious diseases, the treatment of which is regulated by the legislation of the Union Member States (hereinafter referred to as the Member States).

2. For the purposes hereof, the concepts having the following meanings shall be used:

“safety of medical devices” means a lack of unacceptable risk associated with harm to human life, health, and the environment;

“validation” means proving that the requirements intended for a specific use or application are met by providing objective evidence;

“verification” means proving that the established requirements are met based on the presentation of objective evidence;

"Member State concerned" means a Member State, the authorized authority (expert organization) of which carries out the procedure for approving the expert report of the reference Member State;

"proof of the first party" means evidentiary materials (documents) of the medical device manufacturer (protocols of own tests (studies), including those issued by testing laboratories (centers) accredited in the national accreditation system of the Member State, the results of clinical use of the medical device and other materials);

"unified registry of medical devices registered within the framework of the Eurasian Economic Union" means an electronic database of medical devices registered in accordance with these Rules;

"applicant" means the manufacturer of a medical device or its authorized representative;

"quality of a medical device" means the degree of conformity of the set of properties and characteristics of a medical device to its intended purpose set by the manufacturer;

"medical devices for in *vitro* diagnostics" means any instruments, apparatuses, devices, equipment, materials, reagents, calibrators, control materials, and other products used for medical purposes individually or jointly, as well as together with accessories and special software required for their intended use, and intended by the manufacturer for *in vitro* studies of samples of human biological materials to obtain information about a physiological or pathological condition (congenital pathology, predisposition to a certain 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 device model (brand)” means a variant of a medical device characterized by certain design solutions and specific values of indicators of its intended (functional) purpose;

“accessory” means a product that is not a medical device intended by its manufacturer for joint use with one or more medical devices when used in accordance with their intended purpose;

“manufacturer of a medical device”, “manufacturer” means a legal entity or an individual registered as an individual entrepreneur, responsible for the development and manufacture of a medical device, making it available for use on its own behalf, regardless of whether a medical device was developed and/or manufactured by this person or on its behalf by another person(s), and responsible for the safety, quality, and efficiency of the medical device;

“production facility” means a geographically isolated complex designed to perform the entire process of the medical device production or its specific stages;

“marketing authorization application” means a set of documents and materials with the established structure submitted by the applicant during the marketing authorization and expert examination procedures, approval of the expert report, amendments to the marketing authorization application (including by way of a notice), issuance of a duplicate marketing authorization for a medical device, approval of the expert report on a registered medical device, cancellation (invalidation) of the marketing authorization for a medical device, as well as originals and/or copies of other documents related to a specific medical device (decisions of authorized bodies (expert organizations), minutes of meetings of the Advisory Committee for Medical Devices at the Eurasian Economic Commission's Board, documents submitted during the dispute settlement, production facility audit reports, etc.);

"marketing authorization" means a document in a unified form confirming the fact of registration of a medical device in the territory of one or more Member States;

"registration of a medical device", "registration" means the procedure for issuing a permit by the authorized authority of the reference Member State for the release of a medical device in the territory of one or more Member States;

"reference Member State" means a Member State chosen by the applicant whose authorized authority (expert organization) carries out marketing authorization and expert examination;

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

"authorized organizations" means organizations included in the unified registry of authorized organizations entitled to conduct studies (testing) of medical devices for the purpose of their registration;

"authorized representative of the manufacturer" means a legal entity or an individual registered as an individual entrepreneur, who are residents of a Member State and are authorized by the manufacturer in accordance with an agreement or another document provided for by the legislation of the Member States to represent its interests and bear responsibility for the circulation of a medical device within the Union, as well as the fulfillment of mandatory requirements for medical devices.

3. Registration of a medical device is a prerequisite for its release into circulation in the territory of one or more Member States and shall be carried out by the authorized authority of the reference Member State. Along with that, equal requirements shall apply both to medical devices manufactured within

the customs territory of the Union and imported into the Union's customs territory from third countries.

4. In order to register a medical device, an expert organization determined by the authorized authority of the Member State (hereinafter referred to as the expert organization) shall conduct an examination.

5. The document confirming the fact of registration of a medical device is a marketing authorization drawn up in the form and following the rules specified in Annex 1.

The marketing authorization shall be issued indefinitely and shall be valid in the territory of one or more Member States.

6. A registered medical device shall comply with the General Requirements for the Safety and Efficiency of Medical Devices, Their Labeling, and Operational Documentation, approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016 (hereinafter referred to as the General Requirements). The manufacturer (authorized representative of the manufacturer) shall be responsible for the conformity of medical devices to the General Requirements.

7. Manufacturers from the third countries shall appoint an authorized representative of the manufacturer acting during the circulation of a medical device within the Union, and keep information about such a representative of the manufacturer contained in the marketing authorization application up to date.

8. The manufacturer shall ensure the implementation and maintenance of the quality management system of a medical device up to date in accordance with the Requirements for the Implementation, Maintenance, and Evaluation of the Quality Management System for a Medical Devices, Depending on the Potential Risk of Their Use, approved by Decision No. 106 of the Eurasian

Economic Commission's Council dated November 10, 2017 (hereinafter referred to as the Requirements for the Quality Management System).

9. Before submitting an application for examination of a medical device and an application for registration of a medical device to the authorized authority (expert organization) of the reference Member State in the form contained in Annexes 2 and 3 (hereinafter referred to as the marketing authorization and expert examination applications), the applicant shall collect evidence of the safety and efficiency of the medical device and prepare the relevant marketing authorization application.

10. In order to prepare the marketing authorization application, the applicant shall (if required):

a) be entitled to apply to the authorized authority (expert organization) for preliminary consultations on the issues related to marketing authorization and expert examination, including for a fee, in accordance with the procedure established by the authorized authority (expert organization) of the relevant Member State;

b) in order to confirm the conformity of the medical device to the General Requirements:

conduct technical testing, biological testing (studies) in order to assess the effect of a medical device, clinical and clinical laboratory tests (studies) of a medical device, or include available data (proof provided by the first party) in the marketing authorization application;

conduct tests for the purpose of approving the type of measuring instruments (in relation to the medical devices included in the list of types of medical devices subject to classification as measuring instruments during their

registration, approved by Decision No. 42 of the Eurasian Economic Commission's Council dated February 12, 2016) in the manner established by the legislation of the Member State in the field of ensuring the uniformity of measurements, in the authorized (notified) organizations selected by the applicant in accordance with the legislation of the Member State to validate the measuring instruments;

c) ensure periodic (planned) or unscheduled audits of production facilities in order to evaluate the production conditions and the manufacturer's quality management system in accordance with the Requirements for the Quality Management System.

11. During the marketing authorization and expert examination, authorized bodies (expert organizations) shall mutually recognize the results of tests (studies) specified in Subparagraph "b" of Paragraph 10 hereof, provided that they are performed in accordance with the Rules for Technical Testing of Medical Devices, approved by Decision No. 28 of the Eurasian Economic Commission's Council dated February 12, 2016, the Rules for Conducting Research (Tests) Aimed at Biological Evaluation of Medical Devices, approved by Decision No. 38 of the Eurasian Economic Commission's Council dated May 16, 2016, or the Rules for Conducting Clinical and Clinical Laboratory Tests (Studies) of Medical Devices, approved by Decision No. 29 of the Eurasian Economic Commission's Council dated February 12, 2016, respectively, and the legislation of a Member State in the case of tests for the purpose of approving the type of measuring instruments.

12. If required, the authorized authority (expert organization) shall attract third-party experts to participate in the examination, if their special knowledge is needed for the examination.

Representatives of authorized organizations who conducted tests (studies) in relation to a medical device submitted for examination, specified in Subparagraph “b” of Paragraph 10 hereof, as well as representatives of inspecting organizations who conducted an evaluation of the quality management system (audit of production facilities) of the manufacturer of such a medical device, may not be involved in the examination.

During the examination, the expert must be independent of the body or person who appointed the examination, the manufacturer, its authorized representative, or other persons interested in the examination results.

If the expert knows the circumstances preventing it from being involved in the examination or not allowing it to comply with the principles of its conduct, it shall inform the manager of the authorized authority (expert organization) of the reference Member State of the same.

13. The applicant shall be responsible for the accuracy of the information provided in the marketing authorization application.

The documents of the marketing authorization application shall be submitted in Russian in electronic form. If the legislation of the reference Member State does not provide for the possibility of presenting these documents in electronic form, the authorized authority (expert organization) of the reference Member State shall be entitled to request such documents (their copies) in a hard copy.

In the case of submission of the marketing authorization application documents in hard copy, the applicant shall also provide electronic copies thereof on electronic media (in *.pdf format bearing a text layer allowing to select and copy the text, as well as perform a search). Electronic copies of documents shall be submitted in accordance with the classifier of types of documents of the marketing authorization application of a medical device,

approved by Decision No. 48 of the Eurasian Economic Commission's Board dated April 3, 2018.

The operational document or the user manual for the medical device, the maintenance manual, and the text of the medical device labeling shall be further submitted in the official language(s) of the Member States if relevant requirements are contained in the legislation of the Member States.

The documents of the marketing authorization application submitted in a foreign language shall be accompanied by a translation into Russian, certified in accordance with the procedure established by the legislation of the reference Member State.

14. When calculating the term of the procedures provided for by these Rules to be carried out by the authorized bodies (expert organizations), the following terms shall not be taken into account:

a) the period from the date when the authorized authority (expert organization) of the reference Member State sends a request or a notice about the need to eliminate the identified violations and/or submit missing documents or about the need to submit copies of documents on payment for the procedure of approving an expert report in the Member State(s) concerned to the applicant until the date when the authorized authority (expert organization) of the reference Member State receives a response to such a request or notice;

b) the time required for organizing and conducting an audit of the production facility (when the production facilities are audited as part of the marketing authorization and expert examination procedures);

c) the time required for sending a report on the production facility audit findings by the inspecting organization (if its role is not performed by the authorized authority (expert organization)) to the authorized authority (expert organization) to be included in the

marketing authorization application (when the production facilities are audited as part of the marketing authorization and expert examination procedures);

d) the deadline for agreeing on the need to apply to the Advisory Committee for Medical Devices under the Eurasian Economic Commission's Board (hereinafter referred to as the Advisory Committee) with the applicant.

15. The costs of marketing authorization and expert examination procedures, approval of an expert report, amendments to the marketing authorization application (including by way of a notice), issuance of a duplicate marketing authorization, or approval of an expert report on a registered medical device shall be borne by the applicant in accordance with the legislation of the Member State.

16. Registration shall be carried out by the reference Member State based on the results of the examination and approval of the expert report by the Member State(s) concerned.

17. The authorized bodies (expert organizations) of the Member State concerned shall be entitled to learn about the course of the examination in the reference Member State and access relevant documents, including the documents drawn up when the applicant submits additional and clarifying information in the course of marketing authorization and expert examination of a medical device.

18. Information about medical devices in respect of which the procedures provided for by these Rules are carried out, as well as documents contained in the marketing authorization application, except for the operational document or user manual for a medical device, maintenance manuals, labeling and packaging data (full-color (indicating the color coding) layouts of packages and labels), the texts of labeling in Russian and the official languages of the Member States constitute confidential

information and shall be available to the authorized bodies (expert organizations) of the Member States concerned only.

19. Several models (brands) of a medical device, including those related to different types of medical devices in accordance with the nomenclature of medical devices used in the Union, may not be included in the same marketing authorization, provided that these models (brands) meet all the following criteria:

a) the models (brands) of a medical device shall be manufactured by one manufacturer according to one package of the technical documentation;

b) models (brands) of a medical device shall belong to the same class of the potential risk of use;

c) models (brands) of a medical device shall have the same functional purpose and principle of operation;

d) models (brands) of a medical device shall be designed to determine the presence and/or quantitative content of the same clinically (diagnostically) significant analyte (analytes) in a biological sample (for medical devices for *in vitro* diagnostics);

e) models (brands) of a medical device shall have various configurations that do not affect the principle of operation and functional purpose, which allows for the expansion or specialization of their use for medical purposes (as applicable);

f) models (brands) of a medical device shall have different technical parameters (for example, the wavelength of radiation, the size of the light field, resolution, etc.) that do not affect the principle of operation and functional purpose (as applicable);

g) models (brands) of a medical device shall form a standard-sized (model) series (for example, they have different dimensions (overall, linear, volumetric, etc.), shape, color coding, are made of the same materials, etc.) or

are a group of implementation of a medical device (for example, a stationary mobile apparatus (device, system, complex, etc.) with a wall and/or floor mounting, etc.) (as applicable). In this case, the group of implementation of a medical device shall mean the products for which one group drawing of parts and/or one group specification are made;

h) models (brands) of a medical device shall have the same characteristics in terms of:

scope of application;

invasiveness;

sterility (including taking into account the sterilization methods);

frequency of use (single use, multiple uses by one patient, multiple uses by several patients);

operational and design features;

duration of use;

the similarity of materials used in modifications of a medical device and coming into contact with the human body (according to their chemical, toxicological, physical, electrical, morphological, and mechanical properties).

20. The following shall be prohibited in the customs territory of the Union:

a) selection of two or more reference Member States for marketing authorization and expert examination of one medical device;

b) registration of various medical devices under the same name;

c) registration of products, the name of which is contained in the unified registry of registered medicines of the Eurasian Economic Union, the procedure for the generation and maintenance of which was approved by Decision No. 84 of the Eurasian Economic Commission's Council dated November 3, 2016, or coincides with the name of a biologically active food additive, the information about which is contained in the unified registry

of certificates of state registration of products, the procedure for the generation and maintenance of which was approved by Decision No. 80 of the Eurasian Economic Commission's Board dated June 30, 2017, as medical devices. If a medicine or a biologically active food additive is a component of a medical device, then their names can be used in the name of a medical device.

II. Procedures for marketing authorization and expert examination of a medical device

21. For the registration of a medical device, the applicant shall choose a reference Member State and at least one Member State concerned.

22. The applicant shall submit the following documents to the authorized authority (expert organization) of the reference Member State:

a) marketing authorization application containing the marketing authorization and expert examination applications, as well as the documents listed in Annex 4;

b) copies of documents confirming payment for the marketing authorization and expert examination procedures in the reference Member State.

23. The authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of marketing authorization and expert examination applications and documents specified in Paragraph 22 hereof, shall verify the completeness and reliability of the information contained therein.

24. If the marketing authorization and expert examination applications are submitted in violation of the requirements established by these Rules, or they contain false information, or the documents specified in Paragraph 22 hereof are not submitted in full, the authorized authority (expert organization)

of the reference Member State shall, within 7 business days from the date of receipt of such applications and documents, notify the applicant of the need to eliminate the identified violations and/or submit missing documents within 30 business days from the date of posting a relevant notice in the information system of the authorized authority (expert organization) of the reference Member State or from the date of sending the notice to the applicant in the manner specified in the marketing authorization and expert examination applications.

25. If the applicant fails to eliminate the identified violations and/or the missing documents have not been submitted after 30 business days, the authorized authority (expert organization) of the reference Member State shall, within 3 business days, decide to return the marketing authorization and expert examination applications and documents justifying the reasons for the return to the applicant.

26. Within 3 business days from the date of submission of marketing authorization and expert examination applications and documents meeting the requirements hereof, as well as in the case of elimination of violations identified within the period specified in Paragraph 24 hereof and/or submission of documents meeting the requirements hereof, the authorized authority (expert organization) of the reference Member State shall make a decision about the beginning of marketing authorization and expert examination procedures, and post a marketing authorization application containing the marketing authorization and expert examination applications in its information system.

27. The examination shall include (if applicable):

a) assessment of the correct classification of a product as a medical device;

b) assessment of conformity of the potential risk class of the medical device indicated by the applicant in accordance with the Rules for Classification of Medical Devices Depending on the Potential Risk of Use, approved by Decision No. 173 of the Eurasian Economic Commission's Board dated December 22, 2015;

c) assessment of the correct classification of a medical device (models (brands) of a medical device) as a medical device of a certain type in accordance with the nomenclature of medical devices, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015;

d) assessment of conformity of models (brands) of a medical device (if any) included in the same marketing authorization to the criteria established by Paragraph 19 hereof;

e) analysis and evaluation of evidentiary documents (materials) confirming the conformity of a medical device with the General Requirements, including:

analysis of the information provided by the manufacturer on the conformity of the medical device to the General Requirements, including an analysis of the correct identification of the provisions of the General Requirements applicable to the medical device;

assessment of conformity of the technical testing protocols issued by authorized organizations to the Rules for Technical Testing of Medical Devices;

assessment of conformity of the study (testing) protocols for the purpose of evaluating the biological effect of medical devices issued by authorized organizations to the Rules for Conducting Studies (Tests) for the Purpose of Evaluating the Biological Effect of Medical Devices;

analysis of the report on the evaluation of the biological effect of a medical device (to be carried out, among other things, to confirm that the materials coming into contact (interacting) with human tissues have been identified (the brands of materials and their manufacturers have been indicated), as well as to confirm the validity of the absence of the need for studies (testing) to evaluate the biological effect);

analysis of the report on clinical evidence of the efficiency and safety of a medical device (to be carried out to confirm the validity of selecting the methods to prove the clinical efficacy and safety of a medical device, the validity of the data used to prove the clinical efficacy and safety of a medical device, as well as the validity of the conclusion on clinical efficacy and safety for all declared indications for use, taking into account the presence or absence of contraindications);

assessment of conformity of reports on the clinical (clinical and laboratory) tests (studies) of medical devices to the Rules for Conducting Clinical and Clinical Laboratory Tests (Studies) of Medical Devices;

analysis of the validity of the proof provided by the first party (if any) to confirm the conformity of the medical device to the General Requirements, taking into account the class of potential risk of using the medical device (for medical devices referred to the classes 2b and 3 of the potential risk of use, a testing (study) program and rationale for the selected methods should be attached to the proof provided by the first party);

analysis of standards followed by the manufacturer during the design and manufacturing of a medical device;

analysis of the safety and efficacy of a medicinal product as part of a medical device, its impact on the functionality of a medical device, and compatibility of medicine with a medical device (with the exception of medical

devices for *in vitro* diagnostics). The medicine should be registered and approved for use in the state of manufacture of the medicine;

analysis of data on the biological safety of a medical device based on the analysis of all materials of animal or human origin included in the medical device,

information on the selection of sources (donors), material selection, processing, storage, testing, validation of testing procedures, as well as the handling of tissues, cells, and substances of animal or human origin, as well as cultures of microorganisms and viruses;

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

the study of the validity of software based on the analysis of data on its verification and validation, including the information on its development, measures, and means of protection against unauthorized access and cybersecurity, testing by the manufacturer, identification and labeling data;

analysis of a report on the stability of the medical device, and the validity of the declared shelf life;

consideration of the risk analysis report in order to confirm the completeness of the hazards identified in such a report, dangerous situations, and related risks that can be assessed as unacceptable, as well as confirmation of the manufacturer's conclusion that there are no unacceptable risks or the acceptability of risks that are assessed as acceptable in the risk analysis report based on the analysis of the risk-benefit ratio;

confirmation of the validity of the result of the manufacturer's evaluation of the medical device conformity to the General requirements on the basis of the submitted evidentiary materials (documents);

assessment of conformity of the operational document or user manual and maintenance manual to the General Requirements;

assessment of conformity of the medical device labeling to the General Requirements;

analysis of requirements for the medical device specifications;

evaluation of documents confirming the results of tests of medical devices for the purpose of approving the type of measuring instruments (in relation to medical devices included in the list of types of medical devices to be classified as measuring instruments during their registration);

f) analysis of reports on the results of the audit of the medical device production facilities (to be carried out in order to confirm the conformity of the claimed medical device to a group (subgroup) of medical devices, taking into account the class of potential risk of use according to Annex 2 to the Requirements for the Quality Management System, as well as to confirm the reliability of information about the production facilities specified in the marketing authorization and expert examination applications covered by the report on the results of the audit of the medical device production facilities);

g) analysis of data on the certification of the quality management system (if any), including the requirements for compliance with which the manufacturer's quality management system has been certified, and information about certificates (certificate number, date of issue, validity period, name and information about the accreditation of the certification body);

h) proof of the validity of indication of the production facilities of the medical device being registered;

i) analysis of data on the development and production of a medical device (production process diagrams, information on the main stages of production, packaging, testing, and the procedure for release of the final product);

j) analysis of the marketing information provided by the manufacturer;

k) analysis of information provided by the manufacturer on the presence or absence of reports on adverse effects and/or accidents related to the use of a medical device, revocations of the medical device from the market, notifications on the safety of a medical device, approaches to solving such problems by the manufacturer when they occur, descriptions of corrective actions taken, as well as analysis of the ratio of sales, the number of accidents and revocations of a medical device;

l) analysis of the postmarketing plan for collecting the data on the safety and efficiency of a medical device.

28. During the examination, where the materials and information contained in marketing authorization and expert examination applications and documents of the marketing authorization application are not enough to make a decision on the start of the audit of the production facility (when it is required) or for the preparation of an expert report (if there is no need to conduct an audit of the production facilities), the authorized authority (expert organization) of the reference Member State shall send a corresponding request to the applicant (indicating the nature of the comments and ways to eliminate them). The request shall be sent once using the method specified in the marketing authorization and expert examination applications.

The applicant shall provide a response to the request within 60 business days from the date of its receipt. In the case of failure to provide the specified response when due, the authorized authority (expert organization) shall decide that a medical device may not be registered on the basis of the documents available to it.

If the authorized authority (expert organization) of the reference Member State identifies false data or documents submitted by the applicant in response

to the request, or documents compiled or containing text in a foreign language without a certified translation into Russian in accordance with the procedure established by the legislation of the reference Member State, the authorized authority (expert organization) shall, within 2 business days from the date of receipt of such documents, serve to the applicant, in the manner indicated in the marketing authorization and expert examination applications, a decision on the return of these documents with the justification of the reasons for the return and a notice that the applicant may re-submit the documents before the expiration of the period specified in the second indent of this Paragraph.

29. The authorized authority (expert organization) of the reference Member State shall, within 45 business days from the date of its decision to start the marketing authorization and expert examination procedures in respect of the medical device, draw up an expert report in accordance with Annex 5 or, if required, makes a decision to start the audit of the production facilities (provided there are no comments on the documents contained in the submitted application or elimination of the comments specified in the request) and notify the applicant of its decision by sending a notice in the manner specified in the marketing authorization and expert examination applications.

30. When making a decision that an authorized authority (expert organization) of the reference Member State shall start the audit of production facilities, the inspection organization of the reference Member State shall conduct an audit of the production facilities in accordance with the Requirements for the Quality Management System. The duration of the organization and conduct of the audit of the production facility should not exceed 90 business days from the date when the authorized authority (expert organization) decides on the start of the audit of the production facilities.

31. The report on the results of the audit of production facilities shall be sent by the inspecting organization to the authorized authority (expert

organization) of the reference Member State for its inclusion in the marketing authorization application and to the applicant by registered mail with a return receipt requested or in the form of an electronic document bearing an electronic signature within 15 business days from the date of completion of the audit of production facilities. At the same time , if nonconformities are revealed during the audit of the production facilities, the report on the results of the audit of the production facilities, supplemented with information on the elimination of the identified nonconformities, shall be sent by the inspecting organization to the authorized authority (expert organization) of the reference Member State within 15 business days after receiving information from the applicant on the elimination of nonconformities or from the date of expiration of the period established for their elimination.

Where, following the results of the audit of production facilities, changes have been made to the documents of the marketing authorization application for the medical device being registered, such documents, drawn up in accordance with Annex 4, shall be sent by the inspecting organization to the authorized authority (expert organization) of the reference Member State.

32. The authorized authority (expert organization) of the reference Member State shall, within 15 business days from the date of receipt of the report on the results of the audit of production facilities, draw up an expert report in accordance with Annex 5 hereto.

33. The conclusions contained in the expert report should be unambiguous and understandable.

34. The grounds for the issuance of a report on the refusal to register a medical device by the authorized authority (expert organization) of the reference Member State shall be the following:

a) the relevant materials and information contained in the marketing authorization application fail to prove the quality, and/or efficiency, and/or safety of a medical device;

b) the risk of harm to the health of citizens and medical workers due to the use of a medical device exceeds its efficiency;

c) the authorized bodies of state control (supervision) over the circulation of medical devices reveal unreliable data on the efficiency and safety of a medical device and their inconsistency with the data on the medical device contained in the documents of the marketing authorization application.

35. If the expert report regarding the possibility of registration of a medical device contains a negative conclusion, the authorized authority (expert organization)

shall, within 10 business days from the date of registration (receipt) of the expert report, make a decision to refuse registration of a medical device, draw up and issue to the applicant a notice of refusal in the registration of a medical device in the manner specified in the marketing authorization and expert examination applications, with a justification of the reasons for refusal and an attachment of a copy of the expert report issued by the authorized authority (expert organization) of the reference Member State to it.

36. If the expert report on the possibility of registration of a medical device contains a positive conclusion, the authorized authority (expert organization) of the reference Member State shall, within 5 business days from the date of registration of the expert report, place the marketing authorization application and this expert report in its information system and notify the applicant of the need to submit copies of documents on payment for the procedure of approval of the expert report in the Member State(s) concerned within 30 calendar days from the date of sending such a notice to the applicant

in the manner specified in the marketing authorization and expert examination applications.

37. The applicant shall notify the authorized bodies (expert organizations) of the reference Member State and the Member State(s) concerned about the payment for the approval procedures within the time frame established by Paragraph 36 hereof.

38. The approval of the expert report shall form the basis for making a decision on the registration of a medical device in the Member State concerned and issued by the authorized authority (expert organization) of the Member State concerned in the form of an opinion confirming the approval (non-approval) of the expert report in accordance with Annex 6 (hereinafter referred to as the proof of approval (non-approval) of the expert report).

39. The expert report shall be approved by the authorized authority (expert organization) of the Member State concerned in accordance with Section III hereof.

40. Provided that there are no disagreements between the reference Member State and the Member State(s) concerned regarding the approval of the expert report, the authorized authority (expert organization) of the reference Member State shall:

a) within 10 business days from the date of receipt of the proof of approval of the expert report from all authorized bodies (expert organizations) of the Member States concerned or from the date of expiration of the period established for the provision of the specified confirmation by the Member States concerned (provided that the applicant has submitted copies of documents on payment for the procedure of approval of the expert report in the Member States concerned and translations of the operational document or instructions for the use of a medical device, maintenance manual and labeling text into the official languages of the Member States concerned (if required))

to the authorized authority (expert organization) of the reference Member State, decide on the registration of a medical device and place information about the medical device provided for by the Procedure of Generation and Maintenance of an Information System in the unified registry of medical devices registered within the Union;

b) within 10 business days from the date of a decision on registration of the medical device, draw up and issue a marketing authorization and an annex thereto to the applicant in the manner specified in the application for registration of a medical device.

41. Non-approval of the expert report of the authorized authority (expert organization) of the reference Member State in one of the Member States concerned shall form the basis for refusal to register a medical device in the territory of this Member State concerned.

42. If there is a Member State concerned, the authorized authority (expert organization) of which rejected the expert report, the authorized authority (expert organization) of the reference Member State shall, within 10 business days from the date of receipt of a proof of approval (non-approval) of the expert report or from the date of expiration the deadline established for the provision of the specified proof by the Member States concerned from all authorized bodies (expert organizations) of the Member States concerned (provided that the applicant has submitted copies of documents on payment for the procedure of approving the expert report in the Member States concerned and translations of the operational document or instructions for the use of a medical device, maintenance manual and labeling text into the official languages of the Member States concerned (if required) to the authorized authority (expert organization) of the reference Member State), taking into account the nature of the comments made, perform one of the following actions:

a) send a notice to the applicant about the need to approve an application to the Advisory Committee to resolve disagreements regarding the approval of the expert report with the attached copy (copies) of the proof of approval (non-approval) of the expert report. If there is no response from the applicant 15 business days from the date of receipt of the relevant notice, the application to the Advisory Committee shall be considered non-approved;

b) in the case of agreement with the conclusions of the authorized authority (expert organization) of the Member State concerned on the impossibility of registration of a medical device, decide to refuse registration of a medical device. In this case, the authorized authority (expert organization) of the reference Member State shall, within 10 business days from the date of the decision to refuse registration of a medical device, draw up and issue to the applicant, in the manner specified in the marketing authorization and expert examination applications, a notice on refusal to register a medical device (with a justification of the reasons for refusal and attachment of copies of the expert report and proof of the non-approval of the expert report).

43. The authorized authority (expert organization) of the reference Member State shall, within 3 business days from the date of receipt of a response from the applicant regarding the application to the Advisory Committee to resolve differences regarding the expert report:

a) apply to the Advisory Committee in accordance with Section IV hereof (if the applicant approves the application to the Advisory Committee);

b) make a decision on the registration of a medical device without specifying in the marketing authorization of the Member State(s) concerned, the authorized authority (expert organization) of which has rejected the expert report (should the applicant reject the application to the Advisory Committee). In this case, the authorized authority (expert organization) of the reference

Member State shall, within 10 business days from the date of the decision on the registration of the medical device:

place information about the medical device provided for by the Procedure of Generation and Maintenance of the Information System in the unified registry of medical devices registered within the Union;

draw up and issue a marketing authorization and an annex thereto to the applicant in the manner specified in the application for registration of a medical device.

III. The procedure for approving an expert report

44. The procedure for approving an expert report shall be carried out in relation to an expert report issued under the following procedures:

a) procedure for marketing authorization and expert examination of a medical device in accordance with Section II hereof;

b) the procedure for amending the marketing authorization application in accordance with Section V hereof;

c) the procedure for approving an expert report on a registered medical device in accordance with Section VIII hereof.

45. The applicant shall, within the period agreed with the authorized authority (expert organization) of the Member State concerned and not exceeding the period specified in Paragraph 50 hereof, ensure that the authorized authority (expert organization) of the reference Member State and the Member State concerned provide translations of the operational document

or instructions for the use of a medical device, maintenance manual and labeling text to the state language of the Member State concerned (if relevant requirements are contained in the legislation of the Member State concerned).

46. When carrying out the procedure for approving an expert report, the authorized authority (expert organization) of the Member State concerned shall evaluate the completeness and sufficiency of data confirming the safety, quality, and efficiency of the medical device, the correctness of the translation of the operational document or instructions for the use of a medical device, the maintenance manual and the labeling text into the official language of the Member State concerned (if required).

47. The authorized bodies (expert organizations) of the Member States concerned may, if required, using the means of the integrated information system of the Union (hereinafter referred to as the integrated system), send their comments and suggestions to the authorized authority (expert organization) of the reference Member State before this authorized authority (expert organization) issues an expert report.

48. During the approval of the expert report, the authorized bodies (expert organizations) of the Member States may interact with each other in order to address the emerging issues.

49. If there are disagreements between the reference Member State and the Member State(s) concerned regarding the approval of the expert report, the authorized authority (expert organization) of the reference Member State shall make a decision based on the expert report and proof of non-approval of the expert report, including taking into account the results of the settlement of disagreements regarding the approval of the expert report within the Advisory Committee (where the Advisory Committee was applied to).

50. The authorized authority (expert organization) of the Member State concerned shall consider the expert report within 30 business days, calculated from one of the following dates:

when the procedures of marketing authorization and expert examination of a medical device are carried out – from the date of receipt of a notice on payment for the approval procedures by the authorized bodies (expert organizations) of the reference Member State and the Member State(s) concerned;

when the procedure of amending the marketing authorization application is carried out – from the date of placement of the marketing authorization application containing a request for amending the marketing authorization application by the authorized authority (expert organization) of the reference Member State in its information system;

when the procedure of approval of an expert report on a registered medical device is carried out – from the date of placement of the marketing authorization application containing a request for approval of an expert report on the registered medical device by the authorized authority (expert organization) of the reference Member State in its information system.

In this case, the condition for calculating the specified period shall be the presence of funds received as a result of the applicant's paying for the procedure of approving the expert report in the Member State concerned in full on the account of the authorized authority (expert organization) of the Member State concerned.

51. Based on the results of the examination of the expert report, the authorized authority (expert organization) of the Member State concerned shall send to the authorized authority (expert organization) of the reference Member State the proof of the approval (non-approval) of the expert report (with a justification) using the means of an integrated system (including the proof of

the correctness of the translation of the operational document or instructions for the use of a medical device, maintenance manual and labeling text into the official languages of the Member States concerned in accordance with the legislation of the Member States).

52. If the Member State concerned fails to provide proof of the approval (non-approval) of the expert report within the time period established by Paragraph 50 hereof, the expert report shall be considered approved, provided that the applicant has submitted to the authorized bodies (expert organizations) of the reference Member State and the Member State concerned translations of an operational document or instructions for the use of a medical device, maintenance manuals and the labeling text in the official language of the Member State concerned (if relevant requirements are contained in the legislation of the Member State concerned).

53. As part of the procedures for marketing authorization and expert examination of a medical device in accordance with Section II hereof, the grounds for the non-approval of an expert report by the Member State concerned shall be as follows:

a) the grounds provided for in Paragraph 34 hereof;

b) failure by the applicant to provide a translation of the operational document or instructions for the use of a medical device, the maintenance manual, and the labeling text into the official language of the Member State concerned within the agreed period (if required);

c) the absence of funds received as a result of the applicant’s paying for the procedure of approving the expert report in full on the account of the authorized authority (expert organization) of the Member State concerned.

54. In the framework of the procedure for approving an expert report for the registered medical device in accordance with Section VIII hereof, the grounds for the non-approval of an expert report

by the Member State concerned shall be the grounds provided for in Paragraph 34 hereof.

55. As part of the procedure for amending the marketing authorization application in accordance with Section V hereof, the grounds for the non-approval of an expert report by the Member State concerned shall be as follows:

a) the grounds provided for in Paragraph 79 hereof;

b) the absence of translations of the operational document or instructions for the use of a medical device, the maintenance manual, and the labeling text into the official language of the Member State concerned within the agreed period (if required).

IV. Resolution of conflicts regarding the approval of the expert report

56. In the absence of consensus on the issue of approval of an expert report issued within the framework of procedures for marketing authorization and expert examination of a medical device in accordance with Section II hereof, the conflicts shall be resolved by contacting the authorized authority (expert organization) of the reference Member State to the Advisory Committee.

57. The authorized authority (expert organization) of the reference Member State, in agreement with the applicant, shall send to the Advisory Committee a request to consider disagreements (indicating the information about the subject of conflicts and the results of negotiations and consultations). Any materials substantiating the position of the authorized authority (expert organization) of the reference Member State on the subject of conflicts may be attached to the request.

58. After receiving the request and the materials attached thereto from the authorized authority (expert organization) of the reference Member State,

the Advisory Committee shall request from the authorized bodies (expert organizations) of the Member States concerned the materials confirming their position on the subject of conflict.

59. The Advisory Committee shall send a notice on the conflict resolution meeting to the authorized bodies (expert organizations) of the reference Member State and the Member States concerned after they submit the relevant materials.

60. The organization and holding of the conflict resolution meeting shall be ensured by the Advisory Committee. The meeting shall be attended by members of the Advisory Committee who are representatives of authorized bodies (expert organizations). If required, at the suggestion of the authorized bodies, the representatives of healthcare organizations, expert organizations, manufacturers, and other specialists may be invited to participate in the consideration of the issue discussed during the meeting of the Advisory Committee.

61. Following the meeting of the Advisory Committee, an advisory decision shall be made.

62. The deadline for the settlement of conflicts regarding the approval of an expert report should not exceed 30 business days from the date of sending a relevant request and materials to the Advisory Committee by the authorized authority (expert organization) of the reference Member State.

63. Within 3 business days from the date of receipt of the minutes of the meeting of the Advisory Committee on the conflict resolution, the authorized authority (expert organization) of the reference Member State shall, based on the recommendations of the Advisory Committee, decide on the possibility of registering a medical device.

64. If the decision taken in accordance with Paragraph 63 hereof is positive, the authorized authority (expert organization) of the reference

Member State shall, within 3 business days from the date of its adoption:

a) place information about the medical device provided for by the Procedure of Generation and Maintenance of the Information System in the unified registry of medical devices registered within the Union;

b) draw up a marketing authorization and an annex thereto (indicating the Member States concerned, the authorized bodies (expert organizations) of which approved the expert report) and issue the same to the applicant in the manner specified in the application for registration of a medical device;

c) if, following the results of the meeting of the Advisory Committee of the Member State(s) concerned, the authorized authority (expert organization) of which rejected the expert report, send to the applicant, in the manner specified in the marketing authorization and expert examination applications, a notice on the decision made by the authorized authority (expert organization) of the Member State concerned (with a copy of the proof of rejection of the expert report and decision (protocol statement) of the Advisory Committee).

65. If the decision taken in accordance with Paragraph 63 hereof is negative, the authorized authority (expert organization) of the reference Member State shall, within 3 business days from the date of its adoption, draw up and issue to the applicant, in the manner specified in the marketing authorization and expert examination applications, a notice on refusal to register a medical device (with a justification of the reasons for refusal and the attachment of copies of the expert report, the proof of rejection of the expert report and the decision (protocol statement) of the Advisory Committee).

V. The procedure of amending the marketing authorization application

66. The applicant shall, within 90 calendar days from the date of amendment of the documents contained in the marketing authorization application, initiate the procedure for amending the marketing authorization application as appropriate.

67. Amendments to the marketing authorization application requiring registration of a new medical device shall include:

a) amendments entailing a change in the functional purpose and/or the principle of operation of a medical device;

b) inclusion of information on the models (brands) of a registered medical device that do not meet the criteria for inclusion of several models (brands) of a medical device in one marketing authorization in accordance with Paragraph 19 hereof;

c) amendments entailing simultaneous amendment of information about the manufacturer and the production facility(ies) in relation to the information specified in the marketing authorization issued as part of the procedures for marketing authorization and expert examination of a medical device, with the exception of information about the legal form, address, reorganization, and other information contained in the constituent documents.

68. In the event of amendments entailing a change in the operational document or instructions for the use of a medical device, the maintenance manual, and the labeling text, within 180 calendar days from the date of making these amendments, it is allowed to release medical devices corresponding to the documents and information from the marketing authorization application into circulation before these amendments are made. Simultaneous release of medical devices into circulation with an operational document or instructions for the use of a medical device, a maintenance manual, and a labeling text, corresponding documents and information from

the marketing authorization application before and after the amendments thereto are allowed.

69. The procedure for amending the marketing authorization application (with the exception of amendments to be made by way of a notice) requires the approval of the expert report by the Member States concerned as specified in the marketing authorization in accordance with the procedure established by Section III hereof.

70. In order to amend the marketing authorization application, the applicant shall send the following documents and information to the authorized authority (expert organization) of the reference Member State:

a) request for amendments to the marketing authorization application (in hard and/or in electronic copy) in accordance with Annex 7 (hereinafter referred to as the request for amendments);

b) a copy of the document confirming the powers of the authorized representative of the manufacturer (if any);

c) documents and information about the relevant amendments, including the documents confirming the amendments and indicating that they do not entail changes in the properties and characteristics of a medical device affecting its safety, quality, and efficiency, or enhance its properties and characteristics with unchanged functional purpose and/or principle of actions of a medical device;

d) copies of documents confirming payment for the procedure of amending the marketing authorization application in the reference Member State and the procedure for approving an expert report in the Member State(s) concerned, as well as the issuance of a marketing authorization in the reference Member State (if required);

e) original (duplicate) marketing authorization;

f) a list of documents.

71. The authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of the request for amendments, as well as the documents and information specified in Paragraph 70 hereof, check the completeness and reliability of the information contained therein.

72. If the request for amendments is submitted in violation of the requirements hereof and/or contains false information and/or the documents and information specified in Paragraph 70 hereof are not submitted in full, the authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of such a request, documents, and information, notify the applicant of the need to eliminate the identified violations and/or submit missing documents within 30 business days from the date of posting a relevant notice in the information system of the authorized authority (expert organization) of the reference Member State or from the date of sending the notice to the applicant in the manner specified in the request for amendments.

73. If the applicant fails to eliminate the identified violations and/or the missing documents have not been submitted after 30 business days, the authorized authority (expert organization) of the reference Member State shall, within 3 business days, decide to return the request for amendments and documents (with the justification of the reasons for the return).

74. Within 3 business days from the date of submission of the request for amendments, documents, and information that meet the requirements hereof, as well as in the case of elimination of the identified violations and/or submission of documents that meet the requirements hereof within 30 days, the authorized authority (expert organization) of the reference Member State shall decide to start the procedures of amending the marketing authorization application and post in its

information system a marketing authorization application containing a request for amendments and documents confirming the amendments.

75. During the examination, when materials and information contained in the request for amendments and documents confirming the amendments are insufficient, the authorized authority (expert organization) of the reference Member State shall send to the applicant a corresponding request (indicating the comments and ways to eliminate them). The request shall be sent to the applicant once by the method specified in the request for amendments.

The applicant shall provide a response to the request within 60 business days from the date of its receipt. In the case of failure to provide a response within the specified period, the authorized authority (expert organization) of the reference Member State shall make a decision based on the documents available to it.

76. If the authorized authority (expert organization) of the reference Member State identifies false information or documents submitted by the applicant in response to the request, or if the documents are compiled or contain text in a foreign language without a certified translation into Russian in accordance with the legislation of the Member State, the authorized authority (expert organization) of the reference Member State shall, within 2 business days from on the date of receipt of such documents, serve to the applicant a decision on the return of these documents by the method specified in the request for amendments (with a justification of the reasons for the return and a notice that the applicant may re-submit the documents before the expiration of the period specified in the second indent of Paragraph 75 hereof).

77. The authorized authority (expert organization) of the reference Member State shall conduct an expert examination and draw up an expert report in accordance with Annex 8 within 30 business days from the date of

the decision to start the procedure of amending the marketing authorization application.

78. The conclusions contained in the expert report should be unambiguous and understandable.

79. The grounds for the preparation of an expert report on the impossibility of amending the marketing authorization application by the authorized authority (expert organization) of the reference Member State shall be as follows:

a) unreliability of the submitted information justifying the amendments (including those identified during the implementation of state control (supervision) of the circulation of medical devices by authorized bodies);

b) the absence of information in the documents submitted by the applicant confirming that the amendments made to the documents contained in the marketing authorization application do not entail changes in the properties and characteristics of the medical device affecting its safety, quality, and efficiency, or improve the properties and characteristics with the functional purpose

and/or the principle of operation of the medical device remaining unchanged;

c) the need for a new registration of a medical device in accordance with Paragraph 67 hereof.

80. The authorized authority (expert organization) of the reference Member State shall, within 10 business days from the date of registration (receipt) of an expert report on the impossibility of amending the marketing authorization application, decide on the refusal to make these amendments, draw up and issue to the applicant a notice on refusal to amend the marketing authorization application in the manner specified in the request for amendments

(with the justification of the reasons for refusal and attachment of a copy of the

expert report of the authorized authority (expert organization) of the reference Member State and the original (duplicate) marketing authorization.

81. After registration of an expert report on the possibility of amending the marketing authorization application in the reference Member State, the authorized authority (expert organization) of the reference Member State shall post a marketing authorization application containing a request for amendments and an expert report in its information system.

82. In the absence of the Member State(s) concerned, the authorized authority (expert organization) of the reference Member State shall, within 10 business days from the date of issuing an expert report on the possibility of amending the marketing authorization application:

a) decide on amendment of the marketing authorization application and post information on amendments to the marketing authorization application in the unified registry of medical devices registered within the Union in accordance with the Procedure for the Generation and Maintenance of the Information System, as well as scanned copies of documents that have been amended;

b) within 10 business days from the date of the decision to amend the marketing authorization application, notify the applicant thereof by the method specified in the request for amendments, as well as in the case of amendment of the marketing authorization and/or an annex thereto, execute and issue a renewed marketing authorization with an annex thereto, with the same number (indicating the date of the relevant amendments) to the applicant by the method specified in the request for amendments and return the previously issued marketing authorization with an annex thereto, marked invalid (indicating the date thereof).

83. If there is a Member State(s) concerned, and provided that there are no disagreements between the authorized authority (expert organization) of the

reference Member State and the authorized authority (expert organization) of the Member State(s) concerned regarding the approval of the expert report, the authorized authority (expert organization) of the reference Member State shall:

a) within 10 business days from the date of receipt of the proof of approval of the expert report from the authorized bodies (expert organizations) of all Member States concerned, or from the date of expiration of the period stipulated in Paragraph 50 hereof (provided that the applicant has submitted a translation of the operational document or instructions for the use of medical devices, maintenance manuals and labeling text in the official languages of the Member States concerned (if required) to the authorized authority (expert organization) of the reference Member State), decide on amendments to the marketing authorization application and post the information on amendments to the marketing authorization application in accordance with the Procedure for the Generation and Maintenance of the Information System, as well as scanned copies of the documents being amended, in the unified registry of medical devices registered within the Union;

b) within 10 business days from the date of the decision to amend the marketing authorization application, notify the applicant thereof by the method specified in the request for amendments, as well as in the case of amendment of the marketing authorization and/or an annex thereto, execute and issue a renewed marketing authorization with an annex thereto, with the same number (indicating the date of the relevant amendments) to the applicant by the method specified in the request for amendments and return the previously issued marketing authorization with an annex thereto, marked invalid (indicating the date thereof).

84. The non-approval of the expert report of the authorized authority (expert organization) of the reference Member State in one of the Member

States concerned shall form the basis for deleting information about this state from the marketing authorization.

85. If the authorized authority (expert organization) of the Member State concerned rejected the expert report and the authorized authority (expert organization) of the reference Member State agrees with the conclusions of the authorized authority (expert organization) of the Member State concerned regarding the impossibility of amending the marketing authorization application, the authorized authority (expert organization) of the reference Member State shall:

a) within 10 business days from the date of receipt of the proof of approval (non-approval) of the expert report from the authorized bodies (expert organizations) of all Member States concerned or from the date of expiration of the period envisaged in Paragraph 50 hereof, decide to refuse to amend the marketing authorization application;

b) within 10 business days from the date of the decision to reject the amendments to the marketing authorization application, draw up and issue to the applicant, in the manner specified in the request for amendments, a notice on refusal to amend the marketing authorization application (with the justification of the reasons for refusal and a copy of the expert report of the authorized authority (expert organization) of the reference Member State, a copy (copies) of the proof of approval (non-approval) of the expert report and the original (duplicate) marketing authorization attached).

86. If the authorized authority (expert organization) of the Member State concerned rejected the expert report and the authorized authority (expert organization) of the reference Member State does not agree with the conclusions of the authorized authority (expert organization) of the Member State concerned regarding the impossibility of amending the marketing

authorization application, the authorized authority (expert organization) of the reference Member State shall:

a) within 10 business days from the date of receipt of the proof of approval (disagreement) of the expert report from the authorized bodies (expert organizations) of all Member States concerned or from the date of expiration of the deadline set for the provision of the specified confirmation by the Member States concerned (provided that the applicant has submitted a translation of the operational document or instructions for the use of a medical device, maintenance manuals and labeling text in the official languages of the Member States concerned (if required) to the authorized authority (expert organization) of the reference Member State):

decide to amend the marketing authorization application and to delete information about the Member State(s) concerned from the marketing authorization, the authorized authority (expert organization) of which has rejected the expert report;

post information on amendments to the marketing authorization application, as well as scanned copies of documents that have been amended, in the unified registry of medical devices registered within the Union in accordance with the Procedure for the Generation and Maintenance of the Information System;

b) within 10 business days from the date of the decision to amend the marketing authorization application:

notify the applicant about amendment of the marketing authorization application and the exclusion of information about the Member State(s) concerned, the authorized authority (expert organization) of which rejected the expert report, from the marketing authorization in the manner specified in the request for amendments (with a copy of the proof of rejection of the expert report attached);

draw up and issue to the applicant, in the manner indicated in the request for amendments, a renewed marketing authorization with an annex thereto, from which the information about the Member State(s) concerned, the authorized authority (expert organization) of which rejected the expert report, was deleted, and which has been amended in accordance with the request for amendments, with the same number (indicating the date of the relevant amendments);

return the previously issued marketing authorization with an annex thereto, marked invalid (indicating the date thereof) to the applicant in the manner specified in the request for amendments.

VI. The procedure for amending the marketing authorization application by way of a notice

87. The procedure for amending the marketing authorization application by way of a notice shall apply in the following cases:

a) the amendments are related to the validity period of the documents contained in the marketing authorization application (updating of the marketing authorization application documents by the applicant);

b) the amendments are made by the manufacturer of medical devices of class 1 of potential risk of use or non-sterile medical devices of class 2a of potential risk of use, which have passed the assessment of the quality management system of the medical device (including the processes of design and development of medical devices) in accordance with the Requirements for the Quality Management System;

c) the amendments are related to the following information about the manufacturer of the medical device or its authorized representative:

the name of the legal entity (full and abbreviated (if any), including the company name), the registered office and the place of business;

surname, first name, patronymic (if any), place of residence of the individual entrepreneur or the place of business and details of the identity document;

d) changes in the name of a medical device in terms of a trademark and other identifications;

e) the changes provide for the exclusion of information about the model (brand) of a medical device from the marketing authorization.

88. In order to amend the marketing authorization application by way of a notice, the applicant shall send the following documents and information to the authorized authority (expert organization) of the reference Member State:

a) request for amendments to the marketing authorization application by way of a notice (in a hard and/or electronic copy) in accordance with Annex 9 (hereinafter referred to as the request for amendments);

b) a copy of the document confirming the powers of the authorized representative of the manufacturer (if any);

c) documents and information about the relevant amendments, including the documents confirming the amendments and indicating that they do not entail changes in the properties and characteristics of a medical device affecting its safety, quality, and efficiency, or enhance its properties and characteristics with unchanged functional purpose and/or principle of actions of a medical device;

d) reports on the results of primary, periodic (scheduled) and unscheduled audits of the production facilities (in the case provided for in Subparagraph “b” of Paragraph 87 hereof);

e) copies of documents confirming payment for the procedure of amending the marketing authorization application by way of a notice in the

reference Member State, as well as the issuance of a marketing authorization in the reference Member State (if required);

f) the original (duplicate) marketing authorization (with amendments thereto, if required);

g) a list of documents.

89. The request for amendments and documents confirming the amendments (including the reports on the results of audit of the production facilities) shall be posted by the authorized authority (expert organization) of the reference Member State in its information system with access provided to authorized bodies (expert organizations) of the reference Member State and the Member State(s) concerned only.

90. The authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of the request for amendments, as well as the documents and information specified in Paragraph 88 hereof, check the completeness and reliability of the information contained therein (including the validity period of reports on the results of audit of the production facilities).

91. If the request for amendments is submitted in violation hereof, contains false information, and/or the documents and information specified in Paragraph 88 hereof are not submitted in full, the authorized authority (expert organization) of the reference Member State shall, within

7 business days from the date of receipt of such a request, documents, and information, notify the applicant of the need to eliminate the identified violations and/or submit missing documents within 30 business days from the date of posting the relevant notice in the information system of the authorized authority (expert organization) of the reference Member State or from the date

of sending a notice to the applicant in the manner specified in the request for amendments.

92. If, after 30 business days, the applicant fails to eliminate the identified violations and/or submit the missing documents, the authorized authority (expert organization) of the reference Member State shall, within 3 business days, decide to return the request for amendments and documents (with the justification of the reasons for the return).

93. Within 3 business days from the date of submission of the request for amendments, documents, and information that meet the requirements hereof, as well as in the case of elimination of the identified violations and/or submission of documents that meet the requirements hereof within the period established by Paragraph 91 hereof, the authorized authority (expert organization) of the reference Member State shall decide to start the procedures of amending the marketing authorization application by way of a notice and post in its information system a marketing authorization application containing a request for amendments.

94. If the validity period of the report on the results of audit of the production facilities has expired (for the case provided for in Subparagraph “b” of Paragraph 87 hereof), the request for amendments shall be rejected and amendments to the marketing authorization application shall be made in accordance with the procedure provided for in Section V hereof.

95. Amendments to the marketing authorization application by way of a notice shall be made by the authorized authority (expert organization) of the reference Member State within 15 business days from the date of the decision to start the procedure of amending the marketing authorization application by way of a notice.

96. The procedure for amending the marketing authorization application by way of a notice shall not require approval by the Member States concerned.

In this regard, the Member States concerned shall not be indicated in the request for amendments.

97. If the amendments are related to the information contained in the marketing authorization, the authorized authority of the reference Member State shall issue a new marketing authorization with the same number (indicating the date of the relevant amendments).

98. The grounds for the adoption of the decision to reject the amendments to the marketing authorization application by way of a notice shall be as follows:

a) the unreliability of the submitted information justifying the making of amendments by way of a notice (including the expiration of the report on the results of audit of the production facilities);

b) inconsistency of the submitted documents and information with Paragraph 88 hereof;

c) the need for a new registration of a medical device in accordance with Paragraph 67 hereof;

d) the inconsistency of amendments made with the cases specified in Paragraph 87 hereof.

99. The authorized authority (expert organization) of the reference Member State shall, within 5 business days from the date of the decision on rejection of the marketing authorization application by way of a notice, draw up and issue to the applicant, in the manner specified in the request for amendments, a notice on refusal to amend the marketing authorization application by way of a notice, with the justification, as well as return the previously issued marketing authorization (a duplicate thereof) and an annex thereto, if any, to the applicant in the manner specified in the request for amendments.

100. The authorized authority of the reference Member State shall, within 5 business days from the date of a decision on amending the marketing authorization application by way of a notice:

a) place information on amendments to the marketing authorization application in the unified registry of medical devices registered within the Union in accordance with the Procedure for the Generation and Maintenance of the Information System, as well as scanned copies of documents that have been amended;

b) draw up and issue a notice on amendment of the marketing authorization application by way of a notice, as well as, if required, a renewed marketing authorization with an annex thereto, with the same number (indicating the date of the relevant amendments) to the applicant in the manner indicated in the request for amendments;

c) return the previously issued marketing authorization (duplicate) with an annex thereto, if any, marked invalid (indicating the date thereof) to the applicant in the manner specified in the request for amendments.

VII. Procedure for issuing a duplicate marketing authorization

101. In the case of loss (damage) of the marketing authorization, the applicant shall be entitled to apply to the authorized authority of the reference Member State for the issuance of a duplicate marketing authorization (in a hard and/or electronic copy) in accordance with Annex 10.

102. In the case of damage to the marketing authorization, a damaged marketing authorization shall be attached to the application for the duplicate marketing authorization.

103. Within 5 business days from the date of receipt of the application for the duplicate marketing authorization, the authorized authority of the reference Member State shall draw up a duplicate marketing authorization on the letterhead and issue the same to the applicant in the manner specified in the application for the duplicate marketing authorization.

104. If the submitted application for the duplicate marketing authorization is executed improperly and/or false information is indicated therein, the authorized authority of the reference Member State shall issue a decision to refuse to issue a duplicate marketing authorization.

VIII. The procedure for approving an expert report on a registered medical device

105. The procedure for registration of a medical device registered in accordance with these Rules in the Member States not specified in the marketing authorization shall be carried out by approving the expert report by the authorized bodies (expert organizations) of these Member States. Following the results of the approval by the authorized authority of the reference Member State, a marketing authorization shall be issued, indicating all the Member States concerned, the authorized bodies (expert organizations) of which have approved the expert report.

106. The applicant shall submit the following documents (copies of documents) to the authorized authority (expert organization) of the reference Member State:

a) a marketing authorization application containing a request for approval of an expert report on the registered medical device (indicating the Member State(s) concerned not specified in the marketing authorization) (in a hard and/or electronic copy) in accordance with Annex 11 (hereinafter referred to as the request for approval of an expert report) and documents as listed in Annex 12;

b) copies of documents on payment for the issuance of a new marketing authorization in the reference Member State (if there are relevant requirements);

c) copies of documents on payment for the procedure of approval of the expert report in the Member State(s) concerned specified in the request for approval of the expert report.

107. The authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of the request for approval of the expert report and the documents specified in Paragraph 106 hereof, check the completeness and reliability of the information contained therein.

108. If a request for approval of an expert report is submitted in violation of the requirements hereof, contains false information, and/or the documents specified in Paragraph 106 hereof are not submitted in full, the authorized authority (expert organization) of the reference Member State shall, within 7 business days from the date of receipt of such a request and documents, notify the applicant of the need to eliminate the identified violations and/or submit missing documents within 30 business days from the date of posting a relevant notice in the information system of the authorized authority (expert organization) of the reference Member State or from the date of sending a notice to the applicant in the manner specified in the request for approval of the expert report.

109. If, after 30 business days, the applicant fails to eliminate the identified violations and/or submit the missing documents, the authorized authority (expert organization) of the reference Member State shall, within 3 business days, decide to return the request for approval of the expert report and documents (with the justification of the reasons for the return).

110. Within 3 business days from the date of submission of the request for approval of the expert report and documents meeting the requirements hereof, as well as in the case of elimination of the identified violations and/or submission of documents conforming to the requirements hereof, the authorized authority (expert organization) of the reference Member State shall decide on the procedure of approval of an expert report on a registered medical device and post in its information system a marketing authorization application containing a request for approval of an expert report.

111. The approval of the expert report by the Member States concerned as specified in the request for approval of the expert report shall be made in accordance with Paragraphs 46, 48–52, and 54 hereof.

112. Rejection of an expert report in one of the Member States concerned as specified in the request for approval of an expert report shall form the basis for denial in the circulation of the medical device in the territory of this Member State concerned.

113. Within 10 business days from the date of receipt of the proof of approval (non-approval) of the expert report from all authorized bodies (expert organizations) of the Member States concerned as specified in the request for approval of the expert report, or from the date of expiration of the period established by Paragraph 50 hereof, the authorized authority (expert organization) of the reference Member State shall decide on the issuance a renewed marketing authorization (if there are Member States concerned whose authorized bodies (expert organizations) have approved an expert report) or

a refusal to issue a renewed marketing authorization (in the absence of Member States concerned whose authorized bodies (expert organizations) have approved an expert report).

Within 10 business days from the date of the decision to issue a renewed marketing authorization, the authorized authority (expert organization) of the reference Member State shall:

post information about the Member States concerned as specified in the request for approval of the expert report, the authorized bodies (expert organizations) of which have approved the expert report, as well as scanned copies of documents that have been amended, in the unified registry of medical devices registered within the Union in accordance with the Procedure for the Generation and Maintenance of the Information System;

draw up and issue a renewed marketing authorization and an annex thereto, with the same number (indicating all Member States concerned, the authorized bodies (expert organizations) of which have approved the expert report and the date of the relevant amendments) to the applicant in the manner indicated in the request for approval of the expert report;

return the previously issued marketing authorization (duplicate thereof) with an annex thereto, marked invalid (indicating the date thereof) to the applicant in the manner specified in the request for amendments;

issue a notice on non-approval of the medical device by the Member State concerned as specified in the request for approval of the expert report, with a copy of the proof of non-approval of the expert report by the authorized authority (expert organization) of the specified state (if there is a Member State concerned, the authorized authority (expert organization) of which rejected the expert report) to the applicant in the manner specified in the request for approval of the expert report.

Within 10 business days from the date of the decision to refuse to issue a renewed marketing authorization, the authorized authority (expert organization) of the reference Member State shall:

return the previously issued marketing authorization (a duplicate thereof) with an annex thereto to the applicant in the manner specified in the request for approval of the expert report;

issue a notice on refusal to register a medical device by the Member State concerned as specified in the request for approval of the expert report, with a copy of the proof of non-approval of the expert report by the authorized authority (expert organization) of the specified state, as well as the original (duplicate) marketing authorization to the applicant in the manner specified in the request for approval of the expert report.

IX. Procedure for suspension or cancellation of the validity (invalidation) of the marketing authorization

114. The marketing authorization shall be suspended by the authorized authority of the reference Member State in the following cases:

a) based on the results of monitoring of the safety, quality, and efficiency of medical devices in the postmarketing period, when a potential serious threat to human health is identified;

b) based on the results of state control (supervision) over the circulation of medical devices, if there is information about the facts and circumstances posing a threat to the life and health of citizens and medical workers during the use and operation of medical devices;

c) the absence of up-to-date information about the authorized representative of the manufacturer (for manufacturers from the third countries).

115. The decision to suspend the validity of the marketing authorization (indicating the reasons, date, and period of suspension) shall be made by the authorized authority of the reference Member State in accordance with the legislation of that state.

116. The period of suspension of the marketing authorization may not exceed 6 months, while the sale and use of such medical devices in the reference Member State and the Member State(s) concerned shall not be allowed.

117. The authorized authority of the reference Member State shall, within
5 business days from the date of the decision to suspend the validity of the marketing authorization, enter the relevant information into the unified registry of medical devices registered within the Union and inform the authorized bodies of the Member States concerned and the Eurasian Economic Commission of the same using the means of the integrated system, as well as the applicant by transmitting the notice personally subject to receipt confirmation by signature or sending a notice by registered mail with return receipt requested, or sending in electronic form or in the form of an electronic document bearing an electronic signature (indicating the reasons, date and period of suspension of the marketing authorization, as well as the need for the applicant to eliminate the circumstances that led to the suspension of the marketing authorization).

118. The applicant shall, within the time period established by the authorized authority of the reference Member State, eliminate the circumstances that led to the suspension of the marketing authorization and notify that authorized authority of the same in writing (with the attachment of supporting documents). Based on the results of consideration of the documents submitted by the applicant, the authorized authority of the reference Member

State shall decide on the renewal or cancellation of the validity (invalidation) of the marketing authorization (indicating the date of renewal or cancellation of the validity (invalidation) of the marketing authorization).

119. The authorized authority of the reference Member State shall, within 5 business days from the date of the decision on the renewal of the marketing authorization, enter the relevant information into the unified registry of medical devices registered within the Union and notify the applicant of the decision personally, subject to receipt confirmation by signature, or send a notice by registered mail with a return receipt requested, or transfer the same electronically or in the form of an electronic document bearing an electronic signature.

120. The decision to renew the validity of the marketing authorization shall be made in accordance with the legislation of the reference Member State and become effective from the date of its adoption.

121. If the applicant fails to eliminate the circumstances that led to the suspension of the marketing authorization within the prescribed period, the authorized authority of the reference Member State shall, within 3 business days from the date of expiry of the specified period, decide to cancel the validity of (invalidate) the marketing authorization (with a justification).

122. The authorized authority of the reference Member State shall immediately enter the relevant information into the unified registry of medical devices registered within the Union and notify the applicant of the cancellation (invalidation) of the marketing authorization by service of the notice to the applicant personally subject to receipt confirmation by signature, or sending a notice by registered mail with a return receipt requested, or sending the same electronically or in the form of an electronic document bearing an electronic signature.

123. The grounds for the adoption of a decision to cancel the validity of (invalidate) the marketing authorization or to cancel the registration of a medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization) by the authorized authority of the reference Member State shall be as follows:

a) submission of an application for cancellation (invalidation) of the marketing authorization by the manufacturer (in a hard and/or electronic copy) in accordance with Annex 13;

b) identification of cases of submission of false information that could not be established during the registration of a medical device by the applicant (including when the authorized bodies exercises state control (supervision) over the circulation of medical devices);

c) a final and binding decision of a court of the Member State to cancel the validity of (invalidate) the marketing authorization or to cancel the registration of a medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization);

d) provision of information about the facts and circumstances posing a threat to the life and health of citizens and medical workers during the use and operation of medical devices by the authorized authority, based on the results of state control (supervision) over the circulation of medical devices;

e) the loss of medical status by a medical device in connection with the introduction of amendments to the acts included in the legislation of the Union, or on the basis of a decision of the Advisory Committee on the results of work on the settlement of conflicts regarding the classification of products as medical devices.

124. A request for cancellation of validity (invalidation) of the marketing authorization may be submitted by an authorized representative of the manufacturer if the following conditions are met simultaneously:

a) the marketing authorization application contains up-to-date document confirming the powers of the authorized representative of the manufacturer, or such a document is submitted to the authorized authority of the reference Member State together with a request for cancellation of validity (invalidation) of the marketing authorization;

b) submission of a duly certified manufacturer's document confirming its intention to cancel the validity of (invalidate) the marketing authorization to the authorized authority of the reference Member State, together with a request for cancellation of the validity (invalidation) of the marketing authorization.

125. If the request for cancellation (invalidation) of the marketing authorization is submitted in violation of the requirements hereof, the documents are not submitted in full or contain false information, the authorized authority of the reference Member State shall, within 7 business days from the date of receipt of such a request and documents, decide to return the same (indicating the reasons for the return).

126. The authorized authority of the reference Member State shall, within 7 business days from the date of occurrence of one of the grounds specified in Paragraph 123 hereof, decide to cancel the validity of (invalidate) the marketing authorization or to cancel the registration of a medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization).

127. The authorized authority of the reference Member State shall, within 5 business days from the date of a decision to cancel the validity of (invalidate) the marketing authorization or to cancel the registration of a

medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization):

a) post the information on the cancellation (invalidation) of the marketing authorization or on the cancellation of the registration of a medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization), in the unified registry of medical devices registered within the Union;

b) notify the applicant of the cancellation of the validity (invalidation) of the marketing authorization by serving the notice personally subject to receipt confirmation by signature, or sending the same by registered mail with return receipt requested, or sending the same in the electronic form or in the form of an electronic document bearing an electronic signature;

c) notify the applicant about the cancellation of registration of a medical device (models (brands) of a medical device, the information about which is provided in the marketing authorization) and about the need to amend the marketing authorization application by deleting these medical devices (models (brands) of a medical device) by serving the notice personally under signature, or sending it by registered mail with return receipt requested, or sending it in electronic form or in the form of an electronic document bearing an electronic signature.

ANNEX 1

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

**Medical Device Marketing authorization Form
and Its Completion Rules**

I. Medical Device Marketing authorization Form

Emblem of the Eurasian Economic Union (1)

THE EURASIAN ECONOMIC UNION (2)

_____(3)
(name of the authorized authority of the reference Member State)

medical device MARKETING authorizATION (4)

МИ-XY-Z dated _____, 20__ (5)

In accordance with _____ (6)
(number and date of the order of the authorized authority of
the reference Member State on the medical device registration)

this marketing authorization for the medical device has been issued to:
_____(7)
(name and location of the manufacturer)

_____(8)
(name of the production facility (including its place of business) or a link to the annex where two or more production facilities are specified)

_____(9)
(name of the manufacturer's authorized representative
in the territories of the Eurasian Economic Union Member States,
including its location)

to certify that _____(10)
(medical device name)

class of potential risk of using a medical device: __(11)

registered and authorized for circulation in the territory of the following Member States of the Eurasian Economic Union _____(12)
(names of the reference Member State and the Member State(s) concerned)

Models (brands) of a medical device, their composition, accessories, and production facilities are given in the annex (if any) to this marketing authorization of a medical device on __ sheets. (13)
The annex forms an integral part of this marketing authorization for a medical device.

The marketing authorization for a medical device shall be valid indefinitely (14)

Date of the medical device registration: _____ 20__ (15)

Number and date of the order of the authorized authority of the reference Member State on amendment of the marketing authorization for a medical device: No._____ dated _____, 20__ (16)

_____
(surname, name, patronymic of the manager (authorized person)
authorized authority)

_____ L. S. (17)
(signature)

No. _____ (18)

ANNEX TO THE MARKETING authorizATION
FOR A medical device (1)

МИ-XY-Z dated _____, 20__ (2)

No.	Description
1.	Model (brand) of a medical device (if any)
2.	Composition
3.	Accessories (if any)

(3)

No.	Names and addresses of production facilities
1.	…
...	…

(4)

_____
(surname, name, patronymic of the manager (authorized person) of the authorized authority)

_____ L. S. (5)
(signature)

Sheet __(6)

No. _____ (7)

GRZAN

II. Rules of Completing the Marketing authorization for a Medical Device

1. The marketing authorization for a medical device (hereinafter referred to as the marketing authorization)shall be completed by the authorized authority of the reference Member State in Russian using electronic printing products and, if there is a corresponding requirement in the legislation of the reference Member State, in the official language of that state.

2. The marketing authorization shall be completed in Russian and the state language of the reference Member State on different sides of the marketing authorization.

3. The marketing authorization shall be classified as a document of strict accountability and shall be printed on a letterhead, which shall be made by printing and have security features provided for by the legislation of the reference Member State.

If required, the name of the manufacturer, its location (address of a legal entity, place of residence of an individual registered as an individual entrepreneur), and information about the products (model, brand, article , etc.) may be indicated using the letters of the Latin alphabet.

4. The names of the manufacturer, the authorized representative of the manufacturer, and production facilities shall be indicated in the marketing authorization in the following sequence:

a) for residents of the Member States of the Eurasian Economic Union (hereinafter referred to as the Member States and the Union, respectively):

organizational and legal form;

full name (to be indicated in quotation marks for legal entities);

abbreviated name (in parentheses) (if any);

name of the state;

b) for non-residents of the Member States:

full name;

organizational and legal form;

abbreviated name (in parentheses) (if any);

the name of the state (in Russian and/or in the official language of the reference Member State).

The details shall be separated by commas.

5. The address shall be indicated in the marketing authorization in the following sequence:

street name (indicating the element of the urban infrastructure road network), house number, room number (if any);

name of the settlement (indicating the type);

name of the district;

name of the region (region, territory) (indicating the type);

ZIP code;

mailbox number (if any);

name of the state.

For non-residents of the Member States, the address shall be indicated using the letters of the Latin alphabet.

The details shall be separated by commas.

6. Information about the manufacturer and the authorized representative of the manufacturer specified in the marketing authorization, operational document or instructions for the use of a medical device, maintenance manual, as well as in the text of the medical device labeling, must be identical and correspond to the information specified in the document or information confirming the registration of the manufacturer and the authorized representative as a legal entity or an individual entrepreneur.

24. All fields of the marketing authorization shall be filled in (in the original marketing authorization, the fields are unnumbered).

8. The marketing authorization shall specify:

a) in field 1 – the emblem of the Union;

b) in field 2 – the following inscription made within a single line

"THE EURASIAN ECONOMIC UNION";

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

d) in field 4 – the following inscription made within a single line:

"medical device MARKETING authorizATION";

e) in field 5 – registration number and date of issue of the marketing authorization.

The marketing authorization certificate number shall be generated in the following order:

МИ	-	X	Y	-	Z
1		2	3		4

,

where:

element 1 means the medical device;

element 2 means a 2-symbol letter code of the reference Member State in accordance with the international standard ISO 3166-1;

element 3 means a 2-symbol letter code of the Member States concerned in accordance with the international standard ISO 3166-1 (the codes of the Member States concerned that confirmed the approval of the expert report shall be indicated);

element 4 means a 6-digit serial number of the marketing authorization assigned by the authorized authority of the reference Member State (to be assigned automatically from the unified registry of medical devices registered within the Union, the procedure for the generation and maintenance of which

was approved by Decision No. 30 of the Eurasian Economic Commission's Council dated February 12, 2016 , and remain unchanged when a medical device is circulating within the Union);

f) in field 6 – the number and date of the order of the authorized authority of the reference Member State on the medical device registration;

g) in field 7 – full name and location (address of a legal entity) – for a legal entity or surname, first name, patronymic (if any) and place of residence – for an individual registered as an individual entrepreneur;

h) in field 8 – the names and actual addresses of production facilities performing the entire process of medical device manufacturing or its specific stages. If there are two or more production facilities, it is allowed to indicate information about them in the annex to the marketing authorization;

i) in field 9 – the full name of the authorized representative of the manufacturer in the territories of the Member States, its location (address of the legal entity) – for the legal entity or surname, name, patronymic (if any), and place of residence – for an individual registered as an individual entrepreneur. In the absence of an authorized representative of the manufacturer in the territory of the Member State (if the manufacturer is a resident of the Member States), a dash shall be placed in the specified field;

j) in field 10 – the full name of the medical device, including the trademark and other identifications (if any), which shall correspond to the name specified in the expert report;

k) in field 11 – the class of potential risk of using a medical device, confirmed during the examination of a medical device;

l) in field 12 – the names of the reference Member State and the Member State(s) concerned (to be separated by commas);

m) in field 13 – the number of sheets contained in the annex to the marketing authorization (to be filled in if there is an annex);

n) in field 14 – the words “The marketing authorization for the medical device shall be valid indefinitely” shall be indicated;

o) in field 15 – the date of registration of the medical device, which shall be indicated verbally and digitally: date – with two Arabic numerals (in quotes), month – with a word, year – with four Arabic numerals;

p) in field 16 – the date of the most recent amendment of the marketing authorization, which shall be indicated verbally and digitally: date – with two Arabic numerals (in quotes), month – with a word, year – with four Arabic numerals. This field shall be filled in when the marketing authorization application is amended with the issuance of a new marketing authorization with the same number and an indication of the number of a corresponding order on amendment;

q) in field 20 – position, signature, surname, name, and patronymic (if any) of the manager (the authorized person) of the authorized authority, which issued the marketing authorization, bearing the seal of this authorized authority (if any). The signature may not be facsimile;

r) in field 13 – printing number, series, and ordinal number of the marketing authorization letterhead imposed when it is made.

9. If there is information about the models (brands) of a medical device, their composition and accessories, or two or more production facilities, an annex to the marketing authorization shall be filled in and form an integral part of the marketing authorization. Each sheet of the annex shall be numbered. The annex to the marketing authorization shall specify the following:

a) in field 1 – the following inscription made within 2 lines:

“ANNEX TO THE MARKETING AUTHORIZATION
FOR A MEDICAL DEVICE”;

b) in field 2 – the number of the marketing authorization;

c) in field 3 – models (brands) of the medical device, their composition, and accessories (if any);

d) in field 4 – the names and actual addresses of production facilities performing the entire process of the medical device manufacturing or specific stages thereof (if required, specify information about two or more production facilities);

e) in field 20 – position, signature, surname, name and patronymic (if any) of the manager (the authorized person) of the authorized authority which issued the marketing authorization, bearing the seal of this authorized authority (if any); The signature may not be facsimile;

f) in field 6 – the number of the annex sheet shall be indicated;

g) in field 7 – the typographic number affixed during the production of the application form shall be indicated.

10. When filling out the marketing authorization and/or the annex thereto, the indication of information not provided for by these Rules, as well as the use of abbreviations of words (except for the generally accepted ones) and correction of the text shall be prohibited.

11. In the case of loss or damage of the marketing authorization, the authorized authority of the reference Member State shall issue a duplicate marketing authorization. In this case, in the upper right corner of the marketing authorization, the following notes shall be made: “Duplicate issued on _____ 20__ ” and “The original marketing authorization for the medical device is invalidated.”

ANNEX 2

to the Rules for Marketing Authorization
and Expert Examination of Security,
Quality, and Efficiency of Medical Devices

FORM
of a request for examination of a medical device

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

_____
(name of the reference Member State)

_____
(name of the Member State(s) concerned)

REQUEST
for examination of a medical device

_____
(full and abbreviated (if any), including the company name, of the person on whose behalf the registration is made (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests to make an examination of the medical device:

1.	medical device name	
2.	Purpose of the medical device	
3.	Is the medical device intended for in *vitro* diagnostics?	d Yes d No
4.	Scope of application of the medical device (in accordance with the classifier of medical applications of medical devices approved by Decision No. 62 of the Eurasian Economic Commission's Board dated April 16, 2019)	
5.	The class of potential risk of using a medical device	

6.	Should the production facilities be audited (to be indicated if the registered medical device is a medical device of class 1 of potential risk of use or a non-sterile medical device of class 2a of potential risk of use and the initial audit of the production facilities has not been conducted before)?	d Yes d No
7.	The code of the type of medical device (according to the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015)	
8.	Does the medical device contain a medicine?	d Yes d No

9.	Model (brand), composition, and accessories of a medical device			
	No.	Description	Manufacturer	Country
	1.	Model (brand) of a medical device (if any)		
	2.	Composition (if any)		
	3.	Accessories (if any)		

10.	Expiration date (shelf life)	
11.	Storage conditions	

12.	Registration in the country of origin and other countries				
	No.	Name of the country	medical device marketing authorization number (if any)	Date of issue	Validity period
	1.				
	…				

13.	Manufacture	d is performed completely at this production facility d is performed partially at this production facility d is performed completely at another production facility
14.	Information on the manufacturer	

	organizational and legal form, full name and abbreviated name (if any), country, (surname, name, patronymic of the Individual entrepreneur)	number, date of registration	location (registered office of a legal entity, place of residence of an individual entrepreneur)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of the contact person

15.	Information about the production facility(ies)					
	No.	organizational and legal form, full name and abbreviated name (if any), (surname, name, patronymic of the Individual entrepreneur)	number, date, and validity period of the authorization document (if any)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of the contact person
	1.					
	…					

16.	Information about the authorized representative of the manufacturer (if any)					
	organizational and legal form, full name and abbreviated name (if any), country, (surname, name, patronymic of the Individual entrepreneur)	number, date of registration	location (registered office of a legal entity, place of residence of an individual entrepreneur)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of the contact person
17.	Information about the document confirming payment for the examination of a medical device					
18.	Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State:					
	d personally subject to receipt confirmation by signature					

	d by registered mail with return receipt requested d in electronic form via telecommunication channels (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
I hereby guarantee the accuracy and identity of the information contained in the marketing authorization application and request	
Request submission date	
Surname, name, patronymic and title of the manager of the manufacturer (authorized representative of the manufacturer)	
Signature and seal of the manufacturer (authorized representative of the manufacturer)	

ANNEX 3

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for registration of a medical device

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

_____
(name of the reference Member State)

_____
(name of the Member State(s) concerned)

REQUEST
for registration of a medical device

_____
(full and abbreviated (if any), including the company name, the name of the person on behalf of which the registration is made (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests the registration of a medical device

1.	medical device name	
2.	Purpose of the medical device	
3.	Is the medical device intended for in *vitro* diagnostics?	d Yes d No
4.	Scope of application of the medical device (in accordance with the classifier of medical applications of medical devices approved by Decision No. 62 of the Eurasian Economic Commission's Board dated April 16, 2019)	
5.	The class of potential risk of using a medical device	
6.	Should the production facilities be audited (to be indicated if the registered	d Yes

	medical device is a medical device of class 1 of potential risk of use or a non-sterile medical device of class 2a of potential risk of use and the initial audit of the production facilities has not been conducted before)?	d No
7.	The code of the type of medical device (according to the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015)	
8.	Does the medical device contain a medicine?	d Yes d No

9. Model (brand), composition, and accessories of a medical device

No.	Description	Manufacturer	Country
1.	Model (brand) of a medical device (if any)		
2.	Composition (if any)		
3.	Accessories (if any)		

10. Information on the manufacturer

organizational and legal form, full name and abbreviated name (if any), country, (surname, name, patronymic of the Individual entrepreneur)	registration number and date	location (registered office of a legal entity, place of residence of an individual entrepreneur)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of the contact person

11. Information about the production facility(ies)

No.	organizational and legal form, full name and abbreviated name (if any), (surname, name, patronymic of the Individual entrepreneur)	number, date, and validity period of the authorization document (if any)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of

						the contact person
	1.					
	…					

12.	Information about the authorized representative of the manufacturer (if any)					
	organizational and legal form, full name and abbreviated name (if any), country, (surname, name, patronymic of the Individual entrepreneur)	number, date of registration	location (registered office of a legal entity, place of residence of an individual entrepreneur)	place of business	telephone and facsimile numbers, e-mail address (if any)	Surname, name, patronymic and title of the manager, Surname, name, patronymic and title of the contact person

13.	Information about the document confirming payment for the registration of a medical device
14.	Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State: d personally subject to receipt confirmation by signature d by registered mail with return receipt requested d in electronic form via telecommunication channels (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
15.	The method of obtaining the marketing authorization of a medical device and annexes thereto: d in a hard copy in person d in a hard copy, delivered by registered mail with return receipt requested

I hereby guarantee the accuracy and identity of the information contained in the marketing authorization application and request	
Request submission date	
Surname, name, patronymic and title of the manager of the manufacturer (authorized representative of the manufacturer)	
Signature and seal of the manufacturer (authorized representative of the manufacturer)	

ANNEX 4

to the Rules for Marketing Authorization and
Expert Examination of the
Safety, Quality, and Efficiency
Medical Devices

LIST
of documents required for registration of a medical device

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
		1	2a	2b	3		
1.	Request	+	+	+	+	+	according to the forms provided for in Annexes 2 and 3 to the Rules for Marketing Authorization and Expert Examination of Safety, Quality and Efficiency of medical devices, approved by Decision No. 46 of the Eurasian Economic Commission's Council dated February 12, 2016
2.	A power of attorney issued by the manufacturer to represent its interests during registration (if required)	+	+	+	+	+	shall be certified in accordance with the international standards of certification or the standards of certification established by the legislation of the reference Member State
3.	The manufacturer’s contract with an authorized representative (if any) of the manufacturer or a	+	+	+	+	+	the copy shall be certified in accordance with the international standards of certification

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
	copy thereof. If the authorized representative of the manufacturer is not a resident of the reference Member State, a copy of the document confirming the registration of the authorized representative of the manufacturer as a legal entity or individual entrepreneur shall be attached						or the standards of certification established by the legislation of the reference Member State
4.	A copy of the authorization giving the right to manufacturing in the country of the manufacturer with an annex thereto (if any)	+	+	+	+	+	shall be certified in accordance with the international standards of certification or the standards of certification established by the legislation of the reference Member State
5.	A copy of the document or information confirming the registration of the manufacturer as a legal entity or individual entrepreneur	+	+	+	+	+	a copy of the document shall be certified in accordance with the international standards of certification or the standards of certification established by the legislation of the reference Member State; the information shall be certified by the manufacturer
6.	A copy of the certificate of conformity of the quality management system to the requirements of ISO 13485 standard or the corresponding regional or national (state) standard of the Member State of the Eurasian Economic Union (hereinafter referred to as the Member State and the Union, respectively) issued in the name of	+	+	+	+	+	shall be certified in accordance with international standards of certification or the standards of certification established by the legislation of the reference Member State

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
	the manufacturer of medical devices (production facility) (if any)						
7.	Declaration of conformity of the medical device to the mandatory requirements of non-Member States (for example, directives or regulations of the European Union), or an equivalent document (if any) or a copy of such documents	+	+	+	+	+	the copy shall be certified by the manufacturer (authorized representative thereof)
8.	A copy of the marketing authorization of a medical device (certificate of free sale, certificate for export (except for medical devices manufactured for the first time in the territory of a Member State)) issued in the country of the manufacturer (if any)	+	+	+	+	+	shall be certified in accordance with the international standards of certification or the standards of certification established by the legislation of the reference Member State
9.	Information about registration in the other countries with reference to the current sources of such information and an electronic file containing such information, or a copy of the document certifying the registration of a medical device in the other countries (if any)	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
10.	Labeling and packaging data (full-color (indicating the color coding) layouts of packages and labels), labeling text in Russian and the official languages of the Member States (if required). The text of the labeling in the official languages of the Member States	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
	concerned may be submitted after a positive expert report is issued						
11.	Information about development and manufacturing: process diagrams, main stages of manufacturing, packaging, testing, and final product release procedure	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
12.	Information about the manufacturer: name, type of business, registered office, form of ownership, composition of the management bodies, list of business units and subsidiaries involved in the manufacturing of the medical device applied for registration, indicating their status and powers	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
13.	Marketing information (history if there are more than 2 years of postmarketing experience) (if any)	–	–	+	+	+ (except for classes 1 and 2a)	shall be certified by the manufacturer (authorized representative thereof)
14.	Accident reports and revocations (the information shall not be provided for newly developed and designed medical devices):	+	+	+	+	+ (except for class 1)	shall be certified by the manufacturer (authorized representative thereof)
	a list of adverse events (incidents) or accidents related to the use of the product, and an indication of the period during which these cases occurred						
	if there are too many adverse events (incidents), it is required to provide summaries for each of the types of events						

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
	and indicate the total number of the reported events of each type a list of revocations of medical devices from the market and/or explanatory notices with a description of the approach to the consideration of these issues and their solution by manufacturers in each of these cases a description of the analysis and/or corrective actions taken in response to the specified cases						
15.	The list of standards used by the manufacturer during the design and manufacture of medical devices (indicating the name and designation of standards)	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
16.	Information on the conformity of a medical device to the General Requirements for the Safety and Efficiency of Medical Devices, the Requirements for Their Labeling, and Operational Documentation for the Same, approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016 (hereinafter referred to as the General Requirements), with the attachment of documents referenced in the specified information	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
17.	The document establishing requirements for the specifications of a medical device	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
18.	Protocols of technical testing carried out in order to prove the conformity of the medical device to the General Requirements, the test programs or copies of these documents and/or documents containing the proof provided by the first party	+	+	+	+	+ (excluding the reagents, reagent kits, control materials, calibrators, washing solutions, and nutrient media)	copies of the protocols shall be certified by the testing laboratory (center) or in accordance with the certification standards established by the legislation of the reference Member State; copies of the programs shall be certified by the testing laboratory (center) or the manufacturer (authorized representative of the manufacturer); documents containing evidence of the first party shall be certified by the manufacturer
19.	Report on the evaluation of the biological effect of a medical device (if required)	+	+	+	+	–	shall be certified by the manufacturer (authorized representative thereof)
20.	Protocols of studies (testing) for evaluation of the biological effect of a medical device conducted to prove the conformity of the medical device to the General Requirements (if required), research programs (testing), or copies of these documents	+	+	+	+	–	copies of protocols and programs shall be certified by a testing laboratory (center) or in accordance with the certification standards established by the legislation of the reference Member State
21.	A report on the clinical evidence of the efficiency and safety of a medical device or a copy thereof	+	+	+	+	+ (except for class 1)	a copy of the report shall be certified by the manufacturer (authorized representative of the manufacturer)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
22.	A report on the clinical testing (study) of a medical device or a report on the clinical and laboratory testing (study) of a medical device intended for *in vitro* diagnostics (or a copy thereof)	–	–	+	+	+	a copy of the report shall be certified by a medical organization or in accordance with the certification standards established by the legislation of the reference Member State
23.	Risk analysis and management report or a copy thereof	+	+	+	+	+	a copy of the report shall be certified by the manufacturer (authorized representative of the manufacturer)
24.	Data on medicines included in the medical device (composition of the medicine, quantity, data on the compatibility of a medicine with the medical device, registration of the medicine in the country of origin)	+	+	+	+	–	shall be certified by the manufacturer (authorized representative thereof)
25.	Biosafety data (if any)	+	+	+	+	–	shall be certified by the manufacturer (authorized representative thereof)
26.	Data on the sterilization procedure, including the information on the process validation, the results of microbial testing (degree of bioburden), pyrogenicity, sterility (if required), indicating the testing methods and data on the packaging validation (for sterile products)	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
27.	Information about special software (if any): manufacturer's information about software validation	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
28.	The stability research report or a copy thereof (if the report is submitted in a foreign language, it shall be accompanied by a Russian translation of the results and conclusions of the studies) – for products with an expiration date	+	+	+	+	+	a copy of the report shall be certified by the manufacturer (authorized representative of the manufacturer), the original shall be signed by the manufacturer
29.	Operational document or instructions for the use of a medical device in Russian and the official languages of the Member States (if required). An operational document or instruction on the use of a medical device in the official languages of the Member States concerned may be submitted after a positive expert report is issued	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
30.	Maintenance manual – in the absence of data in the operational documentation (if any). This document may be submitted in the official languages of the Member States concerned may be submitted after a positive expert report is issued	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
31.	Report on the results of audit of the production facilities of a medical device or a copy thereof (if any)	+	+	+	+	+	a copy of the report shall be certified by the auditing organization or the manufacturer (authorized representative of the manufacturer)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
32.	A plan for collecting and analyzing data on the safety and efficiency of medical devices at the postmarketing stage	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
33.	Documents confirming the results of tests of medical devices for the purpose of approving the type of measuring instruments (in respect of medical devices included in the list of types of medical devices to be classified as measuring instruments during their registration, approved by Decision No. 42 of the Eurasian Economic Commission's Council dated February 12, 2016), or copies thereof	+	+	+	+	+	copies of documents shall be certified by an organization authorized (notified) in accordance with the legislation of the Member State to conduct testing of measuring instruments, or in accordance with the certification standards established by the legislation of the reference Member State
34.	Photographic images of the general appearance of the medical device and accessories (if any) (measuring not less than 180 mm x 240 mm)	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)
35.	Documents confirming the quality of a medicinal product, biological material, and other substances that are part of a medical device and come into contact with the human body in accordance with the purpose of the medical device, and are intended for use only taking into account the purpose of the medical device determined by the manufacturer, and issued in accordance with the legislation of the country of origin of the medicine, biological	+	+	+	+	–	copies of documents shall be certified by the manufacturer (authorized representative of the manufacturer)

No.	Document name	medical device of the class of potential risk of use				medical device intended for *in vitro diagnostics*	Note
	material and other substance, or copies thereof (as applicable)						
36.	Other documents provided by the applicant	+	+	+	+	+	copies of documents shall be certified by the manufacturer (authorized representative of the manufacturer)
37.	Inventory (if the marketing authorization application is submitted as a hard copy)	+	+	+	+	+	shall be certified by the manufacturer (authorized representative thereof)

ANNEX 5

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

EXPERT REPORT
on the evaluation of the safety, quality
and efficiency of a medical device

_____

(name of the authorized authority (expert organization) of the
reference Member State)

APPROVED BY

_____

(surname, name, patronymic of the manager of the
authorized authority
(expert organization), signature, seal)

_____ 20__

EXPERT REPORT
on the evaluation of the safety, quality and efficiency of a
medical device

No. _____ dated _____, 20__

1. General information about the medical device:

a) the number and date of registration of requests for examination of a medical device and for registration of a medical device;

b) medical device name;

c) manufacturer of the medical device, country;

d) production facility(ies), country;

e) authorized representative of the manufacturer (if any);

f) scope and purpose;

g) type of the medical device in accordance with the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015;

h) class of potential risk of using a medical device;

i) composition of the medical device (model (brand) of the medical device (if any)) and accessories thereto (if any);

j) key specifications of the medical device (model (brand, type) of the medical device (if any)).

2. The results of examination of the safety, quality, and efficiency of the medical device (as applicable):

a) assessment of the correct classification of a product as a medical device;

b) assessment of conformity of the potential risk class of the medical device indicated by the applicant in accordance with the Rules for Classification of Medical Devices Depending on the Potential Risk of Use, approved by Decision No. 173 of the Eurasian Economic Commission's Board dated December 22, 2015;

c) assessment of the correct classification of a medical device (models (brands) of a medical device) as a medical device of a certain type in accordance with the nomenclature of medical devices, the rules of which were approved by Decision of the Eurasian Economic Commission's Board dated December 29, 2015 No. 177;

d) assessment of conformity of the models (brands) of the medical device (if any) included in one marketing authorization to the criteria established by

Paragraph 19 of the Rules for Marketing Authorization and Expert Examination of Safety, Quality, and Efficiency of Medical Devices, approved by Decision No. 46 of the Eurasian Economic Commission's Council dated February 12, 2016;

e) analysis and evaluation of evidentiary documents (materials) confirming the conformity of a medical device to the General Requirements for the Safety and Efficiency of Medical Devices, the Requirements for Their Labeling, and Operational Documentation for the Same, approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016 (hereinafter referred to as the General Requirements):

analysis of the information provided by the manufacturer on the conformity of the medical device to the General Requirements, including an analysis of the correct identification of the provisions of the General Requirements applicable to the medical device;

assessment of conformity of technical testing protocols issued by authorized organizations with the Rules for Technical Testing of Medical Devices, approved by Decision No. 28 of the Eurasian Economic Commission's Council dated February 12, 2016;

assessment of conformity of the protocols of studies (testing) for the purpose of evaluation of the biological effect of medical devices issued by authorized organizations to the Rules for Conducting Studies (Tests) Aimed at the Biological Evaluation of Medical Devices, approved by Decision No. 38 of the Eurasian Economic Commission's Council dated May 16, 2016;

analysis of the report on the evaluation of the biological effect of a medical device (to be carried out, among other things, to confirm that the materials coming into contact (interacting) with human tissues have been identified (the brands of materials and their manufacturers have been

indicated), as well as to confirm the validity of the absence of the need for studies (testing) to evaluate the biological effect);

analysis of the report on clinical evidence of the efficiency and safety of a medical device (to be carried out to confirm the validity of selecting the methods to prove the clinical efficacy and safety of a medical device, the validity of the data used to prove the clinical efficacy and safety of a medical device, as well as the validity of the conclusion on clinical efficacy and safety for all declared indications for use, taking into account the presence or absence of contraindications);

assessment of conformity of reports on clinical (clinical and laboratory) tests (studies) of medical devices to the Rules for Conducting Clinical and Clinical Laboratory Tests (Studies) of Medical Devices, approved by Decision No. 29 of the Eurasian Economic Commission's Council dated February 12, 2016;

analysis of the validity of the proof provided by the first party (if any) to confirm the conformity of the medical device to the General Requirements, taking into account the class of potential risk of using the medical device (for medical devices referred to the classes 2b and 3 of the potential risk of use, a testing (study) program and rationale for the selected methods should be attached to the proof provided by the first party);

analysis of standards followed by the manufacturer during the design and manufacturing of a medical device;

analysis of the safety and efficacy of a medicinal product as part of a medical device, its impact on the functionality of a medical device, and compatibility of medicine with a medical device (with the exception of medical devices for *in vitro* diagnostics). The medicine should be registered and approved for use in the state of manufacture of the medicine;

analysis of data on the biological safety of a medical device based on the analysis of all materials of animal or human origin included in the medical device,

as well as information on the selection of sources (donors), material selection, processing, storage, testing, validation of testing procedures, as well as the handling of tissues, cells, and substances of animal or human origin, as well as cultures of microorganisms and viruses;

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

the study of the validity of software based on the analysis of data on its verification and validation, including the information on its development, measures, and means of protection against unauthorized access and cybersecurity, testing by the manufacturer, identification and labeling data;

analysis of a report on the stability of the medical device, and the validity of the declared shelf life;

consideration of the risk analysis report in order to confirm the completeness of the hazards identified in such a report, dangerous situations, and related risks that can be assessed as unacceptable, as well as confirmation of the manufacturer's conclusion that there are no unacceptable risks or the acceptability of risks that are assessed as acceptable in the risk analysis report based on the analysis of the risk-benefit ratio;

confirmation of the validity of the result of the manufacturer's evaluation of the medical device conformity to the General requirements on the basis of the submitted evidentiary materials (documents);

assessment of conformity of the operational document or user manual and maintenance manual to the General Requirements;

assessment of conformity of the medical device labeling to the General Requirements;

analysis of requirements for the medical device specifications;

evaluation of documents confirming the results of tests of medical devices for the purpose of approving the type of measuring instruments (in respect of medical devices included in the list of types of medical devices to be classified as measuring instruments during their registration, approved by Decision No. 42 of the Eurasian Economic Commission's Council dated February 12, 2016);

f) analysis of reports on the results of audit of the production facilities of medical devices (carried out in order to confirm that the applied medical device belongs to a group (subgroup) of medical devices, taking into account the class of potential risk of use according to Annex 2 to the Requirements for the Implementation, Maintenance, and Evaluation of the Quality Management System of Medical Devices, Depending on the Potential Risk of Their Use, approved by Decision No. 106 of the Eurasian Economic Commission's Council dated November 10, 2017, as well as the proof of the reliability of information about the production facilities specified in the marketing authorization and expert examination requests, which are covered by the report on the results of audit of the production facilities where the medical device is manufactured);

g) analysis of data on the certification of the quality management system

(if any), including the requirements for compliance with which the manufacturer's quality management system has been certified, and information about certificates (certificate number, date of issue, validity period, name and information about the accreditation of the certification body);

h) proof of the validity of indication of the production facilities of the medical device being registered;

i) analysis of data on the development and production of a medical device (production process diagrams, main stages of production, packaging, testing and procedures for the release of the final product);

j) analysis of the marketing information provided by the manufacturer;

k) analysis of information provided by the manufacturer on the presence or absence of reports on adverse effects and/or accidents related to the use of a medical device, revocations of the medical device from the market, notifications on the safety of a medical device, approaches to solving such problems by the manufacturer when they occur, descriptions of corrective actions taken, as well as analysis of the ratio of sales, the number of accidents and revocations of a medical device;

l) analysis of the postmarketing plan for collecting the data on the safety and efficiency of a medical device.

3. General conclusion on approval (non-approval) of the safety, quality and efficiency of a medical device, recommendation on the possibility (impossibility) of the medical device registration.

I have been warned about the responsibility for the accuracy of the information contained in the expert report on the evaluation of the safety, quality, and efficiency of the medical device.

(Surname, name, patronymic of the expert, title, academic degree (title) (if any))	(signature)

ANNEX 6

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

CONCLUSION
confirming the approval (non-approval) of the expert report on the results of examination of the safety, quality and efficiency of the medical device of the Member State of the Eurasian Economic Union, which carries out the medical device registration

_____

(name of the authorized authority (expert organization) of the Member State concerned)

APPROVED BY

_____

(surname, name, patronymic of the manager of the authorized authority
(expert organization), signature, seal)

_____ 20__

CONCLUSION
confirming the approval (non-approval) of the
expert report of the Member State of the Eurasian Economic Union, which carries out the registration of a medical device, based on the results of examination of the safety,
quality and efficiency of the medical device

No. _____ dated _____, 20__

1. The name of the authorized authority (expert organization) of the Member State of the Eurasian Economic Union that carries out the registration of a medical device (hereinafter referred to as the reference Member State).

2. The date of posting the expert report in the information system of the authorized authority (expert organization) of the reference Member State.

3. Expert report number.

4. medical device name (indicating the model (brand), composition and accessories of the medical device).

5. medical device manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)).

6. Production facilities (full and abbreviated names, organizational and legal form of the legal entity, place of business).

7. authorized representative of the manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)) (if any).

8. Applicant.

9. Analysis of the expert report submitted by the authorized authority (expert organization) of the reference Member State following the results of examination of the safety, quality, and efficiency of the medical device, as well as the conformity of the marketing authorization application documents to the established requirements.

10. Confirmation of the correct translation of the operational document or instructions for the use of a medical device, the maintenance manual, and the text of the medical device labeling into the official language in accordance with the requirements of the legislation of the Member State of the Eurasian Economic Union (if applicable).

11. Examination results (conclusions on certain aspects of the expert report shall be indicated).

12. Conclusion (a general conclusion shall be indicated, and in the case of non-approval of the expert report – with the justification of reasons).

13. Information about experts (surname, name, patronymic, academic degree (title) (if any), place of work, and position).

I have been warned about the responsibility for the accuracy of the information contained in the conclusion approving (non-approving) the expert report of the reference Member State based on the results of examination of the safety, quality, and efficiency of the medical device.

_____	_____
(surname, name, patronymic of the expert)	(signature)

ANNEX 7

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for amendment of the marketing authorization application for a
medical device

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

_____
(name of the reference Member State)

_____
(name(s) of the Member State(s) concerned)

REQUEST
for amendment of the marketing authorization application for a medical device

_____
(full and abbreviated (if any), including the company name, the name of the person on behalf of which the amendment is made (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests to amend the marketing authorization application for the medical device

1. medical device name	
2. medical device manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur))	
3. Production facilities (full name, address)	

4. authorized representative of the manufacturer (if any) (full and abbreviated names, organizational and legal form of the legal entity, location (registered office of the legal entity, place of residence of an individual registered as an individual entrepreneur)	
5. Class of potential risk of using a medical device	
6. Code of the type of medical device (according to the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015)	
7. Number of the marketing authorization for the medical device of the Eurasian Economic Union	
8. Information on documents confirming the payment for the procedure of amending the marketing authorization application in the reference Member State and the procedure for approving an expert report in the Member States concerned, as well as issuing a marketing authorization for a medical device in the reference Member State (if required)	
9. Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State	d personally subject to receipt confirmation by signature d by registered mail with return receipt requested d in electronic form (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
10. The method of obtaining a marketing authorization for a medical device and/or an annex thereto (if the changes made will entail amendment of the marketing authorization for a medical device and/or an annex thereto), as well as a previously issued marketing authorization for a medical device and/or an annex thereto with a note that they are invalid	d in a hard copy in person d in a hard copy, delivered by registered mail with return receipt requested

due to the following changes:

Amendments made to the marketing authorization application for a medical device		
No.	Version before amendment	Amendments

1.	…	…

Amendment of the marketing authorization application does not entail changes in the properties and characteristics affecting the safety, quality, and efficiency of the medical device.

I hereby guarantee the accuracy of the information provided.

I hereby guarantee the preservation of the declared safety characteristics and efficiency of the medical device during the entire service life, subject to the compliance with the conditions of operation, transportation and storage of the medical device as established by the manufacturer.

_____
(request submission date)

_____	_____
(surname, name, patronymic and title of the manager of the manufacturer (manufacturer's authorized representative))	(signature and seal of the manufacturer (manufacturer's authorized representative))

ANNEX 8

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

EXPERT REPORT
about the possibility (impossibility) of amending the marketing authorization application for a medical device

_____

(name of the authorized authority (expert organization) of the reference Member State)

APPROVED BY

_____

(surname, name, patronymic of the manager of the authorized authority
(expert organization), signature, seal)

_____ 20__

EXPERT REPORT
about the possibility (impossibility) of amending
the marketing authorization application for a medical device

No. _____ dated _____, 20__

1. medical device name.

2. medical device manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)).

3. authorized representative of the manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered

office of a legal entity, place of residence of an individual registered as an individual entrepreneur)) (if any).

4. Production facilities (full and abbreviated names, organizational and legal form of the legal entity, place of business).

5. Scope and purpose.

6. Type of the medical device in accordance with the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015.

7. Class of potential risk of using a medical device.

8. medical device marketing authorization number.

9. Date of issue of the marketing authorization for the medical device.

10. Amendments:

Data entered into the marketing authorization application during registration	Amendments	Applicant’s justification for amendments

11. Analysis and evaluation of data justifying the amendments.

12. Conclusion on the possibility (impossibility) of amending the marketing authorization application for a medical device (in the case of a negative conclusion – with the justification of reasons).

_____ _____

(Surname, name, patronymic of the expert, title, academic degree (title) (if any)) (signature)

ANNEX 9

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for amendment of the marketing authorization application for a medical device by way of a notice

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

_____
(name of the reference Member State)

REQUEST
for amendment of the marketing authorization application for a medical device
by way of a notice

_____
(full and abbreviated (if any), including the company name, the name of the person on behalf of which the amendment is made (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests to amend the marketing authorization application for the medical device by way of a notice

1. medical device name	
2. medical device manufacturer (full and abbreviated names, organizational and legal form of a legal entity, location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur))	
3. Production facilities (full name, address)	
4. authorized representative of the manufacturer (if any) (full and abbreviated names, organizational and legal form of the legal entity, location (registered office of the legal entity, place of residence of an individual registered as an individual entrepreneur)	

5. Class of potential risk of using a medical device	
6. Code of the type of medical device (according to the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015)	
7. Number of the marketing authorization for the medical device of the Eurasian Economic Union	
8. Information on documents confirming payment for the procedure of amending the marketing authorization application by way of a notice in the reference Member State, as well as the issuance of a marketing authorization for a medical device in the reference Member State (if required);	
9. Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State	d personally subject to receipt confirmation by signature d by registered mail with return receipt requested d in electronic form (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
10. The method of obtaining a marketing authorization for a medical device and/or an annex thereto (if the changes made will entail amendment of the marketing authorization for a medical device and/or an annex thereto), as well as a previously issued marketing authorization for a medical device and/or an annex thereto with a note that they are invalid	d in a hard copy in person d in a hard copy, delivered by registered mail with return receipt requested
Information to be indicated when the amendments are made by the manufacturer of medical devices of class 1 of the potential risk of use and non-sterile medical devices of class 2a of the potential risk of use, who has passed the assessment of the quality management system of medical devices, including the design and development processes, in accordance with the Requirements for the Implementation, Maintenance and Evaluation of the Quality Management System for Medical Devices, Depending on the Potential Risk of Their Use, approved by Decision No. 106 of the Eurasian Economic Commission's Council dated November 10, 2017:	
11. Number of the report on the results of the initial audit of production facilities	
12. Name of the auditing organization that conducted the initial audit of production facilities	

13. Number of the report on the results of periodic (scheduled) audit of production facilities (if any)	
14. Name of the auditing organization that conducted the periodic (scheduled) audit of production facilities	

due to the following changes:

Amendments made to the marketing authorization application for a medical device		
No.	Version before amendment	Amendments
1.	…	…

Amendment of the marketing authorization application does not entail changes in the properties and characteristics affecting the safety, quality, and efficiency of the medical device.

I hereby guarantee the accuracy of the information provided.

I hereby guarantee the preservation of the declared safety characteristics and efficiency of the medical device during the entire service life, subject to the compliance with the conditions of operation, transportation and storage of the medical device as established by the manufacturer.

_____
(request submission date)

_____	_____
(surname, name, patronymic and title of the manager of the manufacturer (manufacturer's authorized representative))	(signature and seal of the manufacturer (manufacturer's authorized representative))

ANNEX 10

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for the issuance of a duplicate marketing authorization for the medical device

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

_____
(name of the reference Member State)

REQUEST
about the issue of a duplicate marketing authorization for a medical device

1. medical device marketing authorization number	
2. medical device name (indicating the model (brand), composition and accessories of the medical device, – in the form of an annex to the request, stamped and signed by the manager of the medical device manufacturer)	
I. Information about the medical device manufacturer	
3. Organizational and legal form and full name of the legal entity or surname, first name, patronymic (if any) of an individual registered as an individual entrepreneur	
4. Abbreviated name of the legal entity (if any)	
5. Company name of the legal entity (if any)	

6. Location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)	
7. Phone number	
8. E-mail address of a legal entity or an individual registered as an individual entrepreneur (if any)	
9. Taxpayer ID	
10. Production facilities (full name, address)	
II. Information about the authorized representative of the manufacturer (if any)	
11. Organizational and legal form and full name of the legal entity or surname, first name, patronymic (if any) of an individual registered as an individual entrepreneur	
12. Abbreviated name of the legal entity (if any)	
13. Company name of the legal entity (if any)	
14. Location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)	
15. Phone number	
16. E-mail address of a legal entity or an individual registered as an individual entrepreneur (if any)	
17. Taxpayer ID	
III. Other information	

18. Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State	d personally subject to receipt confirmation by d signature d by registered mail with return receipt requested d in electronic form (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
19. The method of obtaining a duplicate marketing authorization for a medical device	d in a hard copy in person d in a hard copy, delivered by registered mail with return receipt requested
20. Grounds for issuing a duplicate	d loss of the marketing authorization d damage to the marketing authorization
21. Information about the document confirming the payment for the issue of a duplicate (date and number of the payment order)	

_____
(request submission date)

_____	_____
(surname, name, patronymic and title of the manager of the manufacturer (manufacturer's authorized representative))	(signature and seal of the manufacturer (manufacturer's authorized representative))

ANNEX 11

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for approval of an expert report
for a registered medical device

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

_____
(name of the reference Member State)

_____
(name(s) of the Member State(s) concerned not specified
in the marketing authorization for the medical device)

REQUEST
for approval of an expert report
for a registered medical device

_____
(full and abbreviated (if any), including the company name, the name of the person on behalf of which the request is submitted (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests to carry out the procedure of approval of an expert report for a registered medical device:

1. medical device name	
2. Details of the marketing authorization for the medical device	
3. Class of potential risk of using a medical device	

4. Code of the type of medical device (according to the nomenclature of medical devices of the Eurasian Economic Union, the rules of which were approved by Decision No. 177 of the Eurasian Economic Commission's Board dated December 29, 2015)	
5. Full name and country of the manufacturer, including the location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)	
6. Full names of production facilities, including addresses	
7. Name of the manufacturer’s authorized representative in the territories of the Member States of the Eurasian Economic Union, including the location (registered office of a legal entity, place of residence of an individual registered as an individual entrepreneur)	
8. Information about the document confirming payment for the issuance of the marketing authorization in the reference Member State (if required)	
9. Information about the document confirming payment for the procedure of approving an expert report for a registered medical device in the Member State(s) concerned	
10. Method of receiving notices (decisions) from the authorized authority (expert organization) of the reference Member State:	d personally subject to receipt confirmation by signature d by registered mail with return receipt requested d in electronic form (when this method is chosen, specify the e-mail address(s) to which the notices should be sent) d in the form of an electronic document bearing an electronic signature
11. The method of obtaining the marketing authorization of a medical device and annexes thereto:	d in a hard copy in person

	d in a hard copy, delivered by registered mail with return receipt requested

I hereby guarantee the accuracy and identity of the information contained in the request.

_____
(request submission date)

_____	_____
(surname, name, patronymic and title of the manager of the manufacturer (manufacturer's authorized representative))	(signature and seal of the manufacturer (manufacturer's authorized representative))

ANNEX 12

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

LIST
of documents required for the procedure of approval of the expert report for the registered medical device

Document name	Note
1. Request for approval of an expert report for a registered medical device	according to the form provided by Annex 11 to the Rules for Marketing Authorization and Expert Examination of Safety, Quality and Efficiency of Medical Devices, approved by Decision No. 46 of the Eurasian Economic Commission's Council dated February 12, 2016
2. The manufacturer’s contract with an authorized representative (if any) of the manufacturer or a copy thereof	the copy shall be certified in accordance with the international standards of certification or the standards of certification established by the legislation of the reference Member State
3. A power of attorney issued by the manufacturer or the manufacturer’s authorized representative giving right to represent the interests during the procedure of approval of an expert report for a registered medical device (if required)	in accordance with international standards of assurance or standards of assurance established in accordance with the legislation of a Member State of the Eurasian Economic Union
4. Data on labeling and packaging approved during the registration of a medical device, taking into account the amendments made to the marketing authorization application for a medical device (full-color (indicating the color coding) mock-ups of packages and labels), and labeling text in the official languages of the Member States concerned, specified in the request for approval of an expert report for a registered medical device) (if required)	shall be certified by the manufacturer (authorized representative thereof)
5. An operational document or instruction for the use of a medical device, a maintenance manual approved during the registration of a	shall be certified by the manufacturer (authorized representative thereof)

medical device, taking into account the amendments made to the marketing authorization application for a medical device, in the official languages of the Member States concerned, specified in the request for approval of an expert report for a registered medical device (if required)	
6. Marketing authorization for a medical device, issued by the Eurasian Economic Union, or a duplicate thereof	

ANNEX 13

to the Rules for Marketing Authorization
and Expert Examination of the
Safety, Quality, and Efficiency of Medical
Devices

FORM
of a request for cancellation of the validity (invalidation) of the marketing authorization for a medical device

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

_____
(name of the reference Member State)

REQUEST
for the cancellation of validity (invalidation) of the
marketing authorization for a medical device

_____
(full and abbreviated (if any), including the company name, the name of the person on behalf of which the request is submitted (manufacturer (authorized representative of the manufacturer), the organizational and legal form of the legal entity)

hereby requests to cancel the validity of the marketing authorization for a medical device (to invalidate the marketing authorization for a medical device)

_____
(medical device name (indicating the model (brand), composition and accessories of the medical device))

_____
(date of registration of the medical device and the number of the marketing authorization for the medical device)

due to _____

(insert the reason)

_____

(request submission date)

_____	_____
(surname, name, patronymic and title of the manager of the manufacturer (manufacturer's authorized representative))	(signature and seal of the manufacturer (manufacturer's authorized representative))".

_____