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**EURASIAN ECONOMIC COMMISSION
COUNCIL**

DECISION

February 12, 2016

No. 27

city of Moscow

**On Approval of General Requirements for safety and efficacy of
medical products, requirements for their marking
and operational documentation on them**

In accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraphs 104, 108 and 109 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 “On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union”, the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached General requirements for the safety and efficacy of medical products, requirements for their marking and operational documentation on them.

2. This Decision shall enter into force after 10 calendar days have elapsed from the effective date of the Protocol, signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for the circulation of medical products (medical devices and medical equipment) within the Eurasian Economic Union dated December 23, 2014, but not earlier than after 10 calendar days have elapsed from the date of the official publication of this Decision.

Members of the Council of the Eurasian Economic Commission:

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

APPROVED
by Decision No. 27 of the Council of
the Eurasian Economic Commission
dated February 12, 2016

**GENERAL REQUIREMENTS
for safety and efficacy of medical products, requirements
for their marking and operational
documentation on them**

I. General provisions

1. These General Requirements are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 and establish general requirements for safety and efficacy of medical products, as well as requirements for marking and operational documentation on medical products, released into circulation within the Eurasian Economic Union (hereinafter referred to as the Union).

2. For the purposes of these General Requirements the concepts are used having the following meanings:

“active medical products” – medical products, used separately or in combination with other medical products for which the use of energy other than that produced by man or gravity is necessary.

Medical products intended for the transfer of energy or substances from an active medical product to a user without their significant change are not active medical products. Independent software is considered an active medical product;

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

“instruction for use” - an operational documentation containing information provided by the manufacturer to the user regarding designation, proper and safe use of a medical product, which may include the operation manual, medical application procedure, passport, blank form, installation, adjustment and maintenance instruction, repair, transportation, storage, disposal of a medical product;

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

“adverse event (incident)” – any failure and (or) deterioration in performance, or a medical product malfunction, or inadequacy or incorrectness of supporting information (documentation) for a medical product or side effect not specified in the instructions for use which, directly or indirectly led or could lead to death or serious deterioration of health of users or third parties (while a serious deterioration of health is understood as life-threatening disease, persistent damage of body function or permanent damage of body structure, condition requiring medical or surgical intervention in order to prevent a life-threatening disease, or persistent damage of the body function or permanent damage of body structure, condition requiring hospitalization or a

significant increase in the length of hospital stay of already hospitalized patient, functional dysfunction of the fetus, its death, congenital abnormality or birth trauma);

“undesirable event” - any undesirable medical event, unpredictable disease or damage or undesirable clinical signs (including laboratory indicators other than the norm) in users or third persons associated with the medical product use;

“user” - a patient, medical specialist or any other natural person who uses the medical product as designated by the manufacturer;

“medical product efficacy” - ability of a medical product to meet the purpose specified by the manufacturer.

II. General requirements for safety and efficacy, applicable to all medical products

3. Medical products are designed and manufactured in such a way that, if used under conditions and for purposes that are appropriate to their designation, as determined by the manufacturer and, if necessary, taking into account technical knowledge, experience, education or special training, clinical and physical condition of the user, they have effect in accordance with the purpose determined by the manufacturer and were safe for the user and third persons provided that the risk associated with their use is acceptable when compared to the benefit for the user.

It is not allowed to restrict the interchangeability of medical products by using special technical or software tools or by other means.

4. Decisions made by the manufacturer when designing and manufacturing medical product should comply with the principles of safety, taking into account a generally recognized level of knowledge development. If necessary, the manufacturer manages the risks in such a way that the residual risk associated with any hazard was acceptable. The manufacturer follows the following principles in priority order:

identification of a known or foreseeable hazard and an assessment of the risks associated with it arising from the intended use of the medical product and predictable misuse;

elimination of risks through the adoption of adequate technical and technological solutions in the medical product design and manufacture;

reduction of residual risks by taking adequate protective measures, including alarm signals; informing of users about all residual risks.

5. Medical products are designed, manufactured and packaged in such a way that their performance characteristics and efficacy are not compromised during transportation and storage in accordance with the instruction for use.

6. Medical products should be effective as prescribed by the manufacturer and should be designed and manufactured in such a way that, under normal conditions of use, they comply with the purposes of intended use, determined by the manufacturer.

7. Performance characteristics and efficacy of the medical product should not be altered to such an extent that it poses a threat to the life and health of users and third persons during the useful life of the product determined by the manufacturer, provided that the medical product is exposed to effects that may occur under normal conditions of use and maintenance is performed in accordance with the instruction for use.

8. All known and anticipated risks arising from the medical product use and any undesirable effects from such use are minimized and should be acceptable when compared to the benefit for users obtained from the medical product action provided for by the manufacturer under normal operational conditions.

9. The information necessary to identify this medical product and its manufacturer, country of origin, as well as information for the user (professional or non-professional), relating to the safety of the medical product, its functional properties and performance characteristics, is

provided for each medical product. Such information can be on the medical product, package or in the instructions for use.

10. An information media, its format, content and location should correspond to the medical product, its purpose and technical knowledge, experience, education or training of users.

The information media as restrictions concerning the use, contraindications, precautions or warnings should contain information on residual risks associated with the use of the medical product. The concept “contraindications” is not applicable for medical products for in vitro diagnostics.

11. The information provided for in paragraph 9 of these General Requirements is indicated on the marking and in the instruction for use in Russian, and also in the presence of corresponding requirements in the legislation of the Member States in the state language (state languages) of the Member States.

Such information can contain symbols established by interstate standards, as well as those established by international standards (provided that the medical product safety is not violated due to misunderstanding of the meaning of such symbols by individual users).

III. General requirements for safety and efficacy, applicable to medical products, except for medical products for in vitro diagnostics

1. Chemical, physical and biological properties of medical products

12. When designing and manufacturing medical products, special attention should be paid to:

- 1) the choice of materials used, especially with regard to toxicity and flammability;
- 2) compatibility of the used materials and biological cells, tissues, liquids, substances and their derivatives (hereinafter referred to as the biological materials), taking into account the purpose of the medical product;
- 3) the choice of materials used, taking into account such factors as hardness, wear resistance and fatigue strength.

13. When designing, manufacturing and packing of medical products, the risk posed by pollutants and their residues should be minimized for users and persons involved in the transportation, storage and service of medical products (taking into account the designation of the medical product, as well as duration and frequency of exposure of these substances on the human body).

14. Medical products are designed and manufactured in such a way that they can be used in a safe manner with materials, substances and gases with which they come into contact under normal operational conditions or during maintenance. If medical products are designed for the administration of drug products, their design and manufacture are carried out in such a way that they are compatible with drug products (subject to restrictions on their use) in order to ensure the efficacy of both the drug product and medical product in accordance with the designation.

15. When designing and manufacturing medical products, it should be necessary to minimize risks:

- 1) caused by possible release or leaching of hazardous and (or) harmful substances from the medical products (taking into account their sensitizing effect, carcinogenicity, mutagenicity or negative effect on reproductive function);
- 2) related to the unintentional ingress of foreign substances into the medical product (taking into account the purpose determined by the manufacturer and expected conditions of the medical product use).

2. Infectious and microbial contamination of medical products

16. When manufacturing a medical product, the risk of infection of users and third persons should be eliminated or reduced to an acceptable level. The design of the medical product should ensure ease of operation and maintenance and, if necessary, minimize the risk of any microbial leaks from the medical product and (or) microbial effects during use, and prevent microbial contamination of the medical product or sample by the user or third person.

17. When designing, manufacturing and packing of medical products having a specific microbiological status in accordance with the marking, it should be guaranteed that the microbiological status remains unchanged, subject to the conditions of transportation and storage specified by the manufacturer, unless the protective packaging is impaired or opened.

18. When designing, manufacturing and packing medical products that are delivered in a sterile state, their sterility should be guaranteed under conditions of transportation and storage specified by the manufacturer, unless the protective packaging is broken or opened. Such medical products are packed in a disposable packaging.

19. Sterile medical products or medical products having a special microbiological status are manufactured, processed and, if necessary, sterilized using validated methods, equipment, processes.

20. Medical products that require sterilization should be manufactured under conditions of controlled cleanliness of manufacturing areas.

21. Packaging of non-sterile medical products should ensure their integrity and purity, and if the medical product should be sterilized before use, minimize the risk of microbial contamination, at the same time the package should be compatible with the sterilization method specified by the manufacturer.

3. Medical products, containing a substance, considered a drug product

22. If medical products contain a substance that, if used alone, can be considered a drug product in accordance with paragraph 1 of Article 1 of the Agreement on Common Principles and Rules for Circulation of Medical Products within the Eurasian Economic Union dated December 23, 2014, and which has an additional effect on the human body along with the effect of medical products, confirmation of safety and efficacy of such medical products includes confirmation of safety and efficacy of drug products taking into account its use with the medical products.

4. Medical products, containing materials of biological origin

23. If medical products contain animal biological materials, then the animals used for this purpose should be subject to veterinary control (supervision), according to the results of which they should be recognized healthy taking into account designation of the biological materials used. An animal is recognized healthy in case of absence of diseases that can affect safety and efficacy of the medical product.

The information of the manufacturer of the medical product on biological materials, including selection of animals, their geographical origin, sampling, processing conditions, storage and handling of biological materials, should be stored in the authorized authority of the member state of the Union in health care (hereinafter referred to as the authorized authority of the member state).

Processing, storage, testing and handling of biological materials of animal origin should ensure safety of users and third persons. In particular, safety with respect to viruses, other infectious agents and other pathogens common to humans and animals should be ensured through the use of validated methods of destruction or inactivation during the manufacturing process.

24. In case if medical products contain biological materials of human origin, selection of donors, as well as processing, storage, testing and handling of biological materials of human origin are carried out in accordance with the legislation of the member states of the Union and should ensure optimum safety of users and third persons. In particular, safety for viruses and other infectious agents should be ensured through validated methods of destruction or inactivation during the manufacturing process.

25. In case if medical products contain biological materials of microbial origin, then the treatment, storage, testing and handling of biological materials of this nature should ensure the optimum safety of users and third persons. In particular, safety for viruses and other infectious agents should be ensured through validated methods of destruction or inactivation during the manufacturing process.

5. Medical products applicable under conditions of environmental exposure

26. Medical products are designed and manufactured in such a way that their assembly, adjustment, calibration, use and maintenance under conditions of environmental exposure were carried out in a safe manner and ensured the expected efficacy of medical use.

27. In case if medical products are designed for use in combination with other medical products and (or) equipment, the entire combination, including the connection system, should be safe and should not deteriorate the claimed functional characteristics of medical products. Any known restrictions on the use of this combination are indicated on the label and (or) in the instruction for use. When designing and manufacturing connection systems, possible risks of incorrect connection should be minimized as much as possible.

It is not allowed to use special hardware and (or) software components that exclude or limit the possibility of its use in combination with other medical products and (or) equipment intended for this purpose.

28. Medical products are designed and manufactured in such a way as to eliminate or reduce to an acceptable level:

1) a risk of injury to the user or third persons due to the physical characteristics of the medical product;

2) a risk of error when using medical products due to design characteristics or human factors;

3) a risk associated with objectively predictable external effects or environmental conditions such as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and its differences, humidity and air temperature;

4) a risk associated with the use of medical products in contact with materials, liquids and gases to which the medical products are exposed under normal operational conditions;

5) a risk associated with possible negative interaction between the software of medical products and conditions under which it is operated;

6) a risk of accidental ingress of foreign matters into medical products;

7) a risk of interference caused by other products commonly used in the treatment and diagnostic process;

8) a risk arising from the impossibility of maintenance or calibration of medical products (for example, for implants), due to the aging of the materials used or the loss of accuracy of the measuring or monitoring device.

29. Medical products are designed and manufactured in such a way as to eliminate or minimize the risk of ignition or explosion under normal operational conditions or in the event of a single failure. Particular attention should be paid to medical products used with the use of flammable or explosive substances.

30. Medical products are designed and manufactured in such a way as to promote safe disposal of waste generated after the use of medical products.

6. Medical products related to measuring instruments

31. Medical products included in the list of medical products belonging to measuring instruments for which tests are being carried out for the purpose of the approval of the type of measuring instruments are designed and manufactured in such a way as to provide sufficient accuracy, precision and stability taking into account the purpose of the medical product.

32. Measuring, control or indicator scales are designed in accordance with ergonomic principles, taking into account the purpose of the medical product.

Numerical values should be expressed in conventional units and should be understandable to users.

33. The results of measurements carried out using a medical product which relates to measuring instruments are expressed in units of the International System of Units (SI) or in arbitrary units in accordance with the list of arbitrary units used in the development of technical regulations of the Union (including their correlation with International System of Units (SI)), approved by the Eurasian Economic Commission (hereinafter referred to as the Commission).

7. Radiation protection

34. Medical products are designed, manufactured and packaged in such a way as to minimize exposure of users and third persons to radiation without reducing the radiation levels required to achieve diagnostic and therapeutic purposes.

35. In medical products designed to generate hazardous or potentially hazardous radiation necessary for the achievement of specific medical purposes, if the benefits of using these high-intensity emissions are considered more significant in relation to the danger of radiation, there should be the possibility to control these emissions from the user. When designing and manufacturing such medical devices, reproducibility of variable parameters of the generated radiation should be ensured within the permissible limits.

Medical products designed to generate dangerous visible and (or) invisible radiation are equipped with visual and (or) sound means of warning about the presence (activity) of such radiation.

36. When designing and manufacturing medical products, the effect of unintentionally generated incidental or scattered radiation should be minimized.

37. When designing and manufacturing medical products designed to generate ionizing radiation, the quantitative and geometric parameters of the generated radiation should be regulated taking into account the designation determined by the manufacturer.

Medical products that generate ionizing radiation and intended for radiological diagnostics are designed and manufactured in such a way that, with minimal user's exposure to radiation, the quality of image, necessary for diagnostics, and (or) the results of the studies are provided.

Medical products that generate ionizing radiation and are intended for radiological therapy are designed and manufactured in such a way as to provide control and management of the radiation dose, type, energy and, if necessary, the distribution of the energy of directed radiation.

8. Medical products, including software and autonomous software, being a medical product

38. Medical products including software and autonomous software which is a medical product are designed and manufactured in such a way as to ensure stable, reliable and efficient functioning of these medical products in accordance with the purpose specified by the manufacturer.

9. Active medical products, associated with the energy source or equipped with the energy source

39. For active medical products in case of a single fault, appropriate measures are taken to eliminate or reduce subsequent risks.

40. Active medical products, during the use of which user safety depends on the internal power source, are equipped with a means to determine the state of the power source.

41. Active medical products, during the use of which user safety depends on an external power source, should include an alarm system for reporting a power failure.

42. Active medical products designed to monitor one or more clinical user parameters are equipped with appropriate alarm systems to warn the user of a situation that can lead to death or serious health problems.

43. Active medical products are designed and manufactured in such a way as to minimize the risk of electromagnetic field (electromagnetic interference) creation, which can adversely affect the operation of other medical products, equipment and communication facilities in accordance with their purpose.

44. Active medical products are designed and manufactured in such a way as to provide a level of immunity to electromagnetic interference (interference immunity), ensuring their functioning in accordance with the purpose specified by the manufacturer.

45. Active medical products are designed and manufactured in such a way as to minimize a risk of accidental injury to a user or a third person by electric shock both under normal conditions of medical product operation and under conditions of a single failure, provided that the medical product is installed and maintained in accordance with the manufacturer's instructions.

10. Protection against mechanical and thermal hazards

46. Medical products are designed and manufactured in such a way as to protect the user and third persons against the risk of mechanical damage associated with resistance to movement, instability and presence of moving parts in such medical products.

47. Medical products are designed and manufactured in such a way as to minimize the risk associated with the vibration produced by these medical products by using means which allow to limit vibration, unless vibration is a part of the medical product purpose.

48. Medical products are designed and manufactured in such a way as to minimize the risk associated with the produced noise by using the means used to reduce noise, unless the generated noise is a part of the medical product purpose.

49. Terminals, plugs, connectors and other product for connection of medical products to electrical, hydraulic or pneumatic power sources are designed and manufactured in such a way as to minimize any possible risks.

50. Medical products are designed and manufactured in such a way as to minimize a risk of errors arising from improper connection or switching during operation of equipment or parts in such medical products.

51. Open parts of medical products (except for the parts intended for heat supply or reaching specified temperatures) should not reach potentially dangerous temperatures under normal operating conditions.

11. Protection against risks arising for the user from the supplied energy or substances

52. Medical products intended for supply of energy or substances to a user are designed and manufactured in such a way that the amount of the supplied energy or substance can be set and maintained with accuracy sufficient to ensure user safety.

53. Medical products are equipped with means of prevention and (or) indication of any inconsistencies in the amount of energy or substance that can be dangerous.

54. Information about the functions of the controls and indicators is clearly indicated on the medical product. If there is an instruction for use, or operation manual, or visual means of indication of the operating or adjustment parameters of a medical product, then such information should be understandable to the user.

12. Protection against risks arising from the use of medical products designed by the manufacturer for use by users who do not have special medical education

55. Medical products designed by the manufacturer for use by users without special medical education are designed and manufactured taking into account skills and facilities available to these persons, so that medical products function in accordance with their purpose under conditions of objectively expected actions from these persons.

56. Medical products intended for use by users without special medical education are designed and manufactured in such a way as to minimize the risk of errors during the use of medical products, as well as when interpreting test results.

57. Medical products intended for use by users without special medical education, if it is objectively possible, should have the function of conformance of the fact that, when used, these medical products will function in accordance with the purpose specified by the manufacturer.

13. Requirements for marking of medical products

58. Medical product marking should contain the following information:

- 1) name and (or) tradename of the medical product;
- 2) information required for identification of the medical product as well as information on its designation (if necessary);
- 3) data on the manufacturer, including full and abbreviated (if any) name of a juridical person, location (surname, name, patronymic (if any) and place of residence of a natural person, registered as an individual entrepreneur), postal address of the manufacturer, country origin of the medical product. Postal address of the manufacturer can be indicated on the marking, if it is contained in the instruction for use, attached to the medical product.

Medical products manufactured in the state, which is not a member of the Union, can be marked with additional information about the authorized representative of the foreign manufacturer, including the full and abbreviated (if any) name of a juridical person, location (surname, name, patronymic (if any) and place of residence of a natural person registered as an individual entrepreneur), postal address of the authorized representative of the manufacturer. Additional marking should not obscure the marking containing information about the manufacturer of the medical product;

4) information on the presence of drug products or biological materials as well as nanomaterials in the medical product, if such nanomaterials are not contained in a bound state, excluding the possibility of their entry into the user's body when using a medical product for the intended purpose specified by the manufacturer;

5) a batch code (number) or serial number of the medical product;

6) a period (with the indication of the year and month), before the expiration of which the medical product can be used in a safe manner;

7) a year of manufacture of the medical product, unless the period is indicated, before the expiration of which the medical product can be used in a safe manner. The year of manufacture

of the medical product is included in the batch number or serial number, provided that the year of release is easily identified as a part of such number;

8) information on special conditions of storage and (or) circulation of the medical product (if necessary);

9) information on medical product sterility (if the medical product is delivered in a sterile form) with indication of the sterilization method;

10) a warning or precautionary measures that are specified in such a way as to attract the attention of the user or a third person. This information can be minimized if more detailed information is contained in the instruction for use;

11) information on a single use of a medical product (if the medical product is designed for a single use);

12) information on the restoration of the medical product, indicating a number of restoration cycles performed and any restrictions on the number of restoration cycles (if the medical product for a single use is restored);

13) information on the manufacture of a medical product on the individual order of the user solely for personal use in accordance with the appointment of a medical specialist, issued in writing;

14) information on the purpose of the medical product only for performance of clinical trials for registration purposes;

15) information on the designation of the medical product for exhibition or demonstration purposes only. In this case, the marking requirements specified in subparagraphs 1-14 of this paragraph are not mandatory;

16) information on the inactivation of possible viruses and other infectious agents in the medical product, put in the form of the inscription "antibodies to HIV 1, 2 and hepatitis C and HBsAg viruses are absent" (if the medical product contains serum (plasma) of human blood or human tissue elements).

59. In case if medical products or their components designed for administration to the body and excretion of medicinal products, body fluids or other substances from the human body or for transportation and storage of such agents, liquids or substances contain harmful substances which are carcinogenic, mutagenic or toxic for reproductive function properties depending on their concentration or contain phthalates, then such medical products are subject to special marking. This special marking is applied to the medical product and its packaging or, if necessary, to the outer packaging used to store and transport the medical product.

60. Marking of sterile and non-sterile medical products should provide the ability to distinguish identical or similar types of medical products released into circulation in a sterile and non-sterile form, and should be distinguished in such a way that the user can distinguish a sterile medical product from unsterile one with the help of marking.

61. Marking shall be applied to a medical product. If this is impossible or inappropriate, the marking (partially or completely) may be applied to the packaging for each unit of the medical product, and (or) to the group packaging, and (or) instruction for use.

62. The marking can be supplemented by information on a medical product in a machine-readable format, including using radio frequency identification or barcodes.

63. Medical products that have passed the procedures for registration and confirmation of compliance with the general requirements for safety and efficacy of medical products established within the Union, requirements for the introduction and maintenance of a quality management system of medical products, before release into the circulation within the Union are subject to mandatory marking with a special trademark of circulation in the market of the Union (hereinafter referred to as the special trademark of circulation).

Marking with a special trademark of circulation applied to a medical product is performed by any technological method providing a clear image of it during the entire life of the medical product.

A special trademark of circulation is not applied to a medical product if it is technologically impossible or will pose a threat to the life and health of the user.

14. Requirements for the information contained in the instruction for use of the medical product

64. Instructions for use can be provided to the user in hard copy or in electronic form both together with the medical product or separately from it, including by placement of information on the screen that is part of the medical product. The chosen way of provision of the instruction for use should be suitable and accessible to users. If the instruction for use is provided on media other than paper, the manufacturer should ensure that the consumer is informed of the methods of:

- 1) review of the instruction for use;
- 2) obtaining the current version of the instructions for use;
- 3) obtaining a paper version of the instruction for use.

65. The instruction for use should contain the following information:

- 1) a name and (or) trade name of the medical product;
- 2) information on the manufacturer of a medical product and (or) its authorized representative, including a full and abbreviated (if any) name of a juridical person, location (surname, first name, patronymic (if any) and place of residence of a natural person registered as an individual entrepreneur), postal address, phone number, fax number, e-mail address (if any);
- 3) designation of a medical product with the indication of the user (for example, a patient, a medical specialist, a natural person who uses the medical product according to the designation determined by the manufacturer);
- 4) functional characteristics of the medical product;
- 5) summarized results of clinical trials performed for the purpose of registration of a medical product or reference to a source where such information is available to the user;
- 6) residual risks, contraindications, anticipated and predictable side effects associated with the use of a medical product as prescribed by the manufacturer;
- 7) technical characteristics necessary for the user for the intended use of a medical product as determined by the manufacturer;
- 8) information on availability of a medical product, biological material and (or) nanomaterial;
- 9) information on the order of installation and commissioning (if necessary), as well as the need for preliminary preparation for the medical product use;
- 10) special requirements for premises, special training or special skills of the user and (or) third persons;
- 11) information necessary to verify the correctness of the installation of the medical product and its readiness for safe operation for the intended purpose as determined by the manufacturer, with indication of the following data:
 - maintenance and its frequency, including cleaning and disinfection of the medical product;
 - availability of consumable components of the medical product and procedure for their replacement;
 - need for calibration to ensure the proper and safe operation of the medical product during its lifetime;
 - methods to reduce the risks associated with the installation, calibration or maintenance of the medical product;
- 12) information on special conditions for storage and (or) maintenance of the medical product;
- 13) information on the procedure for the breach of sterile packaging of the medical product before its use (if the medical product is supplied sterile);

14) information on the method of the medical product sterilization (if the medical product is supplied non-sterile with indication of the need for its sterilization before use);

15) information on the proper treatment of the medical product for its reuse, including cleaning, disinfection, packaging and, if necessary, the method of re-sterilization (if the medical product is intended for multiple use), as well as criteria for unserviceability of the medical product;

16) information necessary to identify medical products in order to obtain a safe combination and information on known restrictions on the shared use of medical products (for medical products intended for use with other medical products and / or general purpose products);

17) information on the nature, type, and (if necessary) intensity and distribution of the radiation emitted by the medical product and ways of protection of users or third persons from unintentional radiation during the use of the medical product (if the medical product creates a hazardous or potentially hazardous level of radiation for medical purposes);

18) information for users (warnings, precautions, measures taken, if necessary, and limitations when using the medical product), including:

warning, precautions and (or) measures taken in the event of the medical product failure or deviations in its functioning, which may affect medical product safety;

warning, precautions and (or) measures taken in the event of impact of external factors, associated with the use of the medical product in combination with other medical products and / or equipment or factors such as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and its differences, humidity and air temperature on the operation of the medical product;

warning, precautions and (or) measures taken in case of a predictable risk of electromagnetic interference created by a medical product when conducting and evaluating the results of specific diagnostic studies, medical treatment or during its use (for example, electromagnetic radiation of the medical product that affects other equipment);

information on limitations or incompatibility with the medical product of certain drug products or biological materials (if the medical product is intended for the administration of drug products or biological materials);

warning, precautions and (or) restrictions related to drug substances or biological materials that are part of the medical product;

warning related to the carcinogenic, mutagenic or toxic materials which are a part of the medical product, possible isolation or leaching of which leads to sensitization, allergic reaction or has a negative effect on reproductive function;

warning or precautions taken by the user during disposal of the medical product, accessories and consumables used with it (if any), including the following information:

infectious or microbial danger of the medical product;

medical product environmental hazard;

medical product physical hazard;

19) information on the circumstances under which the user should consult a medical specialist (for medical products intended for use by persons who do not have medical education);

20) data on the release or latest revision of the instruction for use;

21) information on the need to send a message to the manufacturer or his authorized representative about undesirable events that have signs of an adverse event (incident).

66. The instruction for use should be drafted using terms that the user understands and, if necessary, accompanied by figures and diagrams.

The instruction for use can contain individual information for professional and non-professional users.

67. The instruction for use can be presented in a short form or on the marking (for medical products of hazard classes of use 1 and 2a), if the medical product can be used in a safe manner and for the purpose specified by the manufacturer, without the instruction for use.

68. One copy of the instruction for use can be sufficient if several medical products are delivered to one user at the same address. At the request of the consumer, the manufacturer should provide additional copies of the instruction for use.

IV. General requirements for safety and efficacy, applied to the medical products for in vitro diagnostics

1. Chemical, physical and biological properties of medical products for in vitro diagnostics

69. When designing and manufacturing medical products for in vitro diagnostics, special attention should be given to the possible deterioration of analytical performance due to the incompatibility of the materials, samples and (or) analytes used.

70. When designing, manufacturing and packaging medical products for in vitro diagnostics, the risk posed by pollutants and their residues to users and persons involved in the transportation, storage, maintenance and use of medical products for in vitro diagnostics (taking into account the designation of the medical product for in vitro diagnostics, as well as duration and frequency of impact of these substances on the human body).

71. When designing and manufacturing medical products for in vitro diagnostics, the following risks should be reduced:

1) associated with dangerous and (or) harmful substances that can be leached out or leak out of the medical product for in vitro diagnostics (taking into account their sensitizing action, carcinogenicity, mutagenicity or negative effect on reproductive function);

2) associated with the unintentional ingress of foreign substances into the medical product for in vitro diagnostics (taking into account the purpose specified by the manufacturer and anticipated conditions for the use of the medical product for in vitro diagnostics).

2. Infectious and microbial contamination of medical products for in vitro diagnostics

72. When designing and manufacturing medical products for in vitro diagnostics, the risk of infection of users and third persons should be eliminated or reduced to an acceptable level.

The design of the medical product for in vitro diagnostics should ensure ease of handling and maintenance and, if necessary, minimize a risk of microbial leakage from the medical product for in vitro diagnostics and (or) microbial exposure during use, and also prevent microbial contamination of the medical product for in vitro diagnostics or sample by a user or a third person.

73. When designing, manufacturing and packaging medical products for in vitro diagnostics that have a specific microbiological status in accordance with the marking, it should be guaranteed that the microbiological status remains unchanged, in compliance with transportation and storage conditions specified by the manufacturer, unless the protective package is broken or opened.

74. Sterile medical products for in vitro diagnostics or medical products for in vitro diagnostics having a special microbiological status are manufactured, processed and, if necessary, sterilized using validated methods, equipment, processes.

75. Medical products for in vitro diagnostics that require sterilization should be manufactured under controlled production conditions.

76. The package of non-sterile medical products for in vitro diagnostics should ensure their integrity and purity, and if the medical product for in vitro diagnostics should be sterilized before use, minimize the risk of microbial contamination, the package should be compatible with the sterilization method indicated by the manufacturer.

3. Medical products for in vitro diagnostics, Containing materials of biological origin

77. If medical products for in vitro diagnostics contain biological materials of animals, then treatment, storage, testing and handling of biological materials of animal origin should be carried out in such a way as to ensure safety of users and third persons.

Safety with respect to viruses, other infectious agents and other pathogens common to humans and animals should be ensured using validated methods of destruction or inactivation during the manufacturing process. These validated methods do not apply to medical products for in vitro diagnostics, if the activity of viruses and other infectious agents is due to the designation of medical products for in vitro diagnostics or destruction or inactivation process can reduce efficacy of the medical product for in vitro diagnostics.

78. If medical products for in vitro diagnostics contain biological materials of human origin, treatment, storage, testing and handling of biological materials of human origin should be carried out in such a way as to ensure safety of users and third persons.

Safety with respect to viruses and other infectious agents should be ensured using validated methods of destruction or inactivation during the manufacturing process. These validated methods do not apply to medical products for in vitro diagnostics if the activity of viruses and other infectious agents is due to the designation of medical products for in vitro diagnostics or destruction or inactivation process can reduce efficacy of medical products for in vitro diagnostics.

79. If medical products for in vitro diagnostics contain biological materials of microbial origin, treatment, storage, testing and handling of biological materials of this nature should be carried out in such a way as to ensure safety of users and third persons.

Safety with respect to viruses and other infectious agents should be ensured using validated methods of destruction or inactivation during the manufacturing process. These validated methods do not apply to medical products for in vitro diagnostics, if the activity of viruses and other infectious agents is due to the designation of medical products for in vitro diagnostics or destruction or inactivation process can reduce efficacy of the medical product for in vitro diagnostics.

4. Medical products for in vitro diagnostics, used under conditions of environmental exposure

80. Medical products for in vitro diagnostics are designed and manufactured in such a way that their assembly, adjustment, calibration, use and maintenance under conditions of environmental exposure were carried out in a safe manner.

81. In case medical products for in vitro diagnostics are designed for use in combination with other medical products and (or) equipment, the entire combination, including the connection system, should be safe and should not degrade the declared functional characteristics of medical products for in vitro diagnostics. Any known restrictions on the use of this combination are indicated on the marking and (or) in the instruction for use. When designing and manufacturing connection systems, possible risks of incorrect connection should be minimized.

It is not allowed to use special hardware and (or) software components in the medical product for in vitro diagnostics that exclude or limit the possibility of its use in combination with other medical products and (or) equipment intended for this purpose.

82. Medical products for in vitro diagnostics are designed and manufactured in such a way as to eliminate or reduce to an acceptable level:

1) a risk of injury to the user or third persons due to the physical characteristics of the medical product for in vitro diagnostics;

2) a risk of error when using a medical product for in vitro diagnostics due to design characteristics or human factor;

3) a risk associated with objectively predictable environmental exposure or environmental conditions such as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and its differences, humidity and air temperature;

4) a risk associated with the use of medical products for in vitro diagnostics when in contact with materials, liquids and gases to which the medical products for in vitro diagnostics are exposed under normal operational conditions;

5) a risk associated with a possible negative interaction between the software of the medical product for in vitro diagnostics and conditions under which it is operated;

6) a risk of accidental ingress of foreign substances into medical products for in vitro diagnostics;

7) a risk of incorrect identification of samples in the in vitro diagnostics;

8) a risk of interference caused by other products commonly used in the treatment and diagnostic process.

83. Medical products for in vitro diagnostics are designed and manufactured in such a way as to eliminate or minimize a risk of ignition or explosion under normal operational conditions or in case of a single failure. Particular attention should be paid to medical products for in vitro diagnostics, used with flammable or explosive substances.

84. Medical products for in vitro diagnostics are designed and manufactured in such a way as to promote the safe disposal of waste generated after the use of medical products for in vitro diagnostics.

5. Functional characteristics of medical products for in vitro diagnostics

85. Medical products for in vitro diagnostics are designed and manufactured in such a way that their functional characteristics are based on an appropriate scientific and technical basis. Medical products for in vitro diagnostics should function throughout their lifetime in accordance with the purpose, specified by the manufacturer, in terms of:

a) analytical performance characteristics: accuracy (correctness and precision), systematic error, analytical sensitivity, analytical specificity, limit of detection, analytical range, linearity, cut-off point, repeatability, reproducibility, including conditions for its determination, determination of possible interference of endogenous and exogenous nature and cross reactivity;

b) clinical efficacy characteristics: diagnostic sensitivity, diagnostic specificity, predictive value of positive and negative results, likelihood ratio, expected values in a normal or isolated population.

86. If efficacy of medical products for in vitro diagnostics depends on calibrators and (or) control materials, the metrological traceability of their values should be ensured by reference methods and (or) available higher-order reference materials.

87. Numerical values of the results of the study of samples of human biological materials obtained within in vitro diagnostics should be expressed in conventional and standardized units.

6. Radiation protection

88. Medical products for in vitro diagnostics are designed, manufactured and packaged in such a way as to minimize the exposure of users and third persons to potentially hazardous radiation.

89. Medical products for in vitro diagnostics designed to generate potentially hazardous radiation are designed and manufactured in such a way as to guarantee control and (or) regulation of the characteristics and amount of radiation emitted, and are equipped with visual and (or) sound warning means for availability (activity) of such radiation.

7. Medical products for in vitro diagnostics,
comprising software,
and autonomous software, which is
a medical product for in vitro diagnostics

90. Medical products for in vitro diagnostics, comprising software, and autonomous software, which is a medical product for in vitro diagnostics, are designed and manufactured in such a way as to ensure a stable, reliable and efficient functioning of these medical products in accordance with the purpose, defined by the manufacturer.

8. Active medical products for in vitro diagnostics,
connected to an energy source or quipped with
the energy source

91. Active medical products for in vitro diagnostics, during the use of which user safety depends on the internal power source, are equipped with a means for determination of the power source state.

92. Active medical products for in vitro diagnostics are designed and manufactured in such a way as to minimize a risk of creation of electromagnetic fields (electromagnetic interference), which can adversely affect the operation of other medical products, equipment and communication facilities in accordance with their purpose.

93. Active medical products for in vitro diagnostics are designed and manufactured in such a way as to provide a level of immunity to electromagnetic interference (interference immunity) that ensures their functioning in accordance with the purpose specified by the manufacturer.

94. Active medical products for in vitro diagnostics are designed and manufactured in such a way as to minimize a risk of accidental injury to the user or third person by electric shock both under normal conditions of medical product operation and under conditions of a single failure, provided that the medical product is installed and maintained in accordance with the manufacturer's instructions.

9. Protection against mechanical and thermal risks

95. Medical products for in vitro diagnostics are designed and manufactured in such a way as to protect the user and third persons against the risk of mechanical damage associated with resistance to movement, instability and presence of moving parts in such medical products.

96. In case if moving parts are present in in vitro medical products, means of protection of the user against the risk associated with possible destruction of moving parts or their separation are provided.

97. Medical products for in vitro diagnostics are designed and manufactured in such a way as to minimize the risk associated with the vibration produced by these medical products using means allowing to limit vibration, unless vibration is part of the purpose of such medical products.

98. Medical products for in vitro diagnostics are designed and manufactured in such a way as to minimize the risks associated with the generated noise using (if necessary) means used to reduce noise.

99. Terminals, plugs, connectors and other devices of connection of medical products for in vitro diagnostics to sources of electrical, hydraulic or pneumatic energy are designed and manufactured in such a way as to minimize any possible risks.

100. Medical products for in vitro diagnostics are designed and manufactured in such a way as to minimize the risk of errors arising from improper connection or switching during operation of equipment or parts of such medical products.

101. Open parts of medical products for in vitro diagnostics (except for parts designed for heat supply or set temperature value reaching) should not reach potentially dangerous temperatures under normal operational conditions.

10. Protection against the risks, created by medical products for in vitro diagnostics, designed for self-testing by the user and testing near the user

102. Medical products for in vitro diagnostics designed for self-testing by the user or testing near the user are designed and manufactured in such a way that they will function in accordance with the purpose specified by the manufacturer, taking into account the user's skills and operational conditions of the medical product.

103. Medical products for in vitro diagnostics designed for self-testing by the user or testing near the user are designed and manufactured in such a way as to minimize the risk of error of the user who does not have a special medical education, when using such medical products, as well as when sampling or interpreting test results.

104. Medical products for in vitro diagnostics designed for self-testing by the user or for testing near the user, if objectively possible, should have the function of confirmation that when used, these medical products will function in accordance with the purpose specified by the manufacturer.

11. Additional requirements for the marking of medical products for in vitro diagnostics

105. In addition to the marking requirements specified in subsection 13 of Section III of these General Requirements, for medical products for in vitro diagnostics, there are also additional requirements which specify that the marking of medical products for in vitro diagnostics should contain the following information:

- 1) information on the purpose of the medical product for in vitro diagnostics;
- 2) information on the weight (net weight) of the content (in units of weight or volume), number of units or any combination of indicators that accurately reflect the content of the package (if any);
- 3) information on the main ingredients contained in the package of the medical product for in vitro diagnostics;
- 4) a hazard label if the medical product for in vitro diagnostics contains dangerous substances;
- 5) information on the special microbiological status or purity of the medical product for in vitro diagnostics (if necessary);
- 6) information on the purpose of the medical product for in vitro diagnostics for self-testing by the user or for testing near the user (if any).

12. Requirements for the information contained in the instruction for use of the medical product for in vitro diagnostics

106. The instruction for the use of a medical product for in vitro diagnostics should contain the following information:

- 1) a name and (or) trade name of the medical product for in vitro diagnostics;
- 2) information on the manufacturer of the medical product for in vitro diagnostics and (or) its authorized representative, including a full and abbreviated (if any) name of a juridical person, location (surname, name, patronymic (if any) and place of residence of a natural person

registered as an individual entrepreneur), postal address, phone number, fax number, e-mail (if any);

3) a purpose of the medical product for in vitro diagnostics, including:

functional purpose;

a description of what is defined and (or) measured;

specific disturbance, condition or risk factor for the detection, determination or differentiation for which the medical product for in vitro diagnostics are designed (if necessary);

designation of the medical product for in vitro diagnostics for qualitative, semi-quantitative or quantitative determinations;

type of the sample analyzed;

4) information on the purpose of the medical product for in vitro diagnostics for clinical laboratory diagnostics;

5) designation of the medical product for in vitro diagnostics with the indication of the user (e.g., a patient, medical specialist, natural person using the medical product for the purpose specified by the manufacturer);

6) a test principle;

7) a description of reagents, calibrators and control materials;

8) a list of materials and special materials that are required for testing (analysis), but are not included in the scope of delivery of the medical product for in vitro diagnostics;

9) for medical products for in vitro diagnostics intended for use in combination with other medical products, including medical products for in vitro diagnostics, - information for identification of medical products in order to obtain a safe combination and (or) information on known restrictions on shared use of medical products;

10) information on special storage conditions (e.g., temperature and air humidity, lighting, etc.) and (or) handling of users the in vitro medical product;

11) information on stability characteristics of the medical product for in vitro diagnostics (e.g., storage conditions, shelf life after the first opening of the primary container), as well as storage and stability conditions of working solutions (if necessary);

12) information on a sterile condition, sterilization method and plan of actions in case of a sterile package breach (if the medical product for in vitro diagnostics is delivered in a sterile form);

13) information for users (warnings, precautions, measures taken in case of need and limitations when using medical product for in vitro diagnostics), including:

warning, precautions and (or) measures taken in case of malfunction or deviations in the functioning of the medical device for in vitro diagnostics determined by external signs;

warning, precautions and (or) measures taken with respect to predictable external factors such as external electromagnetic fields, electrostatic discharges, radiation, atmospheric pressure and its differences, humidity and air temperature;

warning, precautions and (or) measures taken in case of a predictable risk of electromagnetic interference created by a medical product for in vitro diagnostics for other medical products, equipment and communication facilities;

warning associated with the materials contained in the medical product for in vitro diagnostics that are carcinogenic, mutagenic or toxic, or lead to sensitization, allergic reaction or have negative effect on reproductive function;

warning, precautions and (or) measures taken with respect to a potentially infectious material contained in the medical product for in vitro diagnostics;

14) information on the purpose of a disposable medical product for in vitro diagnostics;

15) information on proper treatment of the medical product for in vitro diagnostics for its reuse, including cleaning, disinfection, packaging and, if necessary, a re-sterilization method (if the medical product for in vitro diagnostics is intended for multiple use);

16) special requirements for premises, special training or special qualifications of the user and (or) third persons (if necessary);

17) information on the conditions necessary for the collection, treatment and preparation of samples, data on the stability of the analyzed samples, including conditions and duration of storage, transport conditions, restrictions on freeze (thawing) cycles;

18) detailed information on the preparation of the medical product for in vitro diagnostics for use;

19) information required to verify the correct installation of the medical product for in vitro diagnostics and its readiness for safe operation for the purpose determined by the manufacturer, with the indication of the following information:

 maintenance scope and frequency, including medical product cleaning and disinfection;

 the need for calibration to ensure the proper and safe operation of the medical product for in-vitro diagnostics during its lifetime;

 methods to reduce the risks associated with installation, calibration or maintenance of the medical product for in vitro diagnostics;

20) recommendations regarding quality control procedures, if necessary;

21) information on the traceability of values which are set for calibrators or control materials, which is provided by available reference measurement methods and (or) standards;

22) testing procedure, including calculations and interpretation of test results, and, if necessary, information on the appropriateness of confirmatory tests;

23) analytical performance characteristics: sensitivity, specificity, correctness, repeatability, reproducibility, limit of detection and measurement range, including information on the effect of known interference, on method limitations and use of available reference materials and analysis methods (if applicable);

24) clinical efficacy characteristics: diagnostic sensitivity and diagnostic specificity (if necessary);

25) biological reference interval, if necessary;

26) information on interfering substances or limitations related to the sample, which may affect the test result;

27) warning and (or) special precautions for safe disposal of the medical product for in vitro diagnostics and accessories (if any) that, if necessary, should cover the following factors:

 infectious or microbial risks, including possibility of contamination of consumables with infectious agents of human origin;

 environmental risks associated with potentially hazardous materials and substances;

 physical risks, including possibility of explosion or fire;

28) for the medical product for in vitro diagnostics intended for self-testing by the user or testing near the user, also the following information should be provided:

 detailed information on testing procedure (preparation of reagents, sampling (preparation of the sample), procedure and interpretation of test results);

 recommendations regarding the user's actions in case of a positive, negative or indefinite test result;

 information on errors of the test and possibility to obtain false-positive or false-negative test results, as well as with regard to factors affecting the test result;

 information on impermissibility for the user to take medical decisions without prior consultation with a medical specialist;

29) data on issue or latest revision of the instruction for use;

30) information on the need to send a message to the manufacturer or his authorized representative about undesirable events that have signs of an adverse event (incident).

107. The instruction for use can be presented in an abbreviated form or on the marking (for medical products for in vitro diagnostics of hazard classes 1 and 2a) if the medical product can be used in a safe manner and for the purpose specified by the manufacturer without the instruction for use.

108. One copy of the instruction for use can be sufficient if several medical products for in vitro diagnostics are supplied to one user at the same address. At the request of the consumer, the manufacturer should provide additional copies of the instruction for use.

V. Evidence of compliance of the medical product
with General Requirements for safety and efficacy
for the purposes of registration

109. Compliance of the medical product with these General Requirements is ensured by meeting requirements established directly by this document or by meeting requirements of standards included in the list of standards, as a result of which, on a voluntary basis, compliance of the medical product with these General Requirements (hereinafter referred to as the list) is ensured in whole or in part.

110. The list is formed on the basis of proposals of the authorized authorities of the Member States, adopted by the Commission's recommendation in agreement with the Member States and subject to updating as necessary.

The procedure for the formation of the list is adopted by the Commission's recommendation.

To include the standards into the list, the authorized authorities of the Member States submit information on the form in accordance with Annex No. 1 to the Commission.

111. For the purposes of registration, compliance of the medical product with these General Requirements is confirmed by the manufacturer or his authorized representative by submitting information on compliance with the established requirements on the form according to Annex No. 2 to the authorized authority of the Member State. The form shall be filled in according to the established procedure.

112. Evidence of the compliance of the medical product with the provisions set forth in paragraphs 3, 6 and 8 of these General Requirements should include a clinical rationale based on clinical data on the medical product.

Seal:

Eurasian Economic Commission. For documents

ANNEX No. 1
to the General Requirements for safety
and efficacy of medical products,
requirements for their marking and operational
documentation on them

FORM
of provision of information for inclusion of standards
in the list of standards, as a result of the use of which
on a voluntary basis compliance of the medical product
with the requirements of safety and efficacy of medical products
is ensured in whole or in part

Standard designation	Standard name	Effective date	Applicable standard sections *	Paragraph of the General Requirements**
1	2	3	4	5

* Applicable sections of the standard are indicated, if not all sections of the standard ensure the presumption of the compliance of the medical products with the General Requirements safety and efficacy of medical products, requirements for their marking and operational documentation on them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016.

** The corresponding clause of the General Requirements for safety and efficacy of medical products, the Requirements for their marking and operational documentation on them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016, is indicated, which is implemented when applying the section of the standard indicated in column 4 of this form.

ANNEX No. 2
to the General Requirements for safety
and efficacy of medical products,
requirements for their marking and operational
documentation on them

**Form of provision of data on compliance
of the medical product with the requirements for safety and efficacy
of medical products and procedure for its filling in**

I. Form of provision of data on compliance of
the medical product with the requirements for safety
and efficacy of medical products

Medical product name:					
Paragraph of the General Requirements:	Applicability to the medical product	Method used to prove compliance	Details of the normative document on the method used	Details of the documents confirming the compliance	Evaluation result
1	2	3	4	5	6

II. Procedure for filling in the form of provision of data
on compliance of the medical product with the requirements
for safety and efficacy of medical products

1. A relevant paragraph of the General Requirements for safety and efficacy of medical products, Requirements for the marking and operational documentation on them, approved by Decision No. 27 of the Council of the Eurasian Economic Commission dated February 12, 2016 (hereinafter referred to as the General Requirements) is indicated in Column 1.

2. The data whether the requirement provided for in paragraph of the General Requirements specified in column 1 is applicable to the medical product (“yes” or “no”) is indicated in column 2. If this requirement is not applicable to the medical product, the column provides an explanation.

3. The method used to demonstrate compliance of the medical product with the requirement provided for in paragraph of the General Requirements specified in column 1 (e.g., standard application, tests using own standardized method, tests using own test method, tests conducted by a third party, or other method) is indicated in column 3.

4. Details of the normative document for the method used to prove the compliance of the medical product with the requirement provided for in paragraph of the General Requirements specified in column 1 are indicated in column 4.

5. Details of documents confirming the compliance of the medical product with the requirement provided for in paragraph of the General Requirements specified in column 1 (test reports, certificates, declarations of conformity, reports on the studies performed, other documents) are indicated in column 5.

6. Opinion on the compliance or non-compliance of the medical product with the General Requirements is indicated in column 6.