

**THE EURASIAN ECONOMIC COMMISSION**

**THE COUNCIL**

**DECISION**

|  |  |  |
| --- | --- | --- |
| March 17, 2022 |  **No. 26** |  Moscow |

**On Amending the Rules for Conducting Studies (Tests) Aimed at the Biological Evaluation of**

**Medical Devices**

In accordance with Paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, Paragraphs 4 and 5 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, Paragraphs 105 and 106 of Annex 1 to the Rules of Procedure of the Eurasian Economic Commission, approved by Decision
No. 98 of the Supreme Eurasian Economic Council on December 23, 2014, the Eurasian Economic Commission's Council **decided**:

1. To amend 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 (hereinafter referred to as the Rules), as attached.

2. To set out that:

studies (tests) aimed at the biological evaluation of medical devices in accordance
with a civil law contract concluded with an authorized organization entitled to conduct such studies (tests) before the effective date of this Decision shall be carried out in accordance with the Rules in force at the time of conclusion of the said contract;

protocols of studies (tests) for the purpose of biological evaluation of medical devices issued in the form provided for in the annex to the Rules in the wording in force at the time of conclusion of the civil law contract shall be accepted for registration of medical devices within the Eurasian Economic Union.

3. 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 ofArmenia** | **For the Republic ofBelarus** | **For the Republic ofKazakhstan** | **For theKyrgyz Republic** | **For the RussianFederation** |
|  |  |  |  |  |

 ANNEX

to Decision No. 26 of the Council

of the Eurasian Economic Commission

dated March 17, 2022

**AMENDMENTS**

**made to the Rules for Conducting Studies (Tests)
Aimed at the Biological Evaluation of Medical Devices**

The Rules shall read as follows:

“APPROVED

by Decision of the Eurasian
Economic Commission's Council

No. 38 dated May 16, 2016

(as amended by Decision No. 26 of the Eurasian
Economic Commission's Council

 dated March 17, 2022)

RULES

for conducting studies (tests) aimed at the biological evaluation of medical devices

I. General Provisions

1. These Rules establish the procedure for conducting studies (tests) aimed at the biological evaluation of medical devices within the framework of the Eurasian Economic Union (hereinafter referred to as the Union) for the purpose of registration (hereinafter referred to as studies (tests)), including the requirements for authorized organizations entitled to conduct studies (tests) (hereinafter referred to as authorized organizations).

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

“medical device category” means a classification feature of a medical device determined when choosing methods for the biological evaluation of a medical device, depending on the group, type, and duration of contact with the medical device;

“material” means a synthetic or natural polymer, metal, alloy, ceramic or other non-viable material, including the non-viable biological tissue (which has no potential for metabolism or reproduction) used as a medical device or a part thereof;

“sample of a medical device” means a product or a representative part thereof directly subjected to studies (testing);

“standard sample of a medical device” means a sample selected from a group of medical devices belonging to the same category, produced by the same manufacturer according to the same technical documentation, and having the same composition (material), scope, and conditions of use. At the same time, a set of standard samples should reflect the totality of a group of homogeneous medical devices in terms of the composition of medical devices, taking into account differences in the properties of medical devices of individual models (brands) in this group.

The other concepts used herein shall have the meanings defined by the acts of the Union authorities in charge of the circulation of medical devices.

3. Studies (tests) shall be carried out in order to establish the compliance of a medical device with the General Requirements for the Safety and Effectiveness 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).

4. When conducting studies (tests), the requirements of the standards included in the list of standards, the voluntary compliance with which ensures the full or partial compliance of medical devices with General Requirements, as well as methods (methods) of studies (tests) certified (validated) and approved in accordance with laws of the Union Member State (hereinafter referred to as the Member State) shall apply.

5. Studies (tests) shall be carried out in the testing laboratories (centers) selected by the applicant, the information about which is included in the unified registry of authorized organizations entitled to conduct studies (testing) of medical devices for the purpose of their registration (hereinafter referred to as the registry of authorized organizations).

The generation and maintenance of the registry of authorized organizations shall be performed by the Eurasian Economic Commission (hereinafter referred to as the Commission) in accordance with the Procedure for the Generation and Maintenance of an Information System in the Field of Circulation of Medical Devices approved by Decision No. 30 of the Eurasian Economic Commission's Council dated February 12, 2016, on the basis of information provided by the Member States' public authorities authorized to implement and/or coordinate the activities in the field of circulation of medical devices (hereinafter referred to as the authorized authorities), using the means of the Union's integrated information system.

6. Studies (tests) shall be carried out in relation to medical devices and/or accessories thereto, directly or indirectly coming into contact with the surface of the human body, its mucous membranes, or internal environments of the body, where the specified interaction (contact) is required to perform their function.

7. The results of studies (tests) shall be considered negative if the provided sample(s) of a medical device do(es) not meet the safety requirements.

8. An authorized organization conducting studies (tests), as well as specialists of this organization conducting studies (tests), may not be in relations affecting their impartiality with the manufacturer of a medical device, its authorized representative, or other persons interested in the results of studies (tests).

Commercial, financial, or other pressure jeopardizing the impartiality of the authorized organization conducting studies (tests) shall be prohibited.

II. Studies (testing) procedure

9. Studies (tests) shall include:

a) determination of sanitary and chemical indicators;

b) biological evaluation *in vitro* and *in vivo*. The types of biological effects shall be subject to evaluation based on the medical device category;

c) microbial studies (tests).

10. In order to conduct studies (tests), the applicant shall submit an application to the authorized organization containing the following information:

a) medical device description;

b) name, location (address of the 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, information about the state registration of a legal entity or individual as an individual entrepreneur,
as well as contact details of the applicant (phone number, email address);

c) name and location of the manufacturer (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;

d) information about the production site(s) – the name of the legal entity or the surname, first name, patronymic (if any) of an individual registered as an individual entrepreneur, as well as the address of the place of business;

e) identification signs of a sample of a medical device (brand, model, weight, volume, date of manufacture (production), expiration date (shelf life), catalog number, factory (serial) number (batch, lot number)) etc. (if applicable));

f) the class of a potential risk of using a medical device, determined in accordance with the Rules of 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;

g) purpose and scope of application of the medical device.

11. The following documents shall be attached to the application:

user manuals and specifications (technical file) for a medical device, including the working drawings, tables, and diagrams required for conducting studies (tests). The requirements for the content of the technical file for a medical device are set forth in Annex 3 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,
for a medical device for *in vitro* diagnostics — Annex 5
to the Requirements for Implementation, Maintenance and Evaluation of Quality Management Systems for the 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;

documents containing data on the labeling and packaging of a medical device (full-color layouts of packages and labels);

the list of standards met by the medical device, as well as methods (techniques) of studies (tests), certified (validated) and approved in accordance with laws of the Member State;

copies of protocols of studies (tests) of a medical device and/or materials from which a medical device and/or accessories thereto are made, conducted in the other authorized organizations and confirming the medical device compliance with General Requirements, and/or protocols of own studies (tests) of a medical device (if available);

documents containing information about medicines in the composition of a medical device, their composition, quantity, and compatibility of the medicine with a medical device (if the medical device includes medicines);

documents containing information about the materials (including the composition, brands, and manufacturers of materials, the presence of disinfectants, biologically active substances, biocellular products, and nanomaterials) from which the medical device and/or accessories thereto are made, as well as documents confirming their compliance with the declared characteristics;

other documents confirming the medical device compliance with the General Requirements (if any).

If the documents are drawn up in a foreign language, they shall be accompanied by a translation into Russian, certified in accordance with the procedure established by laws of the Member State in the territory of which the studies (tests) are conducted.

12. The authorized organization shall, within 10 business days from the date of filing the application specified in Paragraph 10 hereof, analyze the said application and the documents attached thereto and decide on the possibility (impossibility) of conducting studies (tests).

13. If a decision on the possibility of conducting studies (tests) is made, the authorized organization shall enter into a relevant contract with the applicant.

14. Where it is decided that the studies (tests) cannot be conducted, the authorized organization shall notify the applicant of the refusal to conduct studies (tests) in writing (indicating the reasons), and return the original documents attached to the application to the applicant.

15. During the studies (testing), the authorized organization shall cooperate with the applicant in connection with the work being performed.

16. When concluding a contract for conducting studies (tests):

a) the category of the medical device shall be determined;

b) the study (testing) program shall be developed by the authorized organization jointly with the applicant;

c) the study (testing) program shall be agreed upon with the applicant and approved by the manager of the authorized organization.

17. The studies (tests) shall be carried out on samples of a medical device submitted by the applicant in accordance with the study (testing) program.

The samples of medical devices for studies (testing) shall be collected in accordance with the rules, predefined standards or certified (validated) methods (techniques) of studies (testing).

18. The samples of medical devices shall be collected by the applicant or by an authorized organization on his behalf in the presence of the applicant.

If the samples of a medical device are collected by the applicant, the sampling results shall be recorded in the certificate of delivery and acceptance of the medical device samples.

If the medical device samples are collected by an authorized organization on behalf of the applicant, the sampling results shall be recorded in the medical device sampling certificate.

19. At all stages of storage, transportation, and preparation of the collected samples of a medical device for studies (testing), the requirements established in the medical device user manual shall be met.

20. If there is a group of homogeneous medical devices specified in the studies (testing) program, the studies (tests) may be conducted on standard samples of medical devices.

Where the studies (tests) are conducted on standard samples, a relevant entry shall be made in the study (test) protocol.

21. Studies (tests) shall include the following stages:

a) analysis of the documents specified in Paragraph 11 hereof;

b) adjustment of the study (testing) program (if required);

c) receipt of standard samples (if required);

d) collection or receipt of the medical device samples and their identification based on the data provided by the applicant;

e) conducting studies (testing) of a medical device provided for by the study (testing) program;

f) preparation and issuance of the study (test) protocol to the applicant in accordance with the annex and the study (testing) program.

22. Studies (tests) shall be carried out by an authorized organization within 30 business days from the date when the samples of medical devices are received by the authorized organization in accordance with the study (testing) program, provided that the applicant pays for the work performed by the authorized organization in accordance with the concluded contract. The studies (testing) deadline may be adjourned in cases where a longer period is provided for by the method (technique) of studies (testing).

23. The results of each study (test) or series of studies (tests) conducted by an authorized organization shall be formulated accurately, clearly, unambiguously, and impartially.

24. The protocol of studies (tests) shall provide information on the methods (techniques) of studies (tests) for each parameter being evaluated, indicating the details of the relevant documents (for the methods (techniques) of studies (tests) described in the standards, the corresponding paragraphs of the standards shall be indicated).

25. Documents related to the conduct of studies (tests) shall be retained by the authorized organization in a systematized form during the period established by laws of the Member State.

III. Requirements for authorized organizations and the procedure for

assessment of their compliance with the specified requirements

26. The testing laboratory (center) shall be included in the registry of authorized organizations provided that it meets the following criteria:

a) the registration of a testing laboratory (center) or an organization including the testing laboratory (center) as a legal entity in the territory of a Member State in accordance with its laws;

b) availability of valid accreditation of the testing laboratory (center) in the national accreditation system of the Member State;

c) the scope of accreditation of the testing laboratory (center) shall include medical devices and/or groups of homogeneous medical devices, as well as types and methods of studies (testing);

d) availability of a quality management system and conformity of the testing laboratory (center) to the quality management system established in the quality manual of the testing laboratory (center);

e) availability of regulatory legal acts, standardization documents, rules and methods (techniques) of studies (tests) and measurements, including the sampling rules and other documents in the field of accreditation of the testing laboratory (center), as well as the conformity of the testing laboratory (center) to the requirements of these documents;

f) the specialist(s) of a testing laboratory (center) directly involved in the studies (testing) work shall have:

a university degree, or secondary vocational education, or additional vocational education in the major corresponding to the scope of accreditation;

at least 2 years of experience related to studies (tests) and measurements in the field of accreditation specified in the registry of accredited persons.

27. The testing laboratory (center) shall file an application for its inclusion in the registry of authorized organizations to the authorized authority.

The application shall be accompanied by documents confirming that the testing laboratory (center) meets the criteria specified in Paragraph 26 hereof.

The application shall specify the information about medical devices and/or homogeneous groups of medical devices, as well as about the types and methods of studies (testing) included in the scope of its accreditation and in respect of which the testing laboratory (center) files the application.

28. The authorized body shall, within 10 business days from the date of receipt of the application for inclusion in the registry of authorized organizations from the testing laboratory (center), consider the said application and inform the testing laboratory (center) of its decision in writing by personal service of a notice to its representative, or sending of the same by registered mail with return receipt requested, or communicate the same electronically via

telecommunication channels or in the form of an electronic document bearing an electronic digital signature.

29. If the authorized authority decides to include a testing laboratory (center) in the registry of authorized organizations, the information about the testing laboratory (center) shall be sent to the Commission using the means of the integrated information system of the Union for its entry into the registry of authorized organizations, and can also be posted on the official website of the authorized authority on the Internet.

30. Where the testing laboratory (center) fails to meet one of the criteria specified in Paragraph 26 hereof and the application for inclusion of the testing laboratory (center) in the registry of authorized organizations is rejected, the authorized body shall notify the testing laboratory (center) about the reasons for the rejection in writing by personal service of a notice to its representative, or sending of the same by registered mail with return receipt requested, or communicate the same electronically via the telecommunication channels or in the form of an electronic document bearing an electronic digital signature.

31. The decision of the authorized authority shall be challenged in accordance with laws of the Member State.

32. Storage, systematization, and amendment of information about the authorized organizations, as well as its protection against unauthorized access shall be ensured by the authorized authorities.

33. The registry of authorized organizations shall be posted on the information portal of the Union.

34. When the information contained in the registry of authorized organizations is amended, the authorized organization shall, within 30 calendar days (in the case of changes in the information on the status of accreditation of the authorized organization in the national accreditation system of the Member State – within 15 business days), submit an application for amendments to the specified information, as well as documents evidencing these amendments to the authorized authority.

35. The authorized authority shall, within 10 business days from the date of submission of the application for amending the information contained in the registry of authorized organizations by the authorized organization:

a) consider the submitted application and the documents specified in Paragraph 34 hereof;

b) send the relevant information to the Commission using the means of the integrated information system of the Union (where the authorized authority makes a decision on amendments), and may also post the same on its official website on the Internet;

c) inform the authorized organization of its decision in writing by personal service of a notice to its representative, or sending of the same by registered mail with return receipt requested, or communicate the same electronically via the telecommunication channels or in the form of an electronic document bearing an electronic digital signature.

36. The information shall be excluded from the registry of authorized organization in the following cases:

a) an application for exclusion from the registry of authorized organizations signed by the manager of the authorized organization is filed;

b) the testing laboratory (center) or an organization including the testing laboratory (center) are liquidated as a legal entity in accordance with laws of a Member State or the accreditation of an authorized organization in the national accreditation system of a Member State is terminated;

c) the authorized body reveals violations of the study (test) procedure in accordance with laws of a Member State based on the results of state control (supervision) carried out by it;

d) the information and documents provided for in Paragraph 34 hereof were not submitted or were submitted with a delay.

37. The authorized authority shall, within 3 business days from the date of the decision to exclude information from the registry of authorized organizations, ensure the submission of relevant information to the Commission using the means of the integrated information system of the Union.

38. The Commission shall make sure that the registry of authorized organizations is updated within 1 business day from the date of receipt of the relevant information.

39. The information on authorized organizations shall be provided by authorized authorities at the request of the persons concerned in accordance with laws of the Member States.

 ANNEX

to the Rules for Conducting

Studies (Tests)

Aimed at the Biological Evaluation of

Medical Devices

**F O R M**

**of the protocol for conducting studies (tests) aimed at the biological evaluation of a medical device**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(testing laboratory (center) name)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(information about the testing laboratory (center) accreditation:

number and validity period of the accreditation (certificate of accreditation)) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(address and phone number of the testing laboratory (center))

APPROVED BY

Manager of the testing

laboratory (center)

\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (signature) (surname, initials)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_

(date)

L. S.

PROTOCOL

of studies (tests) aimed at the

biological evaluation of a medical device

No. \_\_\_\_\_\_\_

Information about the medical device:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(description, brand, model, catalog number (if any),
intended purpose and scope of application)

Materials of a medical device and its accessories (if any) coming into contact with the human body:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Information about the sample(s) of the medical device:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(quantity, identification signs (brand, model, weight, volume, date of manufacture (production), expiration date (shelf life), catalog number, factory (serial) number (batch, lot number)) etc. (if applicable))

The sample(s) of a medical device is (are) a standard sample: \_\_\_\_yes \_\_\_\_no

Information on the applicant:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(applicant's contact details (phone number, email address))

Information on the manufacturer:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Information about the production facility(ies): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(name – for a legal entity or surname, first name, patronymic (if any) – for an individual registered as an individual entrepreneur, address of the place of business)

The basis for conducting studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Information about the collection of a sample(s) of the medical device, the date of receipt of a sample(s) of medical device:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Standards used as a reference in studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Methods (techniques) of studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place of studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Start date of the studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_

End date of the studies (tests):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_

Conclusion: the presented samples of a medical device

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(meet or do not meet the requirements – specify as applicable)

Submitted documents:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(name, copy or original of the document – specify as applicable, number of pages)

Results obtained from the applicant, other authorized organizations, or external suppliers:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

List of the measuring instruments and test equipment used:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Results of studies (tests):

Table No. \_\_\_

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| No. | The document used a reference for the study (test)(document paragraph) | Indicator name and/or document requirements | Method of the study (test) | Results of the study (test)1 | Conditions of the study (test) (if applicable)2 | Conclusion  |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|  |  |  |  |  |  |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1 Indicating the unit of measurement, as well as the measurement error (if applicable). The results must be unambiguously correlated with the sample of the medical device for which they were obtained.

2 Temperature, humidity, atmospheric pressure, etc.

Testing laboratory (center) specialist

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (signature) (surname, initials)

Annex. Photographic images of a general view of samples of a medical device with accessories required for its intended use (if available), and their labeling.

Notes: 1. The following information should be indicated on the last sheet of the protocol:

“The results of studies (tests) are applicable only to the tested samples of a medical device.

This protocol or a part thereof may not be reprinted without the permission of the testing laboratory (center).”.

2. The footer of the protocol shall contain information ensuring the unique identification of the protocol, the traceability of its components, as well as the end of the protocol.”.

\_\_\_\_\_\_\_\_\_\_\_\_