

**THE EURASIAN ECONOMIC COMMISSION**

**THE COUNCIL**

**DECISION**

|  |  |  |
| --- | --- | --- |
| March 17, 2022 | **No. 25** | Moscow |

**On Amending the Rules for Technical Testing 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 dated December 23, 2014,   
the Eurasian Economic Commission's Council **decided**:

1. To amend the Rules for Technical Testing of Medical Devices approved by Decision No. 28 of the Eurasian Economic Commission's Council dated February 12, 2016 (hereinafter referred to as the Rules), as attached.

2. To set out that:

technical testing of medical devices in accordance with a civil law contract concluded with an authorized organization entitled to conduct such 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 technical testing 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 of Armenia** | **For the Republic of Belarus** | **For the Republic of Kazakhstan** | **For the Kyrgyz Republic** | **For the Russian Federation** |
|  |  |  |  |  |

ANNEX

to Decision No. 25 of the Council

of the Eurasian Economic Commission

dated March 17, 2022

**AMENDMENTS**

**to the Rules for Technical Testing of Medical Devices**

The Rules shall read as follows:

“APPROVED

by Decision of the Eurasian   
Economic Commission's Council

No. 28 dated February 12, 2016

(as amended by Decision No. 25 of the Eurasian   
Economic Commission's Council

dated March 17, 2022)

RULES

for technical testing of medical devices

I. General Provisions

1. These Rules establish the procedure for technical testing of medical devices for the purpose of their registration, including the requirements for authorized organizations entitled to conduct technical tests (hereinafter referred to as the authorized organizations) within the framework of the Eurasian Economic Union (hereinafter referred to as the Union).

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

“tests” mean the experimental determination of quantitative   
and/or qualitative characteristics of properties of the test object as a result of influence on it exercised during its operation, modeling of the object and/or impact on the object;

“test method” means the rules of applying certain principles and means of testing;

“test techniques” means a standard operating procedure that includes a test method, means and conditions of testing, sampling conditions, algorithms for performing operations to determine one or more interrelated characteristics of the object properties, data presentation forms, and calculations required to obtain the result;

“test program” means an organizational and methodological document establishing the object and objectives of tests, types, methods (techniques) of tests, the sequence and scope of experiments conducted, the procedure, terms, conditions, place, and timing of tests.

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. Technical testing shall be conducted 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 technical testing, 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 the declared specifications of a medical device used by the manufacturer to confirm the compliance of a medical device with General Requirements shall apply.

In the absence of standards containing the rules and methods of studies (tests) and measurements included in the specified list of standards, for the purpose of conducting technical tests, test methods (techniques) certified (validated) and approved in accordance with laws of the Member State of the Union (hereinafter referred to as the Member State) may be used.

5. Technical testing shall be carried out at the testing laboratories (centers) selected by the applicant entitled to conduct technical testing, 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. Technical testing shall not be carried out with respect to reagents, reagent kits, control materials, calibrators, washing solutions, and nutrient media.

7. The results of technical testing shall be considered negative if the submitted sample(s) of the medical device do(es) not meet the requirements of the standards, as well as the declared specifications of the medical device, which the manufacturer uses to confirm the medical device conformity to the General Requirements.

8. In respect of medical devices, the technical testing or installation (commissioning) of which requires the obtaining of permits (for example, licenses), construction of individual capital structures, or major repairs, it is allowed to conduct technical testing by specialists of an authorized organization in the territory of the manufacturer of the medical device or in the organization   
where the medical device is located and/or approved for use in accordance with laws of the relevant State.

9. Technical testing in cases specified in paragraph 8 hereof shall comply with the requirements of the current quality management system of the authorized organization.

10. An authorized organization conducting technical tests, as well as specialists of this organization conducting technical 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 tests.

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

II. Technical testing procedure

11. In order to conduct technical 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, software version, 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.

12. 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 the technical testing. 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 draft test program developed by the applicant, indicating the requirements of the standards and/or the declared specifications of the medical device, the proof of conformity to which shall be used by the manufacturer to prove the conformity of the medical device with the General Requirements, as well as test methods (techniques) certified (validated) and approved in accordance with laws of the Member States, which are supposed to be used;

a list of standards to which the medical device conforms, as well as test methods (techniques) certified (validated) and approved in accordance with laws of the Member States;

copies of the protocols of technical tests carried out in the other authorized organizations and proving the conformity of the medical device with the General Requirements, and/or protocols of in-house tests of the medical device (if available);

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 technical tests are conducted.

13. The authorized organization shall, within 10 business days from the date of filing the application specified in paragraph 11 hereof, analyze this application and the documents attached thereto and decide on the possibility (impossibility) of technical testing.

14. If a decision on the possibility of the technical testing is made, the authorized organization shall enter into a relevant contract with the applicant.

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

16. During the technical testing, the authorized organization shall cooperate with the applicant in connection with the work being performed.

17. Technical testing shall be carried out on samples of a medical device submitted by the applicant in accordance with the test program.

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

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 technical 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 test program, the technical testing may be conducted on standard samples of medical devices manufactured according to the unified technical documentation.

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. Where the technical testing is conducted on standard samples, a relevant entry shall be made in the technical testing protocol.

8. The technical testing shall include the following stages:

a) analysis of the documents specified in paragraph 12 hereof;

b) approval of the test program by the authorized organization;

c) collection or receipt of the medical device samples and their identification;

d) obtaining of special equipment developed by the manufacturer for technical testing of a specific medical device and indicated by it in the technical documentation (if required);

e) conducting of tests provided for in the test program;

f) preparation and issuance of the technical testing protocol(s) for a medical device to the applicant in accordance with the annex and the testing program.

22. Technical testing 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 testing program, provided that the applicant pays for the work performed by the authorized organization in accordance with the concluded contract. The deadline for technical tests, in agreement with the applicant, may be adjourned by the head of the authorized organization, but for no more than 20 business days or for another period provided for by the test method (technique).

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

24. The protocol of technical tests shall provide information about the test methods (techniques) for each indicator being determined, indicating the details of the relevant documents (for the test methods (techniques) described in the standards, the corresponding paragraphs of the standards shall indicated).

25. Documents related to the technical testing 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 technical 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 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 technical testing 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 the technical testing 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 technical testing included in the scope of its accreditation and in respect of which the testing laboratory (center) files the application.

28. The authorized authority 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 authority 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 technical testing 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 Technical

Testing of Medical Devices

**F O R M**

**of the protocol for technical testing 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

for technical testing of a medical device

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

Information about the medical device:

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

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

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

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

(quantity, identification signs (brand, model, software version, weight, volume, date of manufacture,   
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 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 during tests:

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

Test methods (techniques):

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

Place of tests:

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

Start date of the tests: \_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_

End date of the 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:

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

Testing results:

Table No. \_\_\_

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| No. | The document used a reference during tests  (document paragraph) | The name of the indicator and/or document requirements | Test method | Test results1 | Test conditions (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 test results 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.”.

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