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EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

February 12, 2016 **No. 28** city of Moscow

On Approval of Rules for Technical Testing of Medical Products

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 Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraphs 105 and 106 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 by Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union", the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached Rules for Technical Testing of Medical Products.

4. This Decision shall enter into force after 10 calendar days have elapsed from the effective date of the Protocol, signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for 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
Seal: *Eurasian Economic Commission. For documents*	Seal: *Eurasian Economic Commission. For documents*	Seal: *Eurasian Economic Commission. For documents*	Seal: *Eurasian Economic Commission. For documents*	Seal: *Eurasian Economic Commission. For documents*
V. Gabrielyan	**V. Matyushevskiy**	**B. Sagintaev**	**O. Pankratov**	**I. Shuvalov**

APPROVED
by Decision No. 28 of the Council of
the Eurasian Economic Commission
dated February 12, 2016

RULES
for technical testing of medical products

I. General provisions

1. These Rules are developed in accordance with paragraph 2 of Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 4 and 5 of Article 4 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 in order to execute the specified Agreement and establish within the Eurasian Economic Union (hereinafter referred to as the Union) the rules for technical testing of medical products, requirements to the authorized authorities, which have a right to perform technical testing of medical products, as well as procedure for evaluation of compliance of the authorized authorities with these requirements.

2. Technical testing of medical product is carried out in accordance with these Rules in order to determine the compliance of medical products with general requirements for safety and efficacy of medical products, requirements for their marking and operational documentation on them, approved by the Eurasian Economic Commission (hereinafter referred to as the general requirements).

When carrying out technical testing, standards included in the list of standards can be used, as a result of the use of which, on a voluntary basis, the compliance of the medical product with general requirements (hereinafter referred to as the list of standards), as well as the technical documentation of the medical product manufacturer, is ensured in whole or in part.

If standards included in the list of standards are absent, test methods, certified (validated) and approved in accordance with the laws of the Member States of the Union (hereinafter referred to as the Member States) can be used to carry out technical testing of medical products.

3. Technical testing of a medical product is carried out on the application of manufacturers of medical products or their authorized representatives in institutions, organizations and enterprises that are included by public authorities authorized to implement and (or) coordinate activities in the field of medical products circulation in the territories of Member States (hereinafter after referred to as the authorized authorities), in the list of organizations authorized to perform research (tests) of medical products for the purpose of their registration (hereinafter referred to as the list of organizations, authorized organizations).

For the purposes of application of these Rules, an authorized representative of a manufacturer means a juridical person or natural person registered as an individual entrepreneur who are residents of a Member State and in accordance with the authority of the manufacturer of the medical product they are authorized to represent his interests and be responsible for the medical product circulation within the Union and compliance with mandatory requirements for medical products.

4. In order to obtain evidence of compliance of the medical product with general requirements, the applicant is entitled to independently apply to authorized organizations in order to carry out technical testing of medical products for compliance with specific standards in whole or in part and (or) certified (validated) test methods, confirming compliance of medical products with general requirements.

5. For medical products for in vitro diagnostics (reagents, reagent kits), no technical testing is performed.

6. The results of technical testing of medical products are considered negative if the submitted samples (sample) of the medical product do not meet general requirements and standards included in the list of standards for compliance with which the test was performed.

7. In exceptional cases, for medical products, transportation of which to an authorized organization is difficult, technical testing is allowed to be performed by experts of the authorized organization in the territory of the manufacturer.

II. Rules for technical testing of medical products

8. For technical testing of a medical product, the applicant submits to the authorized organization an application containing the following information:

a) medical product name;

b) applicant's name, his location (address of a juridical person) - for a juridical person or surname, name, patronymic (if any), place of residence - for a natural person registered as an individual entrepreneur, information on the state registration of a juridical person or natural person as an individual entrepreneur;

c) manufacturer's name, its location (address of a juridical person), addresses of its branches that manufacture products - for a juridical person or surname, name, patronymic (if any), place of residence - for a natural person registered as an individual entrepreneur;

d) identification features of the medical product (brand, model, mass, volume, date of manufacture, expiration dates (life time), etc.) (if any).

9. Together with the application, the applicant submits the following sets of documents:

a) technical and operational documentation for the medical product (working drawings, tables and diagrams, if they are contained in the operational documentation, technical regulations for product launching into manufacture);

b) data on the medical product marking and package;

c) medical product test program developed by the applicant;

d) list of standards included in the list of standards to which the medical product corresponds;

e) protocols of medical product that confirm the compliance of the medical product with general requirements (if any);

e) other documents confirming the compliance of the medical product with general requirements.

10. The authorized organization conducts an analysis of the application and documents attached to it within at most 10 calendar days from the date of filing the application.

If the authorized organization decides to conduct technical testing of the medical product, a corresponding contract with the applicant is concluded.

If a negative decision is taken, the authorized organization notifies the applicant in writing of the refusal to conduct technical testing of the medical product (with indication of reasons).

11. During technical testing, the authorized organization should cooperate with the applicant in connection with the work performed.

12. Technical testing of medical products is carried out on samples of the medical product provided by the applicant.

Medical product samples for technical testing are collected in accordance with the rules established by standards included in the list of standards and (or) certified (validated) test methods.

Medical product samples are collected by the applicant or on his behalf by an authorized organization in the presence of the applicant.

In case if medical product samples are collected by the applicant, information about them is indicated in the application.

In case if medical product samples are collected by the authorized organization on behalf of the applicant, sampling results are documented by the act of medical product sample collection.

At all stages of storage, transportation and preparation for technical testing of collected samples of the medical product, the requirements established in operational documents for the medical product should be observed.

13. If there is a group of homogeneous medical products, it is allowed to conduct technical testing on standard samples of medical products manufactured according to one normative document and using a single technology.

In this case, a batch of standard samples in composition of medical products should reflect the entire set of a group of homogeneous medical products, taking into account differences in properties of certain types of medical products (brands, models) in this set.

In case of technical testing on standard samples, a record about the dissemination of the results of technical testing of standard samples to a certain group of homogeneous medical products is made in the technical test report.

14. Technical testing of the medical product includes the following steps:

a) analysis of technical and operational documentation for the medical product, as well as protocols of previous technical testing (if any);

b) sampling and identification of the medical product;

c) technical testing of the medical product provided for by a test programme for the medical product developed by the applicant and coordinated with the authorized authority;

d) execution and issuance of the protocol of medical product technical testing to the applicant according to the form in accordance with the annex.

15. Results of each technical testing or series of technical testing of the medical product carried out by an authorized organization should be formulated accurately, clearly, unequivocally and objectively.

16. Documents on technical testing of the medical product are stored in the authorized organization in a non-random manner for at least 10 years from the date of completion of technical testing.

III. Requirements for the authorized organizations and procedure for evaluation of their compliance with the specified requirements

17. The list of organizations includes testing laboratories (centers) in accordance with the following criteria:

a) registration of the testing laboratory (center) as a legal entity in accordance with the legislation of the Member State;

b) a testing laboratory (centers) has a valid accreditation certificate in the national accreditation system of the Member State;

c) availability of medical products and (or) groups of homogeneous medical products, as well as types and methods of technical testing of medical products in the field of accreditation of a testing laboratory (center);

d) availability of satisfactory results of interlaboratory comparative tests (interlaboratory comparisons);

e) existence of a management system and compliance with the requirements of the management system established in the quality manual of the testing laboratory (center) in the activity of the testing laboratory (center);

f) existence of normative legal acts, documents in the field of standardization, rules and methods of research (tests) and measurements, including sampling rules, and other documents in the field of accreditation of the testing laboratory (center), and compliance of the testing laboratory (center) with the requirements of these documents;

g) a specialist (specialists) of the testing laboratory (center) who directly performs technical testing has:

higher education, or secondary vocational education, or additional professional education on the profile corresponding to the field of accreditation;

at least, a 3-year experience in research (tests), measurements in the field of accreditation specified in the application for accreditation or in the register of accredited persons.

18. Authorized authorities consider applications of testing laboratories (centers) for inclusion in the list of organizations and notify the testing laboratory (center) of the decision taken in writing not later than 10 calendar days from the date of filing of the application.

Together with the application, documents confirming the compliance of the testing laboratory (center) with the criteria set forth in paragraph 17 of these Rules are also submitted.

In the application for the inclusion of a testing laboratory (center) in the list of organizations, information on medical products and (or) homogeneous groups of medical products, as well as types and methods of technical testing of medical products included in the field of its accreditation, for which the testing laboratory (center) submits an application, is indicated.

If the authorized authority adopts a positive decision, the testing laboratory (center) is included in the list of organizations.

In case if the testing laboratory (center) does not confirm to the specified criteria and the negative decision is taken, the authorized authority notifies the testing laboratory (center) in writing of the refusal causes.

Testing laboratories (centers) included in the unified register of authorities of assessment of the compliance of the Union and having a right to conduct technical testing of medical products are included by authorized authorities in the list of organizations according to the applications of the said testing laboratories (centers) in which their scope of accreditation should be indicated.

19. The decision of the authorized authority is appealed against in accordance with the legislation of the Member State.

20. Authorized authorities ensure storage, systematization, updating and modification of information on authorized organizations, as well as protection against unauthorized access to it.

The list of organizations is posted on the official websites of the authorized authorities in the information and telecommunications network Internet and in the open part of the information system of the Union in the sphere of medical products circulation.

The authorized authorities within 3 working days after introduction of changes to the information contained in the list of organizations place relevant information on their official websites in the information and telecommunications network “Internet”, as well as submit it to the Eurasian Economic Commission using the integrated information system of the Union.

21. Authorized authorities provide information on authorized organizations upon request of interested parties in accordance with the legislation of the Member States.

Seal:

Eurasian Economic Commission. For documents

ANNEX
to the Rules for technical testing
of medical products

FORM
of the protocol of technical testing of medical product

_____
(testing laboratory (center) name)

_____
(accreditation certificate of testing laboratory (center), number, validity)

_____
(address, telephone of the testing laboratory (center))

APPROVED
Head of the testing laboratory (center)

_____ _____
(signature) (initials, surname)
L. S.

PROTOCOL
of technical testing
No._____ dated _____ "___", _____
Page____ / Number of sheets_____

Applicant_____
Product name_____
Test type_____
Basis_____
Manufacturer_____
Batch, lot_____ Date of manufacture_____
Date of expiration (shelf life)_____
Number of samples_____
Date of start and end of testing_____
Standards, on compliance with which testing was performed_____
Test methods_____

Test results:

Indicator name	Standard requirement	Actually obtained results	Temperature (^{0}C) and humidity (%)

Conclusion: presented samples
_____
(comply, do not comply with the requirements – indicate the necessary)

Laboratory specialist _____ _____
(signature) (initials, surname)
Laboratory specialist _____ _____
(signature) (initials, surname)

The test protocol applies only to samples, including typical ones, subjected to testing.

Full or partial reprint of the protocol is prohibited without permission of the testing laboratory (center).

(a record of application of test results of standard samples to a certain list of homogeneous products (if any))