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EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

May 16, 2016 **No. 38** city of Moscow

On Approval of the Rules for Studies (Tests) for Evaluation of Biological Action of Medical Products

In accordance with 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 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 Rules for Studies (Tests) for Evaluation of Biological Action of Medical Products

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
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. 38 of the Council
of the Eurasian Economic Union
dated May 16, 2016

RULES
for studies (tests) for evaluation of biological action of medical products

I. General provisions

1. These Rules are developed in accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and 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 and establish within the Eurasian Economic Union the procedure for studies (tests) for evaluation of biological action of medical products for registration, requirements for authorized organizations having a right to perform studies (tests) for evaluation of biological action of medical products (hereinafter referred to as the authorized organizations) as well as procedure for evaluation of compliance of authorized organizations with these requirements.

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

"hemocompatibility study" - identification of negative biological effects when a medical product contacts human blood or any of its components;

"pyrogenicity study" – examination of absence of chemical agents or other substances in medical products capable to trigger fever response (body temperature rise);

"sterility study" – examination of presence or absence of viable microorganisms in a medical product;

"material" - any synthetic or natural polymer, metal, alloy, ceramic or other non-viable material, including non-viable biological tissue used as a medical product or its part;

"acute systemic toxicity" - an adverse effect that occurs at any time after the administration of a single or multiple doses of the test sample within 24 hours;

"irritant effect" - a localized inflammatory response of the human body to a single, repeated or prolonged exposure to the test material without involving the immune mechanism;

"specification" - a document made in the form of a table defining medical product composition and containing notations and description of its components, accessories and consumables with indication of names and quantity;

"standard sample" - a material with established measurement accuracy and metrological traceability, sufficiently uniform and stable with respect to certain properties, in order to use it when measuring or evaluating quality properties in accordance with the intended purpose;

"authorized representative of the manufacturer" – a juridical person or natural person registered as an individual entrepreneur who is a resident of a member state of the Eurasian Economic Union and authorized in accordance with the Power of Attorney of the manufacturer of a medical product to represent his interests and be responsible for the medical product circulation within the Eurasian Economic Union and fulfillment of mandatory requirements for medical products;

"cytotoxicity" - ability of chemical substances contained in the material to cause pathological changes in cells of the human body.

3. Studies (tests) to evaluate the biological action of medical products (hereinafter referred to as tests) are conducted 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 for them (hereinafter referred to as the general requirements).

When performing tests, 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 the general requirements (hereinafter referred to as the list of standards) is ensured in whole or in part, technical documentation of the manufacturer of the medical product, as well as test methods certified (validated) and approved in accordance with the laws of the member state of the Eurasian Economic Union (hereinafter referred to as member states of the Union, respectively).

4. Tests are carried out at the request of the manufacturer of the medical product or his authorized representative (hereinafter referred to as the applicant) in institutions, organizations and enterprises that are included in the unified register of authorized organizations. The unified register of authorized organizations is placed by the Eurasian Economic Commission in the information system of the Union in the sphere of medical products circulation on the official website of the Union in the information and telecommunications network Internet.

5. In order to obtain evidence of compliance of the medical product with general requirements, the applicant has the right to independently apply to authorized organizations for testing for compliance with specific standards (in whole or in part) and (or) certified (validated) methods, confirming compliance of the medical product with the general requirements.

II. Test procedure

6. Tests are carried out in relation to medical products and (or) accessories to medical products that come into contact with the surface of the human body, its mucous membranes, internal environments of the body.

7. The tests include the examination of:

a) physical and chemical indicators (in terms of the physical chemistry of the materials from which the medical product is made and (or) medical product accessories);

b) sanitary and chemical indicators;

c) biological indicators under in vitro and in vivo conditions.

8. In order to conduct the tests, the applicant submits to the authorized organization an application for testing, containing the following information:

a) medical product name;

b) legal organizational form of the applicant, full and abbreviated (if any) name of a juridical person, location (surname, name, patronymic (if any), place of residence of a natural person registered as an individual entrepreneur), postal address, information on the state registration of a juridical person or natural person as an individual entrepreneur (if the applicant is an authorized representative of the manufacturer, the specified information is also provided in respect of the medical product manufacturer);

c) identification features of the medical product: model, mass, volume, date of manufacture, batch, expiry date (life time) (if any).

9. The following is submitted together with the application:

a) specification of the medical product manufacturer;

b) technical and operational documentation of the manufacturer for the medical product;

c) documents containing information on the regulatory documents for the materials of which the medical device is made and (or) medical product accessories which are in contact with the human body surface, its mucous membranes, internal environment (hereinafter referred to as the materials of which the medical product is made and (or) accessories to the medical product);

d) documents containing data on drug products in composition of the medical product, composition, quantity, data on compatibility of the drug product with the medical product (if the medical product contains drug products);

e) documents containing information on the composition of materials of which the medical product is made and (or) accessories to the medical product;

f) copies of protocols of the test on biocompatibility of the medical product and (or) materials of which the medical product and (or) accessories to the medical product are made (if any);

g) standard samples (if this is provided for by methods of sanitary and chemical studies).

10. In case if the documents referred to in paragraph 9 of these Rules are drawn up in a foreign language, subject to the relevant requirements in the legislation of the Member State a translation of these documents certified by the applicant into the state language (state languages) of the Member State, in the territory of which the tests are carried out, is provided.

11. The authorized organization within no more than 10 calendar days from the date of filing the application, analyzes the submitted application and documents and standard samples attached to it and notifies the applicant of the decision taken.

If the authorized organization makes a decision to conduct tests, a corresponding agreement is concluded.

In case of a negative decision, the authorized organization notifies the applicant in writing of the refusal to carry out tests with indication of reasons and return the standard samples specified in subparagraph “g” of paragraph 9 of these Rules.

In case of disagreement with the refusal to carry out tests, the applicant is entitled to appeal against the refusal in accordance with the procedure established by the legislation of the Member State, the authorized organization of which refused to carry out tests.

12. A test program is developed by the authorized organization in cooperation with the applicant and approved by the head of the authorized organization.

13. Collection of samples (specimens) of medical products (materials of which a medical product and (or) accessories to the medical product is made) for testing is carried out by the authorized organization in accordance with the rules established in the standards included in the list of standards and (or) certified (validated) test methods and is executed by the relevant act.

14. In exceptional cases, for samples (specimens), transportation of which is difficult to the authorized organization, testing by experts of the authorized organization in the territory of the manufacturer is allowed.

15. The tests include the following steps:

a) analysis of the documents specified in subparagraphs “a” – “e” of paragraph 9 of these Rules;

b) sample (specimen) collection and identification of the medical product (materials of which the medical product and (or) accessories to the medical product are made);

c) determination of the duration of contact of the medical product and (or) accessories to the medical product with the human body surface, its mucous membranes, internal environments of the body;

d) performance of tests of the medical product (materials of which the medical device and (or) accessories to the medical product are made) provided for in the test program;

e) registration and issue of a protocol based on the results of tests in accordance with the form provided in the annex to the applicant.

16. Disposable medical products that are put into circulation in sterile form are subjected to sterility studies.

Medical products that come into contact with human blood and its components, implantable medical products, as well as medical products intended for the injection of medical products, are subject to obligatory studies on acute systemic toxicity, cytotoxicity, irritant effect, pyrogenicity, hemocompatibility, bacterial endotoxin content.

The choice of methods of evaluation of the biological action of medical products is based on the category of the medical product, depending on the type and duration of contact with the human body.

17. During the tests, the authorized organization determines:

a) conformity of the medical product (materials of which the medical product and (or) accessories to the medical product are made) to the requirements of the standards included in the list of standards, technical and operational documentation of the manufacturer;

b) compliance of the documentation for the medical product submitted by the applicant with the requirements of the standards included in the list of standards;

c) completeness and objectivity of the characteristics specified by the technical and operational documentation of the manufacturer subject to control during tests, as well as the test methods used;

d) conformity (non-conformity) of the submitted samples (specimens) of the medical product (materials of which the medical product and (or) accessories to the medical product are made) to general requirements.

18. The tests are carried out by the authorized organization within a period of not more than 30 working days from the date of completion of collection of samples (specimens) of the medical product (materials of which the medical product and (or) accessories to the medical product are made) specified in paragraph 13 of these Rules, except for the cases where a longer period is provided for by the test method.

19. Test results are considered negative if the samples (specimens) of the medical product (materials of which the medical product and (or) accessories to the medical product are made) submitted for tests do not confirm to the general requirements.

20. Based on the results of tests of the medical product carried out in order to evaluate the biological action, the authorized organization draws up a protocol according to the form provided for in the annex to these Rules.

21. The test documentation is kept in the authorized organization in a systematic manner for at least 10 years from the date of completion of the tests.

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

22. Testing laboratories (centers) are included in the unified register of the authorized organizations in accordance with the following criteria:

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

b) testing laboratory (center) 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 tests in the field of accreditation of the testing laboratory (center);

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

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

f) availability of regulatory legal acts, documents in the field of standardization, test and measurement rules and methods, including rules for sample (specimen) collection and other documents in the field of accreditation of the testing laboratory (center), as well as compliance of the testing laboratory (center) with the requirements of these documents;

g) specialists of the testing laboratory (center) who directly perform test works have:

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 test and measurements in the field of accreditation specified in the application for accreditation or in the register of accredited persons.

23. 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 no 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 22 of these Rules are also submitted.

In the application for the inclusion of the 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 test 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 carry out tests are included by authorized authorities in the list of authorize organizations according to the applications of the said testing laboratories (centers) in which their scope of accreditation should be indicated.

24. The decision of the authorized authority is appealed against in accordance with the legislation of the Member States.

25. Information on testing laboratories (centers) is introduced in the unified register of authorized organizations by the Eurasian Economic Commission in accordance with the lists of authorized organizations determined by the authorized authorities.

26. 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 the authorized 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.

27. The authorized authorities within 3 working days after introduction of changes to the information contained in the list of authorized 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.

The Eurasian Economic Commission within 1 working day ensures updates of the unified register of authorized organizations.

26. 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 studies (tests) for
evaluation of biological action
of medical products

FORM
of protocol of studies (tests) for biological action
of medical products

_____
(testing laboratory (center) name, address, phone number)

APPROVED
Head of the testing laboratory (center)

_____ _____
(signature) (initials, surname)

L. S.

PROTOCOL
of studies (tests) for evaluation of
biological action of medical products
No._____ dated _____ "_____", _____

_____
(medical product name)

Drafted by:_____
(testing laboratory (center) name)

_____
(place of studies (tests) performance)

Accreditation certificate of the testing laboratory (center) _____
(number, date of issue, field of accreditation)

valid thru _____ "____", 20_____
1. For the period from _____ "____", 20_____ till _____ "_____", 20_____

_____
(testing laboratory (center) name)

Studies (tests) for evaluation of biological action were performed

_____
(name of the medical product, name of accessories to the medical product
required for the intended use of the medical product)

manufactured by _____
(name of the manufacturer, country of manufacture)

Batch Date Expiry date
Lot_____ of manufacture _____ (life time) _____
Number of samples_____

2. Results of tests (studies):

Indicator name	Requirements	Actually obtained results	Temperature (^{0}C) and humidity (%)
1	2	3	4

3. Conclusion.
The presented samples (specimens)
_____
(comply, do not comply with the requirements – indicate the necessary)
Methods _____
(reproducible, not reproducible – indicate the necessary)

Specialist of the testing laboratory (center) _____ _____
(signature) (initials, surname)
Specialist of the testing laboratory (center) _____ _____
(signature) (initials, surname)

This protocol applies only to samples of medical products subjected to studies (tests).