On approval of the Rules for the conduct of technical testing

Invalidated Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated September 6, 2019 № ҚР ДСМ-124. Registered with the Ministry of Justice of the Republic of Kazakhstan on September 10, 2019 № 19356. The footnote. Abrogated by Order of the Minister of Health of the Republic of Kazakhstan dated 21.12.2020 № KR DSM-298/ 2020.

Unofficial translation

Footnote. Abrogated by Order of the Minister of Health of the Republic of Kazakhstan dated 21.12.2020 № KR DSM-298/2020 (effective ten calendar days after the date of its first official publication).

In accordance with clause 3 of article 73 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" I HEREBY ORDER:

1. To approve the attached Rules for the conduct of technical testing.

2. The Committee for Quality and Safety Control of Goods and Services of the Ministry of Health of the Republic of Kazakhstan in accordance with the procedure established by the law shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten calendar days from the state registration of this order, submission to the Department of Legal Service of the Ministry of Health of the Republic of Kazakhstan of information about implementation of measures, stipulated by sub-clauses 1) and 2) of this clause.

3. Control over execution of this order shall be entrusted to the vice-minister of Health of the Republic of Kazakhstan Nadyrov K.T.

4. This order shall come into force upon expiry of ten calendar days after the date of its first official publication.

Minister *Ye. Birtanov*

Approved by the order of the
Minister of Health of the
Republic of Kazakhstan
dated September 6,
2019 no. ДСМ-124

Rules for the conduct of technical testing

Chapter 1. General provisions

1. These Rules for the conduct of technical testing (hereinafter referred to as the Rules) have been developed in accordance with clause 3 of article 73 Кодекса of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" and shall determine the procedure for the conduct of technical testing.

2. Technical testing of medical devices shall be carried out in the form of testing and (or) assessment and analysis of data for verification of quality and safety when their use in accordance with designation, provided for by the documentation of the manufacturer of a medical device.

Chapter 2. Procedure for the conduct of technical testing

3. For conducting technical testing, the manufacturer of a medical device or his official representative shall provide to the testing laboratory:

1) application for the conduct of technical testing of medical devices in the form according to Annex 1 to these Rules;

2) regulatory documents for medical devices indicating the list of standards to which medical devices correspond;

3) technical and operational documentation for a medical product (working drawings, tables and diagrams, technical regulatory documents for putting products into production);

4) a technical testing program for a medical device developed by the applicant;

5) copies of protocols of technical testing of a medical device (if available);

6) data on marking and packaging of a medical device;

7) samples of medical devices.

4. Technical testing of a medical device shall include:

1) analysis of regulatory, technical and operational documentation for a medical device, technical testing programs, as well as protocols of previous testing and decision-making on conducting technical testing;

2) selection of samples and identification of a medical device;

3) conducting technical testing of a medical device in accordance with a technical testing program for a medical device developed by the applicant;

4) execution and issuance of the medical device technical testing report to the applicant.

5. The testing laboratory within 10 calendar days from the date of application for the technical testing of a medical device shall analyze the documents submitted by the applicant.

In case of making decision on conducting technical testing of a medical device, the testing laboratory shall enter into a corresponding agreement with the applicant in

accordance with the Civil Code of the Republic of Kazakhstan dated December 27, 1994.

In case of impossibility to carry out technical testing of a medical device, the testing laboratory shall notify the applicant in writing (arbitrary) of the refusal to conduct technical testing of the medical device (indicating the reasons).

6. Technical testing of medical devices shall be conducted on the samples of a medical device provided by the applicant.

Selection of samples of a medical device shall be carried out by the applicant or on his instructions by the testing laboratory in the presence of the applicant.

In case if selection of the samples of a medical device is carried out by the applicant, this information shall be specified in the application.

In case if selection of the samples of a medical device is carried out by the testing laboratory on instructions of the applicant, the results of selection shall be executed by the act of selection of samples of a medical device in the form according to Annex 2 to these Rules.

Conditions established in the regulatory, technical or operational documentation for a medical device shall be observed at all stages of storage, transportation and preparation for technical testing of selected samples of a medical device.

7. Technical testing shall not be carried out in relation in vitro diagnostic medical device - (reagents, reagent kits).

8. During the technical testing of samples of a medical device, the testing laboratory shall evaluate:

1) compliance of a medical device with the parameters presented in regulatory, technical or operational documentation;

2) the completeness and objectivity of the properties established by regulatory documents to be controlled during the introduction of medical devices, as well as the frequency, control plans and its methods;

3) design and operability of medical devices in terms of safety, usability, operational and ergonomic indicators;

4) marking and packaging of a medical device.

9. In the presence of a group of homogeneous medical devices, technical testing shall be allowed on standard samples of medical devices produced according to one regulatory document and according to a uniform technology.

At the same time, the selection of standard samples in composition of medical devices shall represent the whole range of a group of homogeneous medical devices, taking into account the differences in the properties of individual types of medical devices (brands, models) in this range.

In the case of technical testing on standard samples, the protocol of technical testing shall indicate the distribution of the results of technical testing of standard samples for a specific group of homogeneous medical devices.

10. In the case of large-sized of medical devices of 2b and 3 classes of potential risk of use, the installation of which requires special equipment, technical testing shall be carried out in the form of a technical assessment based on the analysis of technical documentation and documents demonstrating the results of technical testing carried out by the testing laboratories of the manufacturer.

11. The duration of technical testing shall be determined by the purpose and complexity of medical devices, the completeness and quality of the documentation submitted by the applicant, but shall not exceed 30 calendar days, if the period is not determined when considering technical documentation.

12. The results of technical tests carried out by the testing laboratory shall be made out in the form of a protocol of technical tests of a medical device in the form according to Annex 3 to these Rules.

13. The results of technical tests of medical devices shall be considered negative if the submitted samples (sample) of a medical device do not meet the regulatory, technical or operational documentation of a the medical device and (or) the standards included in the list of standards, for compliance with which the technical testing of the medical device has been carried out.

14. Documents for conducting technical testing of a medical device shall be kept in a testing laboratory in a systematic form 10 years from the date of completion of the technical testing.

Annex 1
to the Rules for conduct of
technical testing
Form

Application for the conduct of technical testing

1. Information about a medical device:

1.1	Name of a medical device (indicating a model, brand)		
1.2	Purpose and scope of application of the medical device as determined by the manufacturer		
1.3	Class depending on the degree of the potential risk of use (mark as necessary)	Class 1 Class 2a Class 2б Class 3	☐ ☐ ☐ ☐

1.4	Nomenclature code of the Global Medical Device Nomenclature (if available)		
1.5	Code of the Medical Device Nomenclature of the Republic of Kazakhstan (if available)		
1.6	Presence of a medical preparation in the composition (mark as necessary)	Yes No	☐ ☐

2. Information about the completion of the medical device (indicating a model, brand):

2.1	Main unit (if available)	
2.2	Appliance (if available)	
2.3	Additional components (if available)	
2.4	Software (if available)	
2.5	Expendable materials (if available)	

3. Information about the samples of the medical device

3.1	Package type (mark as necessary)	Primary Secondary	☐ ☐
3.2	Package material		
3.3	Number of units in a package (if necessary)		
3.4	Shelf life / Warranty period		
3.5	Transportation conditions		
3.6	Storage conditions		
3.7	The need for selection of samples by testing laboratory specialists (mark as necessary):	Yes No	☐ ☐

4. Information about the developer/manufacturer of the medical device:

4.1	Developer of the medical device:	
4.1.1	Name of legal entity	
4.1.2	Abbreviated name of the legal entity (if available)	
4.1.3	Country, address (location) of legal entity	
4.1.4	Telephone numbers	
4.1.5	e-mail address of legal entity	
4.2	Manufacturer of the medical device:	
4.2.1	Name of legal entity	
4.2.2	Abbreviated name of the legal entity (if available)	

4.2.3	Country, address (location) of legal entity	
4.2.4	Telephone numbers	
4.2.5	e-mail address of legal entity	
4.3	Authorized representative of the manufacturer of the medical device in the territory of the Republic of Kazakhstan:	
4.3.1	Name of legal entity	
4.3.2	Abbreviated name of the legal entity (if available)	
4.3.3	Country, address (location) of legal entity	
4.3.4	Telephone numbers	
4.3.5	e-mail address of legal entity	
4.4	Place of manufacture of the medical device	

5. Information about the applicant (data under a power of attorney):

5.1	Legal entity:	
5.1.1	name of the legal entity	
5.1.2	Abbreviated name of the legal entity (if available)	
5.1.3	Address (location) of legal entity a	
5.1.4	Telephone numbers	
5.1.5	e-mail address of legal entity	
5.2	Individual, registered as an individual entrepreneur:	
5.2.1	Surname, name, patronymic (if available)	
5.2.2	Telephone	
5.2.3	Fax	
5.2.4	E-mail	
5.3	Bank details:	
5.3.1	Business Identification Number	
5.3.2	Individual Identification Number	
5.3.3	Bank	
5.3.4	Bank account	
5.3.5	Currency account	
5.3.6	Code	
5.3.7	Bank Identification Code	

_____

(Surname, name, patronymic (if available) of the head of the legal entity or other person, authorized to act on behalf of this legal entity)

_____

(Signature)
"__" _____ 20__

Annex 2
to the Rules for conduct of
technical testing
Form

Act of selection of samples of a medical device
no. _____ от "___" _____ 20___

Applicant _____
_____
(name of organization, address)
Address and the place of selection of samples _____
_____
Selection of samples was performed by _____
_____
(Surname, name, patronymic (if available) of a person, performed the selection of samples)
The act was drawn up by _____
_____
(Surname, name, patronymic (if available) of the representative of the testing laboratory)
In participation of _____
_____
(Surname, name, patronymic (if available) of the applicant or his representative)
Samples of presented products were selected in accordance with _____
____
_____
_____
(name of the regulatory document)
For conducting technical testing of a medical device _____
_____
_____
(name of a medical device)
Manufacturer of a medical device _____
__
(full name, country, address)
The visual inspection established: _____
_____

Storage conditions _____
_____
type and condition of tare, package, containers _____
_____
marking on package and labels _____
_____
Samples were selected from the products presented under the name of:

Name of a medical device	Measuring unit	Date of manufacture	Expiry date	Number of selected samples of a medical device
1	2	3	4	5

Representative of the testing laboratory:

_____ _____
(signature) (Surname, name, patronymic (if available)
Applicant

_____ _____
(signature) (Surname, name, patronymic (if available)

Annex 3
to the Rules for conduct of
technical testing
Form

_____
___
(name of the testing laboratory)

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

_____
_____
(address, telephone of the testing laboratory)
Head of the testing laboratory _____ _____
(signature) (initials, surname)
Seal
Medical device technical testing report
no. _____ dated "__" _____
Page ___/Number of sheets _____
Applicant _____
Name of products _____
Type of testing _____
Grounds _____

Manufacturer _____

Series, batch_____ Date of manufacture _____

Expiry date (life time) _____

Amount of samples _____

Dates of beginning and end of testing _____

Standard for compliance with which the testing was conducted _____

Testing methods _____

Testing results:

name of indicator	Standard requirements	Actual findings	Temperature (°C) and humidity (%)

Conclusion: the samples presented _____

_____

(comply with, do not comply with the requirements - indicate as necessary)

Laboratory specialist _____ _____

(signature) (initials, surname)

Laboratory specialist _____ _____

(signature) (initials, surname)

The technical testing report shall apply only to samples including standard, subjected to technical testing.

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(record of the distribution of the results of technical testing of standard samples for a specific list of homogeneous products (if available))

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