On approval of the rules for performing technical tests

Unofficial translation

Order № KR DSM-298/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 21, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 under № 21866

Unofficial translation

In accordance with paragraph 3 of Article 237 of the Code of the Republic of Kazakhstan "On Public Health and Healthcare System" as of July 7, 2020, **I** hereby **ORDER**:

1. To approve the appended rules for performing technical tests.

2. To invalidate Order № KR DSM-124 of the Minister of Healthcare of the Republic of Kazakhstan as of September 6, 2019 "On approval of the Rules for performing technical tests of medical devices" (registered in the State Registration Register of Regulatory Legal Acts under № 19356, published in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan on September 10, 2019).

3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;

3) within ten working days of the state registration of this order, the submission of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan.

4. Control over the execution of this order shall be entrusted to the supervising vice-minister of healthcare of the Republic of Kazakhstan.

5. This order shall be enforced ten calendar days of its first official publication.

Minister of Healthcare of the Republic of Kazakhstan *A.Tsoi*

Approved by Order
№ KR DSM-298/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 21, 2020

Rules for performing technical tests

Chapter 1. General provisions

1. These rules for performing technical tests (hereinafter referred to as the Rules) are developed in accordance with paragraph 3 of Article 237 of the Code of the Republic of Kazakhstan “On Public Health and Healthcare System” as of July 7, 2020 and establish the procedure for performing technical tests.

2. The following terms and definitions are used in these Rules:

1) technical testing of a medical device - testing and (or) evaluation and analysis of data to check the quality and safety when using a medical device in accordance with its purpose specified in the manufacturer’s documentation;

2) testing laboratory - a laboratory, an organization having a material and technical base and qualified personnel to perform technical tests of a medical device.

Chapter 2. Procedure for performing technical tests

3. To perform technical tests, the manufacturer of a medical device or its authorized representative provides organizations accredited to perform technical tests of medical devices (hereinafter referred to as a testing laboratory) with:

1) an application for technical testing of a medical device in accordance with the form in Appendix 1 to these Rules;

2) regulatory documents for a medical device with an indication of the list of standards that medical devices comply with;

3) technical and operational documentation for a medical device (working drawings, tables and diagrams, technical regulatory documents for commencing the production of devices);

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

5) copies of reports of technical tests of a medical device (if any);

6) data on the labeling and packaging of a medical device;

7) a sample of a medical device.

4. Technical tests of a medical device include:

1) analysis of data from regulatory, technical and operational documentation for the medical device, technical test program, as well as reports of earlier performed tests and making a decision on performing technical tests;

2) sampling and identification of the medical device;

3) performance of technical tests of the medical device in accordance with a program of technical tests of the medical device developed by the applicant;

4) documentation of a report of technical tests of the medical device and its issuance to the applicant.

5. The testing laboratory, within 10 (ten) calendar days of submission of an application for technical testing of a medical device, analyzes the documents submitted by the applicant.

If a decision is made to perform technical tests of the medical device, the testing laboratory concludes an appropriate agreement with the applicant in accordance with the Civil Code of the Republic of Kazakhstan as of December 27, 1994.

If it is impossible to perform technical tests of the medical device, the testing laboratory in a written (arbitrary) form notifies the applicant of its refusal to perform technical tests of the medical device (indicating the reasons).

6. Technical tests of medical devices are performed on samples of medical devices provided by the applicant.

Samples of the medical device are selected by the applicant or, on its behalf, by the testing laboratory in the presence of the applicant.

If samples of a medical device are selected by the applicant, this information is indicated in the application.

If samples of a medical device are selected by the testing laboratory on behalf of the applicant, the results of the selection are documented by a certificate of selecting samples of a medical device in accordance with the form in Appendix 2 to these Rules.

At all stages of storage, transportation and preparation for technical testing of selected samples of a medical device, it is necessary to observe the conditions specified in the regulatory, technical or operational documentation for the medical device.

7. Technical tests are not performed in relation to medical devices for diagnostics outside a living organism (in vitro).

8. In the course of technical testing of samples of a medical device, the testing laboratory assesses:

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

2) the completeness and objectivity of the characteristics established by the regulatory documentation that are subject to control during the production of medical devices, as well as the frequency, plans for control and its methods;

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

4) labeling and packaging of a medical device.

9. Given a group of homogeneous medical devices, it is allowed to perform technical tests on standard samples of medical devices produced according to one regulatory document and using the same technology.

In this case, selected standard samples with regard to composition of medical devices reflects the entire set of a group of homogeneous medical devices, taking into account the difference in the properties of individual types of medical devices (brands, models) in this set.

In the case of technical tests on standard samples, the technical test report indicates the extension of the results of technical tests of standard samples to a certain group of homogeneous medical devices.

10. In the case of large medical devices of 2b and 3 classes of potential risk of use, the installation of which requires special equipment, technical tests are performed in the form of a technical assessment based on the analysis of technical documentation and documents confirming the results of technical tests performed by the manufacturer's testing laboratories.

11. The duration of technical tests is determined by the purpose and complexity of medical devices, the completeness and quality of the documentation submitted by the applicant, but does not exceed thirty (30) calendar days.

12. The results of technical tests performed by the testing laboratory are documented as a report of technical testing of a medical device in accordance with the form in Appendix 3 to these Rules.

13. The results of technical tests of medical devices are considered negative if the submitted samples (sample) of the medical device do (does) not comply with the regulatory, technical or operational documentation of the medical device and (or) standards included in the list of standards for compliance with which the technical tests of the medical device were performed.

14. Documents on technical tests of a medical device are retained by the testing laboratory in a systematic form for 10 (ten) years of completion of technical tests.

Appendix 1
to the rules for performing
technical tests
Form

Application for technical testing of a medical device

1. Information on the medical device:

1.1	Name of the medical device (indicating the model, brand)		
1.2	Purpose and scope of the medical device established by the manufacturer		
1.3	Class depending on the degree of potential risk of use (please tick as applicable)	Class 1 Class 2a Class 2b Class 3	☐ ☐ ☐ ☐
1.4	Global Medical Device Nomenclature Code (if any)		
1.5	Code of the Nomenclature of medical devices of the Republic of Kazakhstan (if any)		

1.6	The presence of the medicinal product in the composition (tick as applicable)	Y e s No	☐ ☐

2. Information on the complete set of the medical device (indicating the model, brand):

2.1	Main unit (if any)	
2.2	Accessories (if any)	
2.3	Additional accessories (if any)	
2.4	Software (if any)	
2.5	Consumables (if any)	

3. Information on samples of the medical device:

3.1	Type of packaging (tick as applicable)	Primary Secondary	☐ ☐
3.2	Packing 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 sampling by the testing laboratory’s specialists (tick as applicable):	Y e s No	☐ ☐

4. Information on the developer (manufacturer) of the medical device:

4.1	Medical device’s developer:
4.1.1	Name of the legal entity
4.1.2	Abbreviated name of the legal entity (if any)
4.1.3	Country, address (location) of the legal entity
4.1.4	Phone numbers
4.1.5	Legal entity’s email address
4.2	Medical device’s manufacturer:
4.2.1	Name of the legal entity
4.2.2	Abbreviated name of the legal entity (if any)
4.2.3	Country, address (location) of the legal entity
4.2.4	Phone numbers
4.2.5	Legal entity’s email address
4.3	An authorized representative of the manufacturer of the medical device in the Republic of Kazakhstan:
4.3.1	Name of the legal entity

4.3.2	Abbreviated name of the legal entity (if any)
4.3.3	Country, address (location) of the legal entity
4.3.4	Phone numbers
4.3.5	Legal entity’s email address
4.4	Place of manufacture of the medical device

5. Information on the applicant (data by 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 any)
5.1.3	Address (location) of the legal entity
5.1.4	Phone numbers
5.1.5	Legal entity’s email address
5.2	An individual registered as an individual entrepreneur:
5.2.1	Surname, name, patronymic (if any)
5.2.2	Telephone
5.2.3	Fax
5.2.4	Email address
5.3	Bank details:
5.3.1	Business identification number
5.3.2	Individual identification number
5.3.3	Bank
5.3.4	Payment account
5.3.5	Foreign currency account
5.3.6	Code
5.3.7	Bank identification code

_____ _____

(Surname, name, patronymic (if any) of the applicant) (Signature)

“__” _____ 20__

Appendix 2
to the rules for performing
technical tests
Form

Certificate of selecting samples of the medical device

№ _____ as of “___” _____ 20___

The applicant

_____

_____

(name of the organization, address)

Address and place of selection of samples _____

_____

The samples were selected by _____
_____
(surname, name, patronymic (if any) of the person that selected the samples)
The certificate is drawn up by _____
_____
(surname, name, patronymic (if any) of the representative of the testing laboratory)
together with _____
_____
(surname, name, patronymic (if any) of the applicant or his/her representative)
The samples of the presented product are selected in accordance with _____
_____
_____
_____
(name of the regulatory document) for performing technical tests of
the medical device _____
___
_____
_____
(name of the medical device)
The manufacturer of the medical device is
_____
_____
(full name, country, address)
The inspection established: _____
_____
storage conditions _____
_____
type and condition of boxes, packaging, containers _____
_____
texts on packaging and labels _____
__

The samples are selected from the product presented under the name:

Name of the medical device	Unit of measurement	Date of manufacture	Expiration date	Number of selected samples of the medical device
1	2	3	4	5

Representative of the testing laboratory:
_____ _____

(signature) surname, name, patronymic (if any)
Applicant

_____ _____

(signature) surname, name, patronymic (if any)

Appendix 3
to the rules for performing
technical tests
Form

_____

_____

(name of the testing laboratory)

_____

_____

(accreditation certificate of the testing laboratory, its number, validity period)

_____

_____

(address, telephone of the testing laboratory)

Head
of the testing laboratory

_____ _____

(signature) surname, name, patronymic (if any)
Stamp here

Report of technical testing of the medical device № _____
as of "__" _____ Page _____ (Number of pages _____)

Applicant _____

_____

Name of the product _____

__

Type of testing _____

_____

Ground _____

_____

Manufacturer _____

_____

Batch, lot _____

___

Date of manufacture _____

_____

Expiration date (service life) _____

_____

Number of samples _____

_____

Test start and end dates _____

Standards tested against _____

Testing methods _____

_____

Test results:

Name of the indicator	Requirement of the standard	Actual results obtained	Temperature (°C) and humidity (%)

Opinion: the presented samples

_____

_____

(comply, don't comply with the requirements (indicate as necessary))

The laboratory's specialist _____ _____

_____

(signature) surname, name, patronymic (if any)

The laboratory's specialist _____ _____

_____

(signature) surname, name, patronymic (if any)

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

Full or partial reprint of the report without the permission of the testing laboratory is prohibited.

_____

_____

(record of application of the results of technical tests of typical samples to a certain list of homogeneous products (if any))

_____

_____

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