

**On approval of the regulations for issuing statements (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states**

*Unofficial translation*

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-177/2020 dated November 3, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 5, 2020 under No. 21592.

*Unofficial translation*

In obedience to sub-paragraph 13) of Article 8 of the Code of the Republic of Kazakhstan of July 7, 2020 "On Public Health and Healthcare System" and sub-paragraph 1) of Article 10 of the Law of the Republic of Kazakhstan of 15 April 2013 "On Public Services" **I HEREBY ORDER:**

1. That the attached regulations for issuing statements (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states shall be approved.

2. That certain orders of the Ministry of Healthcare of the Republic of Kazakhstan shall be declared to be no longer in force pursuant to the Annex hereto.

3. That in conformity with the procedure established by the laws of the Republic of Kazakhstan, the Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan shall:

1) ensure state registration hereof with the Ministry of Justice of the Republic of Kazakhstan;

2) post this order on the official web-site of the Ministry of Healthcare of the Republic of Kazakhstan;

3) within ten working days after state registration hereof with the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan information on execution of the actions stipulated by sub-paragraphs 1) and 2) of this paragraph.

4. That the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan shall be charged with control over hereof.

5. That this order shall be put into effect ten calendar days after the date of its first official publication.

*Minister of Healthcare  
of the Republic of Kazakhstan*

*A. Tsoy*

Approved by order  
of the Minister of Healthcare  
of the Republic of Kazakhstan  
No. KR DSM-177/2020  
dated November 3, 2020

**Rules for issuing conclusions (permits) for import into the territory of the Republic of Kazakhstan from non-member states of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes in order to carry out unrelated transplantation, germ cells and embryos**

**Footnote. The Rules as amended by the order of the Minister of Health of the Republic of Kazakhstan dated 07.12.2021 No. ҚР ДСМ -126 (shall be enforced ten calendar days after the day of its first official publication).**

## **Chapter 1. General provisions**

1. These Rules for issuing conclusions (permits) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes in order to carry out unrelated transplantation, germ cells and embryos (hereinafter referred to as the Rules) are developed in accordance with subparagraph 13) of Article 8 of the Code of the Republic of Kazakhstan "On people's health and healthcare system" and subparagraph 1) of Article 10 of the Law of the Republic of Kazakhstan "On public services" (hereinafter – the Law of the Republic of Kazakhstan) and determine the procedure for issuing conclusions (permits) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for unrelated transplantation, germ cells and embryos.

2. The following basic concepts are used in these Rules:

1) products of human vital activity - biological substances released by a human into the internal environment of the body or the external environment;

2) biological materials - samples of physiological and pathological fluids, tissues, secretion and waste products of a person, which include: amniotic fluid, pus, blood, lymph, sputum, colostrum, urine, prostate secretion, mucous membrane mucus, synovial fluid, semen

, cerebrospinal fluid, tissue fluid, pleural fluid, nasal mucus, sweat, transudate, earwax, exudate, biopsy material, histological sections, smears, scrapings, lavage, pathological secretions, scrapings, secretions, physiological secretions, washing, tissue, and samples of deoxyribonucleic acid (hereinafter referred to as DNA);

3) hematopoietic stem cells - hematopoietic cells of the human bone marrow, which have pluripotency and are in the process of life in the bone marrow, peripheral blood and umbilical cord blood;

4) a donor - a person, a human corpse, an animal from which donor blood, its components, other donor material (including sperm, egg cells, tissues of the reproductive organs, germ cells, embryos) are taken, as well as the removal of organs (parts of an organ) and (or) tissues (parts of tissue) for transplantation to the recipient;

5) a cell - the main structural and functional unit of the human body, having its own metabolism, capable of independent existence, self-reproduction and development;

6) a consultation - a study of a person in order to establish a diagnosis, determine treatment tactics and prognosis of a disease with the participation of at least three doctors;

7) a recipient - a patient who has undergone a transfusion of donor blood or components isolated from it and (or) preparations, the introduction of male or female donor material (sperm, egg cells, embryos) or transplantation of organs (parts of an organ) and (or) tissues (parts of tissue) from a donor, as well as artificial organs (parts of organs);

8) bone marrow - a tissue that carries out hematopoiesis, located in the inner part of the bones and includes hematopoietic stem cells, stroma and other components of the microenvironment;

9) informed consent - a procedure for a written voluntary confirmation by a person of his consent to receive medical care and (or) participation in a specific study after receiving information about all aspects of medical care and (or) research that are significant for his decision. Informed written consent is drawn up in the form approved by the authorized body.

## **Chapter 2. Procedure for issuing conclusions (permits) for import into the territory of the Republic of Kazakhstan**

**from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these**

**states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for unrelated transplantation, germ cells and embryos**

3. To obtain a conclusion (permit documents) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for unrelated transplantation, germ cells and embryos, legal entities (hereinafter referred to as the service

recipient) send an application to the territorial departments of the state body in the field of providing medical services (assistance) (hereinafter - the service provider) through the "electronic government" web portal [www.egov.kz](http://www.egov.kz), [www.elicense.kz](http://www.elicense.kz) (hereinafter - the portal), in the form approved by Appendix 1 to these Rules and the list of documents specified in paragraph 8 of the public service Standard "Issuance of conclusions (permits) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for unrelated transplantation, germ cells and embryos" (hereinafter referred to as the Public Service Standard) in accordance with Appendix 2 to these Rules.

To obtain the conclusion, the import and export of germ cells and embryos, hematopoietic stem cells (bone marrow), donor lymphocytes by individuals are not allowed.

4. The list of basic requirements for \ provision of a public service, including a description of the process, form, content and result of the provision, as well as other information, taking into account the specifics of the provision of a public service, is set out in the Public Service Standard.

5. On the day of receipt of documents, the service provider accepts and registers them.

If the service recipient applies after the end of working hours, on weekends and holidays in accordance with the labor legislation of the Republic of Kazakhstan, the acceptance of the application and the issuance of the result of the provision of the public service are carried out on the next working day.

6. The total period for consideration of documents and issuance of a conclusion (permit document) by the service provider is 1 (one) working day.

7. If the service recipient submits an incomplete package of documents, the service provider, within 1 (one) working day from the date of registration of the submitted documents specified in paragraph 8 of the Public Service Standard, prepares a reasoned refusal (in any form) to provide the public service, certified by an electronic digital signature (hereinafter – the EDS) of the authorized person of the service provider, sends to the portal.

8. The result of the provision of a public service is the issuance of an appropriate conclusion (permit) in the form in accordance with Appendix 3 to these Rules or a reasoned refusal to provide a public service in any form.

Conclusion (permit document) for import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for unrelated transplantation, germ cells and embryos is issued for one movement across the border of the Republic of Kazakhstan.

9. The service provider ensures that data is entered into the information system for monitoring the provision of public services in accordance with subparagraph 11) of paragraph 2 of Article 5 of the Law.

Entering data into the information system for monitoring the provision of public services is automated.

10. A complaint against decisions, actions (inaction) of the service provider and (or) their employees on the provision of public services is filed in the name of the head of the service provider.

The complaint of the service recipient received by the service provider directly providing the public service, in accordance with paragraph 2 of Article 25 of the Law of the Republic of Kazakhstan, is subject to consideration within five working days from the date of its registration.

When applying through the portal, information on the procedure for appealing can be obtained by calling the single contact center for the provision of public services.

Pre-trial consideration of a complaint on the provision of public services is carried out by a higher administrative body, an authorized body for assessment and control over the quality of public services (hereinafter referred to as the body considering the complaint) within fifteen working days from the date of its registration.

The complaint is submitted to the service provider, whose decision, action (inaction) is being appealed.

The service provider, whose decision, action (inaction) is being appealed, no later than three working days from the date of receipt of the complaint, sends it and the administrative file to the body considering the complaint.

At the same time, the service provider, whose decision, action (inaction) is being appealed, has the right not to send a complaint to the body considering the complaint, if it makes a decision within three working days that fully meets the requirements specified in the complaint.

Unless otherwise provided by law, the appeal to the court is allowed after an appeal in the pre-trial procedure.

Annex 1 to the Regulations for  
issuing statements (permits)  
for the import of human  
biological materials, hematopoietic  
stem cells, bone marrow, donor  
lymphocytes for the purpose of unrelated,  
transplantation, germ cells and embryos  
into the Republic of Kazakhstan from  
states  
that are not members of the Eurasian  
Economic Union, and export from the  
territory  
of the Republic of Kazakhstan to these  
states

Application for a statement (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states

We, (Name of the importing (exporting) organisation, its address) hereby request permission to import (export) of haematopoietic stem cells, bone marrow, donor lymphocytes into (from) the territory (territories) of the Republic of Kazakhstan for the purpose of unrelated transplantation pursuant to Contract No. \_\_\_\_\_ of \_\_\_\_\_ (date)

\_\_\_\_\_  
\_\_\_\_\_  
(name, quantity)

\_\_\_\_\_  
\_\_\_\_\_  
(please indicate the specific purpose of the import/export)

Availability of the donor's/patient's consent \_\_\_\_\_

Recipient/sender \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
(Name, registered office, country)

Destination/sending country \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
The following documents are enclosed:

\_\_\_\_\_  
\_\_\_\_\_  
(position of the head of organisation) (signature)

\_\_\_\_\_  
\_\_\_\_\_  
(surname, first name, patronymic (if any))

issuing statements (permits)  
for the import of human  
biological materials, hematopoietic  
stem cells, bone marrow, donor  
lymphocytes for the purpose of unrelated,  
transplantation, germ cells and embryos  
into the Republic of Kazakhstan from  
states  
that are not members of the Eurasian  
Economic Union, and export from the  
territory  
of the Republic of Kazakhstan to these  
states  
Document form

**Standard of the public service “Issuance of conclusions (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these state”**

1	Name of the service provider	Territorial subdivisions of the agency of the public authority in the area of health services (care) (hereinafter the provider)
2	Methods of providing the public service	E-government web portal www.egov.kz, www.elicense.kz
3	Term of rendering a public service	1 (one) working day. (the date of registration and receipt of documents shall not be included in the term of public service provision)
4	Form of public service delivery	Electronic (fully automated).
5	Result of rendering a public service	Statement (permits) for the import of human biological materials, haematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union and export from the territory of the Republic of Kazakhstan to these states or a reasoned refusal to provide the public service.
6	The amount of the fee charged to the service recipient when providing a public service and the manner in which it is charged in cases	

	stipulated by the legislation of the Republic of Kazakhstan	A public service shall be provided free of charge.
7	Working hours	<p>1) Service provider - Monday to Friday from 9.00 to 18.30 with lunch break from 13.00 to 14.30, except weekends and public holidays;</p> <p>2) Portal - 24 hours a day, except for technical breaks related to the maintenance work (when the recipient of the service is contacted after office hours, on weekends and public holidays, the application submission and delivery of the results of public service shall be provided on the next working day)</p>
8	List of documents required for the provision of the public service	<p>1. In order to obtain statements (permits) for import of hematopoietic stem cells, bone marrow, donor lymphocytes into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states for the purpose of unrelated transplantation</p> <p>1) a statement pursuant to Annex 1 hereto.</p> <p>2) an electronic copy of the results of biosafety testing of haematopoietic stem cell samples, bone marrow, donor lymphocytes for the purpose of unrelated transplantation.</p> <p>2. To obtain conclusions (permission documents) on import to the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union and export from the territory of the Republic of Kazakhstan to these states of samples of human biological materials of stem cells and embryos intended for diagnostic scientific purposes:</p> <p>1. an application;</p> <p>3. To obtain statements (permits) to import into the territory of the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union and export from the territory of the Republic of Kazakhstan to these states samples of human biological materials, hematopoietic stem cells, bone</p>



		<p>marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos</p> <p>1) application according to Annex 1 hereto;</p> <p>2) electronic copy of the document confirming the scientific activity</p>
9	<p>Grounds for refusal to provide a public service established by the legislation of the Republic of Kazakhstan</p>	<p>1) establishment of unreliability of documents submitted by the service recipient in order to receive a public service and (or) data (information) contained therein</p> <p>2) non-compliance of the service recipient and (or) submitted materials, objects, data and information required for the provision of a public service with the requirements established by the legal acts of the Republic of Kazakhstan</p>
10	<p>Other requirements with account taken of the peculiarities for the provision of the public service, including those provided in electronic form and via the State Corporation</p>	<p>1. The beneficiary shall be able to obtain information on the procedure and status of the provision of the public service remotely via the "personal office" of the portal, as well as the unified contact centre.</p> <p>2. Contact telephone numbers of reference services on public service rendering shall be indicated on the internet-resource of the authorized body in the sphere of health care <a href="http://www.gov.egov.kz">www.gov.egov.kz</a>.</p> <p>telephone numbers of the single contact centre on public service rendering - 1414,8- 800- 080 -777.</p>

Annex 3 to the Regulations for issuing statements (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated, transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states

Document form

## STATEMENT

(permit) for the import of human biological materials, hematopoietic stem cells, bone marrow,

**donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states**

No. (year)	____/20 Month	/ ____ / ____ date
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\_\_\_\_\_  
\_\_\_\_\_  
(Name of the issuing authority)

Issued to \_\_\_\_\_

\_\_\_\_\_  
(Country, name of organisation, registered office)  
Type of transportation \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_/ / \_\_\_\_\_

\_\_\_\_\_  
(section of the Unified Goods List) (HS Code)

Item name	Quantity	Unit of measure
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Recipient/sender\* \_\_\_\_\_  
(name, legal address, country)

Destination/sending country\* \_\_\_\_\_

Country of import \_\_\_\_\_

\_\_\_\_\_  
Country of export \_\_\_\_\_

\_\_\_\_\_  
Purpose of import/export \_\_\_\_\_

\_\_\_\_\_  
Time limit for temporary importation (exportation) \_\_\_\_\_

\_\_\_\_\_  
Ground: \_\_\_\_\_

Further information \_\_\_\_\_

Transit country \_\_\_\_\_  
(cross-border transit)

Signature \_\_\_\_\_ Date \_\_\_\_\_

The statement is valid through \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
(first name, surname and patronymic (if any) (position)

\_\_\_\_\_  
(signature)

<\*> to be completed with due account for the requirements for categories of goods

Annex 4 to the Regulations for  
issuing statements (permits)  
for the import of human  
biological materials, hematopoietic  
stem cells, bone marrow, donor  
lymphocytes for the purpose of unrelated,  
transplantation, germ cells and embryos  
into the Republic of Kazakhstan from  
states  
that are not members of the Eurasian  
Economic Union, and export from the  
territory  
of the Republic of Kazakhstan to these  
states  
Document form

**Statement (permits) for the import of human biological materials, hematopoietic stem cells, bone marrow, donor lymphocytes for the purpose of unrelated transplantation, germ cells and embryos into the Republic of Kazakhstan from states that are not members of the Eurasian Economic Union, and export from the territory of the Republic of Kazakhstan to these states**

№ \_\_\_\_/20 / \_\_\_\_ / \_\_\_\_ date (year/month/number)

\_\_\_\_\_  
((Name of the issuing authority)

Issued to \_\_\_\_\_

\_\_\_\_\_  
(Country, name of organisation, registered office)

Type of transportation \_\_\_\_\_

Name	Quantity	Unit of measure
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Recipient/sender\* \_\_\_\_\_  
(name, legal address, country)

Destination/sending country\* \_\_\_\_\_

\_\_\_\_\_  
Purpose of import/export \_\_\_\_\_

Time limit for temporary importation (exportation) \_\_\_\_\_

Ground: \_\_\_\_\_

Further information \_\_\_\_\_

Transit country \_\_\_\_\_

\_\_\_\_\_  
(cross-border transit)

Signature \_\_\_\_\_ Date \_\_\_\_\_

The statement is valid through \_\_\_\_\_

\_\_\_\_\_  
first name, surname and patronymic (if any) (position)

\_\_\_\_\_  
(first name, surname and patronymic (if any) (signature)

Annex to order  
of the Minister of Healthcare  
of the Republic of Kazakhstan  
No. KR DSM-177/2020  
dated November 3, 2020

**List of orders of the Ministry of Healthcare of the Republic of Kazakhstan that are no longer in force**

1. Order of the Acting Minister of Healthcare of the Republic of Kazakhstan No. 151 of March 26, 2014 "On approval of the Rules for issuance of statements (permits) for the import into the territory of the Republic of Kazakhstan and export from the territory of the Republic of Kazakhstan of hematopoietic stem cells, bone marrow in case of their transfer for the purpose of unrelated transplantation, as well as samples of cells, tissues, biological fluids and secretions, including products of human vital functions, physiological and pathological excretions, smears, scrapes, wipes intended for diagnostic scientific purposes or obtained in the process of biomedical research" (registered with the Register of State Regulatory Legal Acts of the Republic of Kazakhstan under No. 9372, published on June 2, 2014 in Adilet, the information and legal system);

2. Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan No.650 of July 25, 2016 "On amendments to Order of the Acting Minister of Healthcare of the Republic of Kazakhstan No.151 of March 26, 2014 "On approval of the Rules for issuing statements (permits) to import into the territory of the Republic of Kazakhstan and export from the territory of the Republic of Kazakhstan hematopoietic stem

cells, bone marrow in case of their transfer for the purpose of non-related transplant, as well as samples of cells, tissues, biological fluids and secretions, including products of human vital functions, physiological and pathological excretions, smears, scrapes, washes intended for diagnostic scientific purposes or obtained in the process of biomedical research" (recorded in the Register of State Regulatory Legal Acts of the Republic of Kazakhstan under No. 14152, published in Adilet, the information and legal system on September 8, 2016);

3. Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-25 of October 9, 2018 "On Amendments to Order of Acting Minister of Healthcare of the Republic of Kazakhstan No. 151 of March 26, 2014 "On Approval of Rules for Issuance of Statements (Permits) for the Import into and Export from the Republic of Kazakhstan of Haemopoietic Stem Cells, Bone Marrow in case of their Movement for the Purpose of Non-Parental Transplantation as well as Cell Samples, tissues, biological fluids and secretions, including products of human vital functions, physiological and pathological excretions, smears, scrapes, washes intended for diagnostic scientific purposes or obtained in the process of biomedical research" (registered with the Register of State Regulatory Legal Acts of the Republic of Kazakhstan under No. 17626, published in the Reference Regulatory Legal Acts Bank of the Republic of Kazakhstan on November 14, 2018 in electronic form);

4. Paragraph 1 of the list of certain orders in the field of health care, which are amended, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan № KR DSM-27/2020 dated April 4, 2020 "On amendments to certain orders in the field of health care" (registered with the Register of State Registration of Regulatory Legal Acts of the Republic of Kazakhstan under No. 20333, published on April 13, 2020 in the Reference Bank of Regulatory Legal Acts of the Republic of Kazakhstan in electronic form)