APPROVED
by Decision No. 299 of
the Customs Union Commission
dated May 28, 2010

(as amended by Decisions of the Customs Union Commission N 341 of 17.08.2010,
N 383 of 20.09.2010, N 432 of 14.10.2010)

Face of the form

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CUSTOMS UNION OF THE REPUBLIC OF BELARUS, THE REPUBLIC OF KAZAKHSTAN AND THE RUSSIAN FEDERATION

_____

(competent authority of the Party)

_____

(head of the competent authority)

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(name of an administrative-territorial entity)

**CERTIFICATE**
**of state registration**
№ _____ dated __ _____ ____

Products:

_____

_____

_____

_____

(names of products, regulatory and (or) technical documents whereby the products are manufactured, name and location of the manufacturer (producer), recipient)

conform to_____

passed state registration, were entered in the Register of state registration certificates and approved for manufacturing, marketing and use

The present certificate is issued on the basis of (list the examined test protocols, name of the organization (testing laboratory, centre) that conducted research, other examined documents):

The period of validity of the state registration certificate covers the whole period of manufacture or delivery of controlled goods to the territory of the Customs Union

Signature, name, position of the authorized person issuing the document and the seal of the authority (institution) issuing the document

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(Name/Signature)

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Appendix No. 1
to the Uniform certificate of state registration

# REGULATIONS
## for procedure of executing a Uniform Document certifying safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements

(as amended by Decisions of the Customs Union Commission N 341 of 17.08.2010, N 383 of 20.09.2010, N 432 of 14.10.2010)

1. The Regulations for procedure of executing a Uniform Document certifying safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements (hereinafter – "Regulations") establish the procedure for arranging, executing and issuing a document confirming safety of products (goods) – certificate of state registration for goods included in Part II of the Single List of Goods subject to sanitary-and-epidemiologic supervision (control) at the customs border and on the customs territory of the Customs Union.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

Within the framework of these Regulations, the Parties are the member states of the Customs Union.

2. Operations aimed at issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements are carried out by competent authorities of the Parties upon applications of individual entrepreneurs, legal entities (hereinafter – "applicants") at their expense.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

An applicant for a document certifying safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements is:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

for controlled goods manufactured on the Customs Union customs territory – the manufacturer (producer) of controlled goods;

for controlled goods manufactured outside the Customs Union customs territory – the manufacturer (producer), supplier (importer) of controlled goods.

3. The period of preparation of a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements can not exceed 30 calendar days from the date of application.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

4. The procedure for execution of a document certifying safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements comprises:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

reception and registration of an application;

expertise of submitted documents including documents provided by the applicant and the results of laboratory research (tests) of controlled goods for

compliance with the Common Sanitary Requirements <1>;

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<1> The Common Sanitary Requirements apply until adoption of EurAsEC technical regulations for this type of controlled goods.

harmonization of the necessary information in accordance with the legislation of the Party where state registration is conducted;

entering information on controlled goods in the Register of state registration certificates (hereinafter – "Register of certificates");

executing and issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

5. Samples (specimens) of controlled goods manufactured on the Customs Union customs territory for laboratory research (tests) are taken by laboratories of competent authorities accredited (certified) in the national accreditation (certification) systems of the Parties and registered in the Single Register of Certification Authorities and Testing Laboratories (Centres) of the Customs Union in the quantity sufficient for conducting tests; sampling is documented in the form of a sampling certificate.

Samples (specimens) of controlled goods manufactured outside the Customs Union customs territory for the purpose of executing a certificate of state registration shall be submitted together with a covering letter of the manufacturer (producer).

6. Laboratory tests of controlled goods for the purpose of executing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements shall be conducted by laboratories of competent authorities accredited (certified) in the national accreditation (certification) systems of the Parties and registered in the Single Register of Certification Authorities and Testing Laboratories (Centres) of the Customs Union, with a view to ascertain safety of controlled goods in accordance with the Common Sanitary Requirements.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

7. The decision on issuance of a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements shall be taken by competent authorities on the basis of positive results of documentation expertise and the results of laboratory research (tests) of controlled goods.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

8. The following documents shall be submitted for the purpose of issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

1) for controlled goods manufactured on the Customs Union customs territory:

application;

copies of documents whereby the products are manufactured (standards, technical specifications, regulations, technological instructions, specifications, formulae, data on composition) certified by the manufacturer (producer);

written notification of the manufacturer (producer) that the manufactured products (product samples) meet the requirements of the documents whereby the products are manufactured <2>;

(as amended by Decision of the Customs Union Commission No 383 of 20.09.2010)

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<2> The notification is accepted in the form of copies of the quality certificate, safety (quality) data sheets, certificates of quality certified by the manufacturer (producer), or a letter of the manufacturer (one of the listed documents shall be submitted).

(footnote added by Decision of the Customs Union Commission No 383 of 20.09.2010)

manufacturer's document on application (operation, use) of controlled goods (instruction, manual, regulation, recommendation) (if any) or a copy thereof certified by the applicant;

copies of controlled goods labels (package) or their models certified by the applicant;

copies of documents on specific activity of a biologically active dietary supplement (for preparations containing unknown components, unofficial prescriptions) certified by the applicant;

certificate of sampling;

declarations of the manufacturer (producer) on the presence of genetically engineered or modified (transgenic) organisms, nanomaterials, hormones, pesticides in foodstuffs;

research (test) protocols (hygienic expertise reports), scientific reports, expert reports;

(as amended by Decision of the Customs Union Commission No 383 of 20.09.2010)

extract from the Unified State Register of Legal Entities or from the Unified State Register of Individual Entrepreneurs;

The applicant bears responsibility for authenticity of documents submitted with the purpose of obtaining a document confirming safety of products (goods).

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

2) for controlled goods manufactured outside the Customs Union customs territory:

application;

copies of documents whereby the products are manufactured (standards, technical specifications, regulations, technological instructions, specifications, formulae, data on composition) certified in accordance with the legislation of the Party where state registration is conducted;

declarations of the manufacturer (producer) on the presence of genetically engineered or modified organisms, nanomaterials, hormones, pesticides in foodstuffs;

manufacturer’s document on application (operation, use) of the controlled goods (instruction, manual, regulation, recommendation) (if any) or a copy thereof certified by the applicant;

written notification of the manufacturer (producer) that the manufactured products (product samples) meet the requirements of the documents whereby the products are manufactured <3>;

(as amended by Decision of the Customs Union Commission No 383 of 20.09.2010)

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<3> The notification is accepted in the form of copies of the quality certificate, safety (quality) data sheets, certificate of analysis, certificate of quality, certificate of free sale, or a letter of the manufacturer certified in accordance with the legislation of the Party where state registration is conducted (one of the listed documents shall be submitted).

(footnote added by Decision of the Customs Union Commission No 383 of 20.09.2010)

copies of product labels (package) certified by the applicant;

original documents on specific activity of a biologically active dietary supplement (for preparations containing unknown components, unofficial prescriptions) or copies thereof certified in accordance with the legislation of the Party where state registration is conducted;

original documents on toxicological characteristics of a preparation (for pesticides, agrochemicals, crop protecting agents and plant growth regulators) or copies thereof certified in accordance with the legislation of the Party where state registration is conducted;

copy of a document, issued by the competent health care authorities (other authorized state bodies) of the country of manufacturing of a biologically active dietary supplement, food additive, disinfection (disinsection, deratization) agent, cosmetic product, confirming safety and permitting free circulation of these products on the territory of the manufacturing country, certified in accordance with legislation of the Party where registration is conducted, or the manufacturer’s information that it is not necessary to obtain such document;

(as amended by Decision of the Customs Union Commission No 432 of 14.10.2010)

research (test) protocols, scientific reports, expert reports;

copies of documents confirming import of controlled goods samples to the Customs Union customs territory certified in accordance with the legislation of the Party where state registration is conducted.

Translation of the manufacturer's (producer's) documents from foreign languages shall be certified in accordance with the legislation of the Party where state registration is conducted.

The applicant bears responsibility for authenticity of documents submitted with the purpose of obtaining a document confirming safety of products (goods).

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

9. It is not allowed to request documents that are not specified in Clause 8 of the present Regulations.

(as amended by Decision of the Customs Union Commission No 432 of 14.10.2010)

10. Issuance of a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements may be refused in the following cases:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

non-conformity of controlled goods with the Common Sanitary Requirements;

if submitted documents and (or) information do not comply with the requirements of the legislation of the Party where state registration is conducted, as well as contain invalid data;

if the statutory grounds for executing and issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements, stipulated by the legislation of the Party where state registration is conducted, are missing;

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

if the current level of scientific development does not allow to determine safety requirements for controlled goods and conditions of their production and circulation, as well as if there are no methodologies for determination and measurement of hazard in such products and in human environment;

availability of information about cases of harmful effect of controlled goods on human health and human environment in the course of production, circulation and use (application) of the products.

The decision on refusal in writing or in the form of an electronic document, stating the reasons for refusal, within three working days shall be forwarded to the applicant, heads (their deputies) of competent authorities of the Parties, as well as entered in the Eurasian Economic Community information system for technical regulation, sanitary and phytosanitary measures and the Integrated information system of external and mutual trade of the Customs Union.

11. A certificate of state registration is valid from the date of issue till the termination of deliveries of products to the territory of the Customs Union and (or) manufacturing of products on the Customs Union customs territory.

12. Documents confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements issued by the competent authorities of the Parties prior to entry into force of the Customs Union Agreement on Sanitary Measures are in force only on the territory of the Party that issued these documents within the period specified in them but not later than January 1, 2012.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

Information on reissuance shall be immediately entered in the national Register of state registration certificates.

13. Competent authorities of the Parties when issuing a Uniform Document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements shall accept documents confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and

hygienic requirements issued by competent authorities of the Parties prior to entry into force of the Customs Union Agreement on Sanitary Measures, in terms of compliance of controlled goods with the Common Sanitary Requirements.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

Research (test) protocols (hygienic expertise reports) of products (goods), based on which current documents confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements have been issued (sanitary-and-epidemiologic reports, state registration certificates, reports of state sanitary-and-hygienic expertise, certificates of state hygienic registration) are also accepted for state registration on condition that they had been issued prior to July 1, 2010.

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

14. The Parties recognize research (test) protocols of testing laboratories (centers), specified in Clause 6 of the present Regulations, based on which the documents confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements have been issued.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

15. In case of differing safety parameters of controlled goods set by the Common Sanitary Requirements for the Parties, the information on this discrepancy is indicated in the column “Conform to” of the Uniform Document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements, specifying the parameters and standards, the name of the Party on whose territory circulation of such controlled goods is not permitted. When issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements for foodstuffs the column “Name of Product” shall specify the constituent food additives of foodstuffs, as well as information about presence of genetically engineered or modified (transgenic) organisms, nanomaterials.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

16. A document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements is subject to reissuance without conducting additional or repeated research (tests) in the following cases:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

errors (misprints) in a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements, made through a competent authority's fault, detected in the course of circulation of controlled goods;

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

change of the organizational legal form, de jure address, name of the manufacturer or applicant;

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

Paragraph was deleted - Decision of the Customs Union Commission No 432 of 14.10.2010 ;

issuance of a new regulatory legal act containing requirements to controlled goods, whose adoption does not entail changes in hygienic safety parameters, composition of products.

In cases mentioned above circulation of controlled goods is not suspended for the period necessary for reissuing documents confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

Replacement of a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements is not required in case of making amendments to regulatory and (or) technical documents whereby the products are manufactured, which do not concern safety parameters of controlled goods and (or) information on indications (contraindications) for use of certain types of foodstuffs by certain groups of population.

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

17. When issuing a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements it is assigned a number formed in the following manner:

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

XX.XX.XX.XX.XXX.X.XXXXXX.XX.XX

1 2 3 4 5 6 7 8 9

Position 1 – a two-character country code, ALPHA2 (BY – Belarus, KZ – Kazakhstan, RU – Russia).

Position 2 – a two-digit numeric code of a country region or an institution (from 01 to 99; a region code is set independently by the National Central Register and reported to the Single Register).

Position 3 – a two-digit alphanumeric (letters of the Russian alphabet) code of an organization, unique for the region (from 01 to 99, from “АА” to “ЯЯ”, combinations of numbers and letters are possible; a region code is set independently by the National Central Register and is reported to the Single Register).

Position 4 – a two-digit numeric code of a workplace unique in this organization (the code is set independently within the organization, reporting to higher Registers is not required).

Position 5 – a three-digit numeric code according to the Unified Classifier of Products.

Position 6 – letter “E”.

Position 7 - a six-digit numeric code of the state registration certificate issued in the current year in this organization; at the beginning of the year it is set at “1”.

Position 8 – two-digit numeric code of month (serial number of month: from 01 to 12).

Position 9 – two-digit numeric code of year (last two digits of the year: from 00 to 99).

The Unified Classifier of Products:

001 - cosmetic products;

002 - disinfection, disinsection and deratization agents for use in the home, at therapeutic and prophylactic institutions and other facilities (except for those used in veterinary medicine);

003 – biologically active dietary supplements;

004 - dietary nutrition products;

005 - food products for children;

006 – mineral water, bottled drinking water;

007 - specialized products;

008 – potentially hazardous chemical and biological substances and preparations made on their basis, constituting potential hazard to humans (except for medicinal preparations), individual substances (compounds) of natural or artificial origin that can have adverse effects on human health and environment in the context of production, use, transportation, processing and in household use;

009 - food additives;

010 – technological aids for food industry

011 – foodstuffs derived from genetically engineered or modified organisms;

012 - personal hygienic items for children and adults;

013 – materials, equipment, facilities and other technological tools of water conditioning, designed for use in utility and drinking water supply systems;

014 – oral hygiene products;

015 - household chemical products;

016 – clothing;

017 – tonic beverages;

018 – alcoholic beverages including low alcoholic products and beer;

019 - products intended for contact with foodstuffs.

18. Information that can not be placed in the certificate of state registration due to space limits shall be placed in the Appendix to the certificate of state registration, drawn up in accordance with Appendix No.3.

It is allowed to combine several product names of the same manufacturer, produced according to the same technical specifications, having the same component (ingredient) composition, hygienic characteristics, scope of application, but with slight differences, not relevant from hygienic perspective (for example: different form or volume of product, percentage composition, different color or flavor due to addition of coloring or flavoring agents).

Amendments are made to the Appendix to a state registration certificate without requesting additional research (test) protocols, hygienic expertise reports, expert reports for products if these amendments concern addition of information not related to safety parameters of controlled goods, information on indications (contraindications) for use of certain types of foodstuffs by certain groups of population, and information that has no hygienic value (such as indication of additional forms and volumes of goods, types of consumer package, trade marks).

(paragraph added by Decision of the Customs Union Commission No 432 of 14.10.2010)

(clause 18 added by Decision of the Customs Union Commission No 341 of 17.08.2010)

19. Disputes between competent authorities of the Parties related to execution and issuance of a document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements shall be settled through mutual consultations between competent authorities determined by the Parties.

(as amended by Decision of the Customs Union Commission N 432 of 14.10.2010)

20. A document confirming safety of products (goods) in terms of their compliance with sanitary-epidemiologic and hygienic requirements and appendix(es) thereto belong to strict reporting forms securing counterfeit protection. The degree of protection is determined by the legislation of the Party where state registration is conducted.

(as amended by Decision of the Customs Union Commission No 432 of 14.10.2010)

Appendix No. 2
to the Uniform certificate of state registration

# REGULATIONS
## for the Register of state registration certificates

1. The present Regulations establish the procedure for maintenance of the Register of state registration certificates (hereinafter – "Register").

2. The Register is maintained with the purpose of informing consumers, manufacturers and suppliers of products, as well as securing effective regulation of foreign and mutual trade on the Customs Union customs territory, carrying out customs, tax, transport and other types of state control.

3. The Register is maintained in the form of an electronic database protected from damage and unauthorized access, and is periodically published in electronic form.

4. The Register is maintained using specialized software ensuring storage and exchange of information.

5. Entering information on issued state registration certificates in the Register, generation of reports on issued state registration certificates, preparation and transfer of information to the Register is carried out by competent authorities of the Parties.

Competent authorities of the Parties transfer information to the Register in electronic form as new information about issuance of state registration certificates becomes available to the correspondent national registers.

6. The Register is maintained by the Customs Union Commission based on information provided by competent authorities and institutions of the Parties issuing state registration certificates, through the integration gateway and the integration center of each Party.

7. The information of the Register is publicly available and is published on the daily updated specialized search engine of the Customs Union website on the Internet.

8. Competent authorities of the Parties, the Customs Union Commission provide the information contained in the Register to interested parties.

Appendix No. 3
to the Uniform certificate of state registration

(added by Decision of the Customs Union Commission No 341 of 17.08.2010)

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CUSTOMS UNION

OF THE REPUBLIC OF BELARUS, THE REPUBLIC OF KAZAKHSTAN AND THE RUSSIAN FEDERATION

_____

(competent authority of the Party)

_____

(head of the competent authority)

_____

(name of an administrative-territorial entity)

APPENDIX

TO THE CERTIFICATE OF STATE REGISTRATION

dated «___»_____ _____ № _____

(information not included in the text of state registration certificate)

Signature, name, position of the authorized person issuing the document and the seal of the authority (institution) issuing the document

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(Name/Signature)

locus sigilli