

Translation from Russian

**MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION**

**STATEMENT OF COMPLIANCE
of manufacturer (foreign-based manufacturer)
of pharmaceutical products for human use
with the requirements of the Good Industrial Practices**

No. GMP-0115-000177/17

Part 1

The Ministry of Industry and Trade of the Russian Federation hereby confirms that

"Tekhnolog" Special Design Engineering Bureau
(Federal State Unitary Enterprise)

(full and abbreviated corporate name (if any) of manufacturer (foreign-based manufacturer) of pharmaceutical products for human use)

with registered office situated at the following address

192076, St. Petersburg, Ust-Slavyanka, Sovetsky Prospekt, 33-a

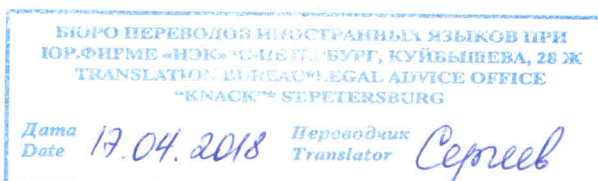
carrying on business as manufacturers of pharmaceutical products for human use at the following address

192076, St. Petersburg, Ust-Slavyanka, Sovetsky Prospekt, 33-a

has passed an inspection as part of the licensing supervision over compliance of the licence requirements in manufacturing pharmaceutical products under licence No. 00269-JIC dated 22 February, 2017, in accordance with the legislation of the Russian Federation or has passed an inspection as regards the registration certificate(s) referring to manufacturers based outside of the Russian Federation, in accordance with the requirements of the **Good Industrial Practices** as approved by Order No. 916 of the Ministry of Industry and Trade of the Russian Federation dated 14 June, 2013.

Page 1 of 7

0000605



As is evidenced by the information available from the inspections of the manufacturer under review, of which the latest was carried out on 02/02/2017, it does comply with the requirements of the Good Industrial Practices as approved by Order No. 916 of the Russian Ministry of Industry and Trade dated 14 June, 2013.

This Statement reflects the status of conformity of the manufacturing facilities of the manufacturer (foreign-based manufacturer) of pharmaceutical products for human use as of the time of the above-stated inspection and should not be interpreted as a document testifying to the status of conformity after over 3 (three) years from the date of this inspection.

The Statement is valid provided all its pages (of both Part 1 and Part 2) are issued.

The authenticity of this Statement can be checked against the register of statements of compliance of manufacturers of pharmaceutical products for human use with the requirements of the Good Industrial Practices, available from the official website <http://www.minpromtorg.gov.ru>, <http://www.минпромторг.рф>. Should this statement be missing from the register of statements of compliance of manufacturers of pharmaceutical products for human use with the requirements of the Good Industrial Practices, please report to the Russian Ministry of Industry and Trade.

This Statement is valid for 3 years as from the inspection completion date.

Deputy Minister (signature) **S.A. Tsyb**

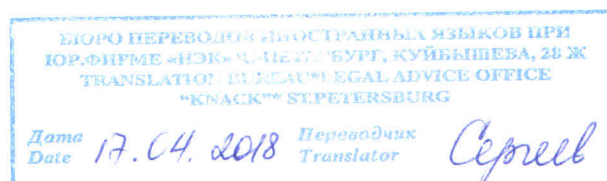
Seal: "Ministry of Industry and Trade of the Russian Federation (MINPROMINTORG ROSSII) * Primary State Registration Number (OGRN) 1047796323123"



**MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION**
GMP-0115-000177/17

Part 2

Manufacture and quality control
I. MANUFACTURING OPERATIONS – PHARMACEUTICAL PRODUCTS
<i>1. Sterile products</i>
<input type="checkbox"/> 1. Products prepared aseptically (processing operations for the following dosage forms):
<input type="checkbox"/> great-volume liquid dosage forms
<input type="checkbox"/> small-volume liquid dosage forms
<input type="checkbox"/> dispersions
<input type="checkbox"/> lyophilisates
<input type="checkbox"/> solid dosage forms and implants
<input type="checkbox"/> soft dosage forms
<input type="checkbox"/> other products
<input type="checkbox"/> 2. Terminally sterilized products (processing operations for the following dosage forms):
<input type="checkbox"/> great-volume liquid dosage forms
<input type="checkbox"/> small-volume liquid dosage forms
<input type="checkbox"/> solid dosage forms and implants
<input type="checkbox"/> soft dosage forms
<input type="checkbox"/> other products, dosage forms
<input type="checkbox"/> 3. Release quality control testing
<i>2. Non-sterile products</i>
<input checked="" type="checkbox"/> 1. Non-sterile products (processing operations for the following dosage forms):
<input type="checkbox"/> hard-shelled capsules
<input type="checkbox"/> soft-shelled capsules
<input type="checkbox"/> chewable dosage forms
<input type="checkbox"/> impregnated dosage forms
<input type="checkbox"/> liquid dosage forms for external application
<input type="checkbox"/> liquid dosage forms for internal use
<input type="checkbox"/> medicinal gases
<input type="checkbox"/> other solid dosage forms
<input type="checkbox"/> pressurized pharmaceutical products
<input type="checkbox"/> radionuclide generators
<input type="checkbox"/> soft dosage forms
<input type="checkbox"/> medicated suppositories
<input type="checkbox"/> tablets



<input type="checkbox"/> transdermal patches
<input type="checkbox"/> intraruminal devices
<input checked="" type="checkbox"/> other products, dosage forms:
- pharmaceutical substances produced through chemical synthesis;
- pharmaceutical substances derived from chemical raw materials.
<input checked="" type="checkbox"/> 2. Release quality control testing
<i>3. Biological pharmaceutical products</i>
<input type="checkbox"/> 1. Biological pharmaceutical products:
<input type="checkbox"/> blood products
<input type="checkbox"/> immunological products
<input type="checkbox"/> somatic-cell-based products
<input type="checkbox"/> gene-therapy products
<input type="checkbox"/> tissue engineering products
<input type="checkbox"/> biotechnological products
<input type="checkbox"/> products extracted from animal sources or human organs (tissues)
<input type="checkbox"/> other products
<input type="checkbox"/> 2. Release quality control testing (list of product types):
<input type="checkbox"/> blood products
<input type="checkbox"/> immunological products
<input type="checkbox"/> somatic-cell-based products
<input type="checkbox"/> gene-therapy products
<input type="checkbox"/> tissue engineering products
<input type="checkbox"/> biotechnological products
<input type="checkbox"/> products extracted from animal sources or human organs (tissues)
<input type="checkbox"/> other products

Deputy Minister (signature) S.A. Tsyb

25 August, 2017

(date of issuance of the Statement)

Seal: "Ministry of Industry and Trade of the Russian Federation (MINPROMINTORG ROSSII) * Primary State Registration Number (OGRN) 1047796323123"

БЮРО ПЕРЕВОДОВ ИНОСТРАННЫХ ЯЗЫКОВ ЦРП ЮР.ФИЛМЕ «НЭК» «ЛЕСИТ» БУЛТ, КУЙБЫШЕВА, 28 Ж TRANSLATION BUREAU*LEGAL ADVICE OFFICE "KNACK" ST.PETERSBURG	
Дата Date	Переводчик Translator
17.04.2018	Cepreil

**MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION**

GMP-0115-000177/17

4. Other products or manufacturing activities
<input checked="" type="checkbox"/> 1. Manufacture of:
<input type="checkbox"/> herbal products
<input type="checkbox"/> homeopathic products
<input checked="" type="checkbox"/> other products:
- pharmaceutical substances produced through chemical synthesis: processing stages (manufacture of intermediate products, manufacture of pharmaceutical raw substance, purification, crystallization/recrystallization, isolation, desiccation, trituration, immediate (primary) packaging, secondary packaging);
- pharmaceutical substances derived from chemical raw materials: processing stages (purification, crystallization/recrystallization, desiccation, trituration, immediate (primary) packaging, secondary packaging).
<input type="checkbox"/> 2. Sterilization of active agents (ingredients), excipients, finished products:
<input type="checkbox"/> filtration
<input type="checkbox"/> dry heat sterilization
<input type="checkbox"/> steam (moist heat) sterilization
<input type="checkbox"/> chemical sterilization
<input type="checkbox"/> gamma-ray sterilization
<input type="checkbox"/> electron beam sterilization
<input type="checkbox"/> 3. Miscellaneous
<input type="checkbox"/> 3. Primary (immediate) packaging:
<input type="checkbox"/> hard-shelled capsules
<input type="checkbox"/> soft-shelled capsules
<input type="checkbox"/> chewable dosage forms
<input type="checkbox"/> impregnated dosage forms
<input type="checkbox"/> liquid dosage forms for external application
<input type="checkbox"/> liquid dosage forms for internal use
<input type="checkbox"/> medicinal gases
<input type="checkbox"/> other solid dosage forms
<input type="checkbox"/> pressurized pharmaceutical products
<input type="checkbox"/> radionuclide generators
<input type="checkbox"/> soft dosage forms
<input type="checkbox"/> medicated suppositories
<input type="checkbox"/> tablets

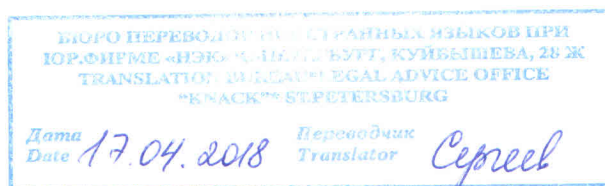
<input type="checkbox"/> transdermal patches
<input type="checkbox"/> intraruminal devices
<input type="checkbox"/> other products, dosage forms
<input type="checkbox"/> 5. Secondary (commercial) packaging
<input checked="" type="checkbox"/> 6. Release quality control testing
<input type="checkbox"/> 7. Microbiological testing: sterility
<input type="checkbox"/> 8. Microbiological testing: non-sterility
<input checked="" type="checkbox"/> 9. Chemical (physical) testing
<input type="checkbox"/> 10. Biological testing
II. QUALITY CONTROL FOR IMPORTED PHARMACEUTICAL PRODUCTS
<input type="checkbox"/> 1. Quality control for imported pharmaceutical products
<input type="checkbox"/> microbiological testing: sterility
<input type="checkbox"/> microbiological testing: non-sterility
<input type="checkbox"/> chemical (physical) testing
<input type="checkbox"/> biological testing
<input type="checkbox"/> 2. Release quality control testing (certification of series) for imported products
<input type="checkbox"/> Sterile products:
<input type="checkbox"/> products prepared aseptically
<input type="checkbox"/> terminally sterilized products
<input type="checkbox"/> Non-sterile products
<input type="checkbox"/> Biological pharmaceutical products:
<input type="checkbox"/> blood products
<input type="checkbox"/> immunological products
<input type="checkbox"/> somatic-cell-based products
<input type="checkbox"/> gene-therapy products
<input type="checkbox"/> tissue engineering products

Deputy Minister (signature) S.A. Tsyb

25 August, 2017

(date of issuance of the Statement)

Seal: "Ministry of Industry and Trade of the Russian Federation (MINPROMINTORG ROSSII) * Primary State Registration Number (OGRN) 1047796323123"



MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION

GMP-0115-000177/17

<input type="checkbox"/> biotechnological products
<input type="checkbox"/> products extracted from animal sources or human organs (tissues)
<input type="checkbox"/> other products
<input type="checkbox"/> 3. Other importation activities:
<input type="checkbox"/> physical importation site
<input type="checkbox"/> importation of intermediate product to be further processed
<input type="checkbox"/> other

Deputy Minister (signature) S.A. Tsyb

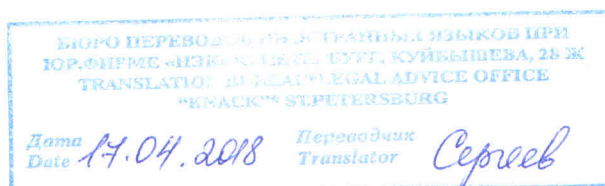
25 August, 2017

(date of issuance of the Statement)

Seal: "Ministry of Industry and Trade of the Russian Federation (MINPROMINTORG
ROSSII) * Primary State Registration Number (OGRN) 1047796323123"

Page 7 of 7

0001874



Translation from Russian

**MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION
LICENCE**

No. 00269-JIC (LC)

dated 22 February, 2017

To carry on business as manufacturers of pharmaceutical products

Schedule of activities related to manufacture of pharmaceutical products: as stated in the
Appendix to the Licence

This Licence is issued to the following enterprise (organisation):

**"Tekhnolog" Special Design Engineering Bureau
(Federal State Unitary Enterprise)**

Primary registration number of entry about state registration of legal entity

(OGRN) 1027806084151

Taxpayer Identification Number

(INN) 7811000580

Registered office:

192076, St. Petersburg, Ust-Slavyanka, Sovetsky Prospekt, 33-a

Place of licensed business activities:

192076, St. Petersburg, Ust-Slavyanka, Sovetsky Prospekt, 33-a

This Licence is issued for a term of: _____ **for perpetuity**

This Licence is issued upon licensing authority's decision - order (decree)

No. _____ dated _____

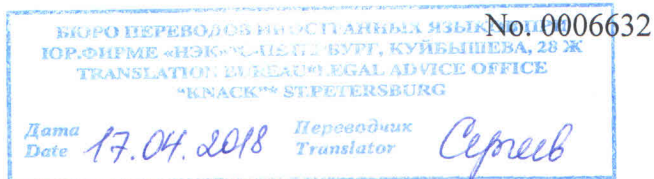
This Licence is reissued upon licensing authority's decision - order (decree)

No. 538 dated 22 February, 2017 "On re-issuance (renewal) of licence to carry on business as manufacturers of pharmaceutical products in compliance with Part 9, Clause 18 of the Federal Act No. 99-ФЗ dated 4 May, 2011, "On licensing certain business activities"

This Licence has **1** appendix (-ices), which is (are) its integral part,
consisting of **1** sheet(s).

Deputy Minister (signature) S.A. Tsyb

Seal: "Ministry of Industry and Trade of the Russian Federation (MINPROMINTORG
ROSSII) * Primary State Registration Number (OGRN) 1047796323123"



Translation from Russian

Series ФC (FC)

0034551

**FEDERAL SERVICE FOR SUPERVISION
OVER HEALTHCARE INDUSTRY**

LICENCE

No. ФC (FC)-99-02-006483

dated 29 March, 2018

To carry on business as
(indicate licensed type of business activity)

pharmaceutical business operators

Activities (services) to be performed (provided) as part of the licensed type of business in compliance
with Part 2, Clause 12 of the Federal Act "On licensing certain business activities":

(indicate as per the schedule of activities (services) prescribed by the regulation on licensing the appropriate business activity)

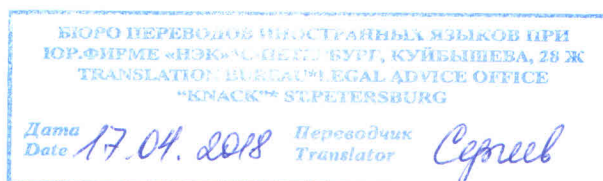
As stated in the appendix (-ices) to the Licence

This Licence is issued to: (indicate the full and (if any) abbreviated corporate name (business name included), the
legal entity form, the full name of sole trader, the title and requisite elements of the latter's identity document)

**PHARMCORP Limited Liability Company
PHARMCORP LLC
PHARMCORP Limited Liability Company**

Primary State Registration Number (OGRN) of legal entity (sole trader) **1167847466270**

Taxpayer Identification Number **7813266810**



Registered office and places of business licensed

(indicate the registered office address (residence address for sole trader) and addresses of places of business activities (provision of services) to be performed (provided) as part of the licensed type of business)

**197198, St. Petersburg, Bolshoy Prospekt (Petrograd Side), 29A, liter "Б (B)",
Suite 209.**

Addresses of places of business activities as stated in the appendix (-ices)

This Licence is issued to be valid for a term:

☒ for perpetuity

☐ to be valid until (date) _____

(to be indicated where the federal acts that govern the business activities specified in Part 4, Clause 1 of the Federal Act "On licensing certain business activities" provide for a different term of validity of licence)

This Licence is issued upon licensing authority's decision - order (decree)

No. **1996**

dated **29 March, 2018**

This Licence is reissued upon licensing authority's decision - order (decree)

No. _____

dated _____

This Licence has **1** appendix (-ices), which is (are) its integral part, consisting of **1** sheet.

Head of Federal Service (signature) _____

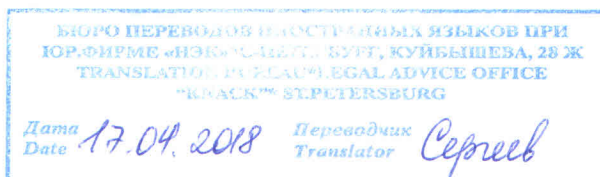
(authorized officer's title)

(authorized officer's signature)

M.A. Murashko

(authorized officer's full name)

Seal: "Ministry of Public Healthcare of the Russian Federation * Federal Service for
Supervision over Healthcare Industry"



Series ФС (FC)

0144425

**FEDERAL SERVICE FOR SUPERVISION
OVER HEALTHCARE INDUSTRY**

APPENDIX No. 1 to
Licence No. **ФС(FC)-99-02-006483**

dated **29 March, 2018**

to carry on business as

pharmaceutical business operators

issued to (corporate name with legal entity form mentioned, sole trader's full name)

PHARMCORP Limited Liability Company

Addresses of places of business activities (provision of services) to be performed (provided)
as part of the licensed type of business

**192177, St. Petersburg, 3rd Rybatsky Proyezd, 3, lit. "E", part of Suite 38-H
(Nos. 15-23)**

Management of wholesale trade in pharmaceutical products for human use

**wholesale trade in pharmaceutical products for human use;
storage of pharmaceutical products for human use;
transportation of pharmaceutical products for human use;**

Head of Federal Service (signature) M.A. Murashko
(authorized officer's title) (authorized officer's signature) (authorized officer's full name)

Seal: "Ministry of Public Healthcare of the Russian Federation * Federal Service for
Supervision over Healthcare Industry"

The above Appendix is an integral part of the Licence

