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.

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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
1. Sterile products
☐ 1. Products prepared aseptically (processing operations for the following dosage forms):
☐ great-volume liquid dosage forms
☐ small-volume liquid dosage forms
☐ dispersions
☐ lyophilisates
☐ solid dosage forms and implants
☐ soft dosage forms
☐ other products
☐ 2. Terminally sterilized products (processing operations for the following dosage forms):
☐ great-volume liquid dosage forms
☐ small-volume liquid dosage forms
☐ solid dosage forms and implants
☐ soft dosage forms
☐ other products, dosage forms
☐ 3. Release quality control testing
2. Non-sterile products
☒ **1. Non-sterile products (processing operations for the following dosage forms):**
☐ hard-shelled capsules
☐ soft-shelled capsules
☐ chewable dosage forms
☐ impregnated dosage forms
☐ liquid dosage forms for external application
☐ liquid dosage forms for internal use
☐ medicinal gases
☐ other solid dosage forms
☐ pressurized pharmaceutical products
☐ radionuclide generators
☐ soft dosage forms
☐ medicated suppositories
☐ tablets

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

MINISTRY OF INDUSTRY AND TRADE
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4. Other products or manufacturing activities
☒ **1. Manufacture of:**
☐ herbal products
☐ homeopathic products
☒ **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).
☐ 2. Sterilization of active agents (ingredients), excipients, finished products:
☐ filtration
☐ dry heat sterilization
☐ steam (moist heat) sterilization
☐ cchemical sterilization
☐ gamma-ray sterilization
☐ electron beam sterilization
☐ 3. Miscellaneous
☐ 3. Primary (immediate) packaging:
☐ hard-shelled capsules
☐ soft-shelled capsules
☐ chewable dosage forms
☐ impregnated dosage forms
☐ liquid dosage forms for external application
☐ liquid dosage forms for internal use
☐ medicinal gases
☐ other solid dosage forms
☐ pressurized pharmaceutical products
☐ radionuclide generators
☐ soft dosage forms
☐ medicated suppositories
☐ tablets

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☐ transdermal patches
☐ intraruminal devices
☐ other products, dosage forms
☐ 5. Secondary (commercial) packaging
☒ **6. Release quality control testing**
☐ 7. Microbiological testing: sterility
☐ 8. Microbiological testing: non-sterility
☒ **9. Chemical (physical) testing**
☐ 10. Biological testing
II. QUALITY CONTROL FOR IMPORTED PHARMACEUTICAL PRODUCTS
☐ 1. Quality control for imported pharmaceutical products
☐ microbiological testing: sterility
☐ microbiological testing: non-sterility
☐ chemical (physical) testing
☐ biological testing
☐ 2. Release quality control testing (certification of series) for imported products
☐ Sterile products:
☐ products prepared aseptically
☐ terminally sterilized products
☐ Non-sterile products
☐ Biological pharmaceutical products:
☐ blood products
☐ immunological products
☐ somatic-cell-based products
☐ gene-therapy products
☐ 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
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GMP-0115-000177/17

☐ biotechnological products
☐ products extracted from animal sources or human organs (tissues)
☐ other products
☐ 3. Other importation activities:
☐ physical importation site
☐ importation of intermediate product to be further processed
☐ 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"

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Translation from Russian

MINISTRY OF INDUSTRY AND TRADE
OF THE RUSSIAN FEDERATION

LICENCE

No. 00269-ЛС (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"

No. 0006632

БЮРО ПЕРЕВОДОВ И ИЗУЧЕНИЯ ЯЗЫКОВ
ЮР.ФИРМЕ «НЭК»-ЦЕНТР БУРГ, КУЙБЫШЕВА, 28 Ж
TRANSLATION BUREAU LEGAL ADVICE OFFICE
"KNACK" ST.PETERSBURG
Дата Date 17.04.2018 Переводчик Translator Сергеев

Translation from Russian

Series ФС (FC) 0034551

FEDERAL SERVICE FOR SUPERVISION OVER HEALTHCARE INDUSTRY

LICENCE

No. **ФС (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**

БЮРО ПЕРЕВОДОВ ИНОСТРАННЫХ ЯЗЫКОВ ПРИ ЮР.ФИРМЕ «НЭК» С-ПЕТЕРБУРГ, КУЙБЫШЕВА, 28 Ж
TRANSLATION BUREAU AT LEGAL ADVICE OFFICE "KNACK" ST.PETERSBURG
Дата Date 17.04.2018 Переводчик Translator Сергеев

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 (В)", 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) 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"

БЮРО ПЕРЕВОДОВ ИНОСТРАННЫХ ЯЗЫКОВ ПРИ
ЮР.ФИРМЕ «НЭК» С.-ПЕТЕРБУРГ, КУЙБЫШЕВА, 28 Ж
TRANSLATION BUREAU AT LEGAL ADVICE OFFICE
"KNACK" ST.PETERSBURG
Дата 17.04.2018 Переводчик Сергеев
Date Translator

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

БЮРО ПЕРЕВОДОВ И ИНОСТРАННЫХ ЯЗЫКОВ ПРИ ЮР.ФИРМЕ «ИЗК» САНКТ-ПЕТЕРБУРГ, ЖУКОВСКОГО, 28 Ж
TRANSLATION BUREAU AND LEGAL ADVICE OFFICE "IZK" ST.PETERSBURG
Дата Date 17.04.2018 Переводчик Translator Сергеев