

CERTIFIED TRANSLATION INTO ENGLISH

Schedule 1

MEDICAL DEVICES WHOLESALE LICENSE

License number:	515-04-3934/2020-11
Date of issue:	September 3, 2020

Wholesale (name)
"PHOENIX PHARMA"

Business name: "PHOENIX PHARMA" d.o.o.

Registered office: Belgrade, Bore Stankovića 2

Legal grounds for the license: Medical Devices Act ("Official Serbian Gazette", number 105/17)

This License applies to:

- all wholesale transactions the entire territory of the Republic of Serbia
- part of wholesale transactions, namely: part of the territory of the Republic of Serbia
- registered medical devices unregistered medical devices
- medical devices for clinical trials
- medical devices from non-EU countries
- medical devices for conformance testing by a notified body
- medical devices which are source of ionizing radiation
- perform labelling of medical devices with a label or an additional label

Licensing inspection date: August 20, 2020



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Wholesale location¹		
1	Address and contact details: Novi Sad, Privrednikova 2 021/518271; Fax: 021/2538001 E-mail: office@phoenihpharma.rs	First and last name, qualifications and contact details of the person in charge of wholesale activities: Vesna Tošić, MSc, BSc in Pharmacy Tel: 063/478359
Wholesale location²		
1	Type: general medical devices; Class I:	Categories: 02, 03, 04, 05, 08, 09, 10, 11
2	Type: general medical devices; Class Im:	Categories: 04, 05, 09
3	Type: general medical devices; Class Is:	Categories: 02, 03, 05, 08, 10, 11
4	Type: general medical devices; Class IIa:	Categories: 02, 03, 04, 05, 07, 08, 09, 10, 11, 12
5	Type: general medical devices; Class IIb:	Categories: 02, 03, 04, 05, 07, 08, 09, 10, 12
6	Type: general medical devices; Class III:	Categories: 02, 03, 04, 07, 08, 09, 10, 12
7	Classes: List A, List B, Self-testing, Other	Categories: 06
8	Class AIMD	Categories: 01

This license confirms the conformity with the requirements for the wholesale of medical devices specified by Medical Devices Act ("Official Serbian Gazette", No. 105/17) and implementing regulations.	
	Minister <i>(Signed)</i> Zlatibor Lončar, MD <i>(Round seal: Ministry of Health, Belgrade, Republic of Serbia)</i>

The Medical Devices Wholesale License is valid for a period of five years in accordance with the law governing medical devices.

Delivered to:
1 "PHOENIX PHARMA" d.o.o.
Belgrade, Bore Stankovića 2
2 Records Office

5153020.0039.290.doc/2/JJ

1 each and any wholesale location is specified
2 each and any assigned activity is specified
3 each and any medical device is specified (excl. medical devices for conformance testing)

.....**the end of translation**.....



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I, the undersigned sworn-in court translator, appointed by the decision of the Ministry of Justice of the Republic of Serbia no. 740-06-968/2000-04 of April 12, 2000, hereby certify that this translation into English is fully true to the original text written in the Serbian language. My commission is permanent.

In Belgrade, September 25, 2020
No. 5443/2020



The image shows a handwritten signature in blue ink that overlaps a circular blue stamp. The stamp contains the text "SRPSKI PREVODILAC ZA ENGLJSKI JEZIK" around the top edge and "BEOGRAD" at the bottom. In the center of the stamp, the name "Maja Popović" is printed in blue.

Maja Popović
Sworn-In Court Translator for English

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Republic of Serbia
MINISTRY OF HEALTH
No. 515-04-3934/2020-11
Date: September 3, 2020
Belgrade, Nemanjina 22-26
GP

Pursuant to Article 122, paragraph 10 of the Medical Devices Act ("Serbian Official Gazette" nos. 105/17), Article 37 of the Inspection Supervision Act ("Serbian Official Gazette" no. 36/15, 44/18 and as amended, 95/18) and Article 136 and 184 of the General Administrative Procedure Act ("Serbian Official Gazette" no. 18/16), deciding in relation to the request for the issuance of a license for **wholesale of medical devices** submitted by "**PHOENIX PHARMA**" d.o.o. Beograd, Bore Stankovića 2, the Serbian Minister of Health hereby renders the following

DECISION

I "**PHOENIX PHARMA**" d.o.o. Beograd, Bore Stankovića 2, **IS HEREBY GRANTED THE LICENSE** for the wholesale – **import, export, supply, storage and distribution** of the **medical devices of the following classes and categories** in the territory of the Republic of Serbia:

Class I:

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 08 - ophthalmological and optical medical devices
- Category 09 - reusable instruments
- Category 10 - disposable medical devices
- Category 11 - technical aids for disabled persons

Class Im:

- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus
- Category 09 - reusable instruments

Class Is:

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 05 - hospital equipment - apparatus
- Category 08 - ophthalmological and optical medical devices
- Category 10 - disposable medical devices
- Category 11 - technical aids for disabled persons

Class IIa:

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices



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- Category 04** - electromechanical medical devices
- Category 05** - hospital equipment - apparatus
- Category 07** - inactive implantable medical devices
- Category 08** - ophthalmological and optical medical devices
- Category 09** - reusable instruments
- Category 10** - disposable medical devices
- Category 11** - technical aids for disabled persons
- Category 12** - diagnostic and therapeutic medical devices

Class IIb:

- Category 02** - anesthesia and respiratory medical devices
- Category 03** - dental medical devices
- Category 04** - electromechanical medical devices
- Category 05** - hospital equipment - apparatus
- Category 07** - inactive implantable medical devices
- Category 08** - ophthalmological and optical medical devices
- Category 09** - reusable instruments
- Category 10** - disposable medical devices
- Category 12** - diagnostic and therapeutic medical devices

Class III:

- Category 02** - anesthesia and respiratory medical devices
- Category 03** - dental medical devices
- Category 04** - electromechanical medical devices
- Category 07** - inactive implantable medical devices
- Category 08** - ophthalmological and optical medical devices
- Category 09** - reusable instruments
- Category 10** - disposable medical devices
- Category 12** - diagnostic and therapeutic medical devices

Class: List A, List B, Self-Testing, Other

- Category 06** - "In vitro" diagnostic medical devices

Class: AIMD

- Category 01** - active implantable medical devices

at the common business and storage facilities with a total surface area of 3,391.63 m², the space with the total area of 492.10 m² (with common rooms encompassing 1,579.18 m²) in Novi Sad, Privrednikova 2 are provided for the wholesale of medical devices.

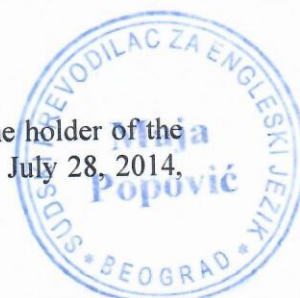
II The integral part of the Decision is Schedule 1 - the License for wholesale of medical devices.

III The License under item I hereof is issued for the period of 5 years.

IV Item 5 of the Decision no. 515-04-02984/2014-11 rendered by the **Ministry of Health** on July 28, 2014 regarding the wholesale of medical devices defined in the body thereof is hereby rendered **invalid**.

Explanation

"PHOENIX PHARMA" d.o.o. Beograd, Bore Stankovića 2, is the holder of the decision no. 515-04-02984/2014-11 rendered by the Ministry of Health on July 28, 2014.



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for the wholesale – **import, export, supply, storage and distribution** of medicines and medical devices stated in the body of the Decision in the territory of the Republic of Serbia at the business and storage facilities with a total surface area of 3,391.63 m² in Novi Sad, Privrednikova 2, namely: 1. Medicines for human use of the ATC classification stated in the body thereof, 2. Herbal medicines, 3. Traditional medicines, 4. Homeopathic medicines; 5. Medical devices stated in the body thereof, 6. Starting substances for the production of medicines and preparation of galenic and magistral medicines in the original packaging.

On June 8, 2020, “PHOENIX PHARMA” d.o.o. Beograd, Bore Stankovića 2, submitted a request for the issue of the license for the wholesale, namely: **import, export, supply, storage and distribution** of medical devices stated in the body hereof in the territory of the Republic of Serbia at the business and storage facilities for the wholesale of medicines, medical devices and starting substances for the production of medicines and preparation of galenic and magistral medicines in the original packaging listed in the body of the Decision no. 515-04-02984/2014-11 dated July 28, 2014 (common storage). In the common business and storage facilities for the wholesale of medicines and medical devices with the total area of 3,391.63 m², the space with the total area of 492.10 m² (with common rooms encompassing 1,579.18 m²) was provided for the wholesale of medical devices in Novi Sad, Privrednikova 2. The applicant enclosed necessary evidence.

Acting upon the submitted request, pursuant to Article 118, paragraph 3, item 2 of the Medical Devices Act (“Serbian Official Gazette” no. 105/17) the enclosed documents, facilities and equipment for storage and keeping of medical devices were inspected as well as the means of transportation and the fulfillment of conditions regarding the professional qualifications of the personnel were verified, as determined in the inspector’s record no. 515-04-3934/2020-11 dated August 20, 2020.

Based on directly established facts and submitted documents, it was determined that the requirements had been met with regard to the wholesale of medical devices pursuant to Art. 69, 70 and 71 of the Medical Devices Act (“Serbian Official Gazette” no. 105/17) and Art. 3, 8, 9, 11, 12, 13, 16, 18, 19, 21, 25 and 26 of the Rules on the Terms of Medical Devices Wholesale (“Serbian Official Gazette” no. 84/18), as it is decided in item I hereof.

Pursuant to Article 3, item 2 of the Rules on the Terms of Medical Devices Wholesale (“Serbian Official Gazette” no. 84/18), the integral part of the Decision is Schedule 1 - license enclosed to this Decision, as stated under item II hereof.

Pursuant to Article 73, paragraph 4 of the Act, the license is issued for a period of 5 years as established under item III hereof.

By this Decision, item 5 of the Decision of the Ministry of Health no. 515-04-02984/2014/11 dated July 28, 2014 regarding the wholesale of medical devices of classes and categories stated therein becomes invalid.

This decision is final in the administrative procedure.

One may initiate an administrative dispute against this decision by filing a claim to the Administrative Court within 30 (thirty) days after the receipt of the decision.

The applicant paid the fee for this decision in accordance with the National Administrative Fees Act (“Serbian Official Gazette” no. 61/17, 118/17, 3/18, 50/18 and 38/19).

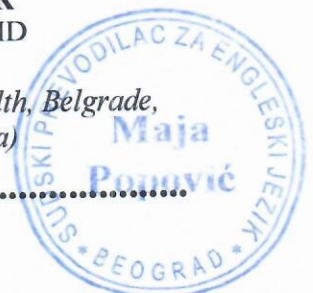
Delivered to:

1. “PHOENIX PHARMA” d.o.o. Beograd, Bore Stankovića 2
2. Records Management Office

MINISTER
Zlatibor Lončar, MD
(Signed)

(Round seal: Ministry of Health, Belgrade,
Republic of Serbia)

.....the end of translation.....



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Maja Popović
Sworn-In Court Translator for English