

CERTIFIED TRANSLATION INTO ENGLISH

(Coat of Arms)

Republic of Serbia

MINISTRY OF HEALTH

No. 515-04-3935/2020-11

Date: December 7, 2020

Belgrade, Nemanjina 22-26

Phone: 011 26-00-749

GP

Pursuant to Article 212, paragraph 6 of the Medicines and Medical Devices Act ("Serbian Official Gazette" nos. 30/2010 and 107/2012) and Article 192, paragraph 1 of the General Administrative Procedure Act ("Official Gazette of the Federal Republic of Yugoslavia" nos. 33/97 and 31/01, "Serbian Official Gazette" no. 30/10), deciding in relation to the request for the issuance of a license for wholesale trade of medical devices submitted by the Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, the Serbian Minister of Health hereby renders the following

DECISION

I The Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, **IS HEREBY GRANTED THE LICENSE** for the **wholesale of medical devices – import, export, supply, storage and distribution** in the territory of the Republic of Serbia, at the business and storage facilities for medicines and medical devices in Leskovac at the address: Moravska 73, with a total surface area of 4,102.83 m² (419.05 m² has been provided for the storage of medical devices), namely the following:

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 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 Im

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

Class IIa

- Category 02 - anesthesia and respiratory medical devices
- Category 03 - dental medical devices
- Category 04 - electromechanical medical devices
- Category 05 - hospital equipment - apparatus



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- 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

- Category 06 "in vitro" diagnostic medical devices

Class LIST B

- Category 06 "in vitro" diagnostic medical devices

Class OTHER

- Category 06 "in vitro" diagnostic medical devices

Class Self-Testing Products

- Category 06 "in vitro" diagnostic medical devices

Class AIMD

- Category 01 - active implantable 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 The Decision no. 515-04-07513/2017-11 rendered by the Serbian Ministry of Health on October 20, 2017 regarding the wholesale of medical devices defined in the body thereof IS HEREBY REVOKED.

E x p l a n a t i o n

The Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", address: Belgrade-Čukarica, Bore Stankovića 2, is the holder of the



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decision no. 515-04-07513/2017-11 of October 20, 2017 rendered by the Ministry of Health, 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 in Leskovac, address: Moravska 73, with a total surface area of 4,262.15 m².

On June 8, 2020, the Limited Liability Company “PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)”, address: Belgrade-Čukarica, Bore Stankovića 2, submitted a request to the Ministry of Health for the issue of the new license for the wholesale, namely: import, export, supply, storage and distribution of medical devices stated in the body hereof for the purpose of complying the business operations with the new legislations. 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 at the address in Leskovac, Moravska 73 in business and storage facilities with a total surface area of 4,102.83 m² (419.05 m² has been provided for the storage of medical devices and 1,654.86 m² for common areas – offices, wardrobe, sanitary facilities) 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. 515-04-3935/2020-11 dated December 2, 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, the Decision of the Ministry of Health no. 515-04-07513/2017-11 dated October 20, 2017 is revoked as stated under item 5 of paragraph I hereof.

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 of the receipt of the decision.

The applicant paid the fee for this decision pursuant to the tariff no. 182 of 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,
Belgrade-Čukarica, Bore Stankovića 2
2. Records Management Office

MINISTER
Zlatibor Lončar, MD
(Signed)
(Round seal: Ministry of Health, Belgrade,
Republic of Serbia)



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Schedule 1

MEDICAL DEVICES WHOLESALER LICENSE

License number:	515-04-3935/2020-11
Date of issue:	December 7, 2020

Wholesale (name):
PHOENIX PHARMA DOO BEOGRAD

Business name: **PHOENIX PHARMA DOO BEOGRAD**

Registered office: Belgrade-Čukarica, Bore Stankovića 2

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

This License applies to:

- all wholesale transactions
 - part of wholesale transactions, namely:
 - registered 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
- the entire territory of the Republic of Serbia
 - part of the territory of the Republic of Serbia
 - unregistered medical devices

Licensing inspection date: December 2, 2020



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Wholesale location¹		
1	Address and contact details: Leskovac, Moravska 73 Contact: 016/230-920; 011/353-81-00 E-mail: <u>office@phoenix.pharma.rs</u>	First and last name, qualifications and contact details of the person in charge of wholesale activities: Nataša Stanić, née Bogdanović, grad. pharmacist Personal ID no. 0205969745055
Assigned activities²		
1	Type of activity:	
Medical devices³		
1	Type: general medical devices; Class: I	Categories: 02, 03, 04, 05, 08, 09, 10, 11
2	Type: general medical devices; Class: Is	Categories: 02, 03, 05, 08, 10, 11
3	Type: general medical devices; Class: Im	Categories: 04, 05, 09
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	"In vitro" diagnostic medical devices Class: List A, List B, Other, Self-testing products	Categories: 06
8	Active implantable medical devices Class: AIMD	Categories: 01
This license confirms the conformity with the requirements for the wholesale of medical devices specified by Medical Devices Act ("Serbian Official 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-Čukarica, Bore Stankovića 2
2. Records Management Office

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, certify hereby that this translation into English is fully true to the original text written in the Serbian language. My commission is permanent.

In Belgrade, October 4, 2021
No. 6118/2021



The image shows a handwritten signature in blue ink, which appears to be 'Maja Popović'. Overlaid on the signature is a circular blue stamp. The stamp contains the text 'PREVODILAC ZA ENGLJSKI JEZIK' around the top inner edge, 'Maja Popović' in the center, and 'BEOGRAD' at the bottom. There are also small stars on either side of 'BEOGRAD'.

Maja Popović
Sworn-In Court Translator for English