Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-01-07600/2020-11
Date: 4 August 2022
Belgrade, Nemanjina 22-26
Tel.: 011 311 49 49
SI

The Minister of Health of the Republic of Serbia, in consideration of the application of Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", Belgrade-Čukarica, 2 Bore Stankovića Street, for the issuance of a Marketing Authorization for the wholesale of medical devices, and pursuant to Article 212, Paragraph 6 of the Law on Medicines and Medical Devices ("Official Gazette of the Republic of Serbia", No. 30/10 and 107/12) and Article 192, Paragraph 1 of the Law on General Administrative Procedure ("Official Gazette of the FRY", No. 33/97 and 31/01 and "Official Gazette of the Republic of Serbia", No. 30/10), renders the following

D E C I S I O N

I THE MARKETING AUTHORIZATION IS HEREBY ISSUED to Limited Liability Company **"PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)",** Belgrade-Čukarica, 2 Bore Stankovića Street, **for the wholesale of medical devices – import, export, procurement, storage and distribution,** in the territory of the Republic of Serbia, in the common storage space for medicines and medical devices in Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš, with total surface area of 5,577.92 m^2 (for the storage of medical devices, 448.90 m^2 has been provided), for the following **medical devices**:

Class I
Category 02 – anaesthetic and respiratory medical devices
Category 03 – dental medical devices
Category 04 – electromechanical medical devices
Category 05 – hospital – apparatus medical devices
Category 08 – ophthalmic and optical medical devices
Category 09 – reusable instruments
Category 10 – single-use medical devices
Category 11 – assistive technology devices

Class Is
Category 02 – anaesthetic and respiratory medical devices
Category 03 – dental medical devices
Category 05 – hospital – apparatus medical devices
Category 08 – ophthalmic and optical medical devices
Category 10 – single-use medical devices

SUDSKI PREVODILAC ZA ENGLESKI JEZIK • COURT INTERPRETER FOR THE ENGLISH LANGUAGE • PANČEVO • LJUBICA BRAJER •

Category 11 – assistive technology devices

Class Im
Category 04 – electromechanical medical devices
Category 05 – hospital – apparatus medical devices
Category 09 – reusable instruments

Class IIa
Category 02 – anaesthetic and respiratory medical devices
Category 03 – dental medical devices
Category 04 – electromechanical medical devices
Category 05 – hospital – apparatus medical devices
Category 07 – inactive implantable medical devices
Category 08 – ophthalmic and optical medical devices
Category 09 – reusable instruments
Category 10 – single-use medical devices
Category 11 – assistive technology devices
Category 12 – diagnostic and therapeutic medical devices in radiology

Class IIb
Category 02 – anaesthetic and respiratory medical devices
Category 03 – dental medical devices
Category 04 – electromechanical medical devices
Category 05 – hospital – apparatus medical devices
Category 07 – inactive implantable medical devices
Category 08 – ophthalmic and optical medical devices
Category 09 – reusable instruments
Category 10 – single-use medical devices
Category 12 – diagnostic and therapeutic medical devices in radiology

Class III
Category 02 – anaesthetic and respiratory medical devices
Category 03 – dental medical devices
Category 04 – electromechanical medical devices
Category 07 – inactive implantable medical devices
Category 08 – ophthalmic and optical medical devices
Category 09 – reusable instruments
Category 10 – single-use medical devices
Category 12 – diagnostic and therapeutic medical devices in radiology

Class: LIST A, LIST B, self-testing, other
Category 06 – in vitro diagnostic medical devices

Class AIMD
Category 01 – active implantable medical devices

SUDSKI PREVODILAC ZA ENGLESKI JEZIK • COURT INTERPRETER FOR THE ENGLISH LANGUAGE • PANČEVO • LJUBICA BRAJER

II Appendix 1 – Marketing Authorization for the Wholesale Trade of Medical Devices **is an integral part of the Decision.**

III The Marketing Authorization referred to in Item I of this Decision is issued for a period of 5 years.

IV Decision No. 515-04-01023/2014-11 dated 26 May 2014, issued by the Ministry of Health of the Republic of Serbia, **IS HEREBY CANCELLED**.

Statement of Reasons

Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", Belgrade-Čukarica, 2 Bore Stankovića Street, holds Decision number: 515-04-01023/2014-11, dated 26 May 2014, issued by the Ministry of Health of the Republic of Serbia, for the wholesale trade – import, export, procurement, storage and distribution of the medicines and medical devices stated in the operative part of this Decision, in the territory of the Republic of Serbia, in the business and storage premises in Belgrade, Čukarica, 2 Bore Stankovića Street, with total surface area of 4,231.47 m^2.

On 19 October 2020, Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", Belgrade-Čukarica, 2 Bore Stankovića Street, submitted to the Ministry of Health the Application for the issuance of a new Marketing Authorization for the wholesale trade – import, export, procurement, storage and distribution of medical devices of the following classes and categories: class: I, categories: 02, 03, 04, 05, 08, 09, 10, 11; class: Is, categories: 02, 03, 05, 08, 10, 11; class: Im, categories: 04, 05, 09; class: IIa, categories: 02, 03, 04, 05, 07, 08, 09, 10, 11, 12; class: IIb, categories: 02, 03, 04, 05, 07, 08, 09, 10, 12; class: III, categories: 02, 03, 04, 07, 08, 09, 10, 12; class: List A, List B, Self-Testing and Other; category: 06, class: AIMD, category: 01, from the storage space in Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš, with total surface area of 5,577.92 m^2 (for the storage of medical devices, 448.90 m^2 has been provided). The Application has been submitted for the purpose of brining the business operations in compliance with new legal regulations and due to an increase in the total surface area of the storage space for the performance of the activity. Along with the Application, the client has submitted the required evidence.

In consideration of the said Application and pursuant to Article 118, Paragraph 3, Item 2 of the Law on Medical Devices ("Official Gazette of the RS", No. 105/17), inspection control has been performed of the documentation, space and equipment for the location and storage of medical devices in Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš, and of the means of transport, as well as the verification of the fulfilment of requirements regarding the education of employees, as stated in the Inspector's Records number: 515-01-07600/2020-11, dated 1 August 2022.

Based on the established facts and submitted documentation, it has been established that the prescribed requirements for the performance of the activity of wholesale trade of medical devices are fulfilled in accordance with Articles 69, 70 and 71 of the Law on Medical Devices ("Official Gazette of the RS", number 105/17) and Articles 3, 8, 9, 11, 12, 13, 16, 18, 19, 21, 25 and 26 of the Rulebook on the Requirements for Wholesale Trade of Medical Devices, ("Official Gazette of the RS", No. 84/18), and therefore it has been decided as stated in Item I of the operative part of this Decision.

SUDSKI PREVODILAC ZA ENGLESKI JEZIK • COURT INTERPRETER FOR THE ENGLISH LANGUAGE • PANČEVO • LJUBICA BRAJER •

Pursuant to Article 3, Paragraph 2 of the Rulebook on the Wholesale Trade of Medical Devices ("Official Gazette of the RS", number 84/18), Appendix 1 to the Marketing Authorization, appended to this Decision as well, is an integral part of the Decision, as stated in Item II of the operative part of this Decision.

Pursuant to Article 73, Paragraph 4 of the Law, the Marketing Authorization is issued for a period of 5 years, as determined in Item III of the operative part of this Decision.

By the issuance of this Decision, Decision No. 515-04-01023/2014-11, dated 26 May 2014, issued by the Ministry of Health, is cancelled.

This Decision is final in the administrative procedure.

Against this Decision, an administrative dispute may be instituted before the competent court within 30 (thirty) days from the Decision receipt date.

The applicant has paid the republic administrative fee for this Decision, pursuant to Tariff Number 182 of the Law on Republic Administrative Fees ("Official Gazette of the RS", No. 61/17, 118/17, 3/18, 50/18 and 38/19).

MINISTER

(Signature)

Dr Zlatibor Lončar

Round seal: Republic of Serbia – Belgrade – Ministry of Health

Delivered to:

1. "PHOENIX PHARMA" d.o.o.
Belgrade-Čukarica, 2 Bore Stankovića Street
2. Archive

SUDSKI PREVODILAC ZA ENGLESKI JEZIK • COURT INTERPRETER FOR THE ENGLISH LANGUAGE • PANČEVO • LJUBICA BRAJER •

Appendix 1

MARKETING AUTHORIZATION FOR THE WHOLESALE TRADE OF MEDICAL DEVICES

Marketing Authorization number:	515-01-07600/2020-11
Date of issue:	4 August 2022

Wholesaler (name):
PHOENIX PHARMA DOO BEOGRAD

Business name: **PHOENIX PHARMA DOO BEOGRAD**
Seat address: Belgrade-Čukarica, 2 Bore Stankovića Street
The legal grounds for the issuance of the Marketing Authorization: Law on Medical Devices ("Official Gazette of the RS", number 105/17)

The Marketing Authorization covers:

☒ All wholesale transactions

☐ Part of wholesale transactions, in particular:

☒ Registered medical devices

☒ Medical devices for clinical trials

☒ Medical devices from non-EU countries

☒ Medical devices for the assessment of compliance by a notified body

☐ Medical devices that are sources of ionizing radiation

☒ Activities of labeling medical devices with labels or additional labels

☒ The whole territory of the Republic of Serbia

☐ Part of the territory of the Republic of Serbia, in particular:

☒ Unregistered medical devices

Date of the inspection control on the basis of which the Marketing Authorization is issued: 1 August 2022

SUDSKI PREVODILAC ZA ENGLESKI JEZIK • COURT INTERPRETER FOR THE ENGLISH LANGUAGE • PANČEVO • LJUBICA BRAJER

Information on the place of wholesale trade[1]		
1.	Address and contact: Belgrade, Čukarica, 2 Bore Stankovića Street – Makiš Contact: 011/35 38 100 E-mail: office@phoenixpharma.rs	Name and surname, education and contact of the person responsible for wholesale trade: **Jelena Srećković, BSc in Pharmacy** Contact: 062/282 957 E-mail: jelena.sreckovic@phoenixpharma.rs
Delegated activities[2]		
1.	Type of activity: /	
Medical devices[3]		
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.	Type: In vitro diagnostic medical devices; **Class: List A, List B, self-testing, other**	Category: **06**
8.	Type: Active implantable medical devices; **Class: AIMD**	Category: **01**
This Marketing Authorization confirms the fulfillment of the requirements for the wholesale trade of medical devices, prescribed by the Law on Medical Devices ("Official Gazette of the RS", No. 105/17) and the regulations passed for its enforcement.		
Delivered to: 1. "PHOENIX PHARMA" d.o.o. Belgrade-Čukarica, 2 Bore Stankovića Street 2. Archive		**Minister** (Signature) **Dr Zlatibor Lončar**

Round seal: Republic of Serbia – Belgrade – Ministry of Health

The Marketing Authorization for the wholesale trade of medical devices is issued for a period of five years, in accordance with the law governing medical devices.

[1] State all the places of wholesale trade for which the Marketing Authorization is issued
[2] State all delegated activities
[3] State all medical devices (other than medical devices for the assessment of compliance)

I, Ljubica Brajer, Official Court Interpreter for the English language, appointed by Decision No. 740-02-00106/92-03 dated 3 June 1993, issued by the Minister of Justice of the Republic of Serbia, hereby certify with my signature and seal that this is a true and accurate translation of the text originally composed in Serbian.

Ljubica Brajer
Official Court Interpreter for the English Language

SUDSKI PREVODILAC ZA ENGLESKI JEZIK · OFFICIAL COURT INTERPRETER FOR THE ENGLISH LANGUAGE · PANČEVO · LJUBICA BRAJER