Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 515-04-3130/2021-15
Date: 25 May 2021
Belgrade, Nemanjina 22-26
Tel.: 011 20-68-744
DB66

The Minister of Health of the Republic of Serbia, in consideration of the application of Limited Liability Company PHOENIX PHARMA DOO, BEOGRAD, Belgrade-Čukarica, 2 Bore Stankovića Street, for the issuance of a Marketing Authorization for the wholesale of medical devices, and pursuant to Article 122, Paragraph 10 of the Law on Medical Devices ("Official Gazette of the Republic of Serbia", number 105/17), Article 37, Paragraph 1 of the Law on Inspection Control ("Official Gazette of the RS", No. 36/15, 44/18 and state law, 95/18), and Articles 136 and 180 of the Law on General Administrative Procedure ("Official Gazette of the RS", No. 18/16), 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**, 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, from business and storage premises in **Šimanovci, 25 Dositejeva Street,** with total surface area of 7,248.28 m² (for the storage of medical devices, 624.73 m² 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
Category **11** – assistive technology devices

2

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

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

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

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

Class AIMD
- Category 01 – active implantable medical devices

II Appendix I – 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.

1

IV Decision No. 515-04-7638/2020-11, dated 27 January 2021, issued by the Ministry of Health of the Republic of Serbia, **IS HEREBY CANCELLED**

Statement of Reasons

Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD", Belgrade-Čukarica, 2 Ilove Stankovića Street, holds Decision number: 515-04-7638/2020-11, dated 27 January 2021, issued by the Ministry of Health of the Republic of Serbia, for the wholesale trade of medical devices – import, export, procurement, storage and distribution of the classes and categories stated in the operative part of this Decision, in the territory of the Republic of Serbia, from the business and storage premises in Šimanovci, 33 Dositejeva Street, with total surface area of 6,194.01 m².

On 19 April 2021, due to a decrease in the total surface area of the storage space from 6,010.01 m² to 5,248.20 m², Limited Liability Company "PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA)", Belgrade-Čukarica, 2 Ilove Stankovića Street, submitted to the Ministry of Health the Application for the issuance of a new Marketing Authorization for the wholesale trade, in particular: import, export, procurement, storage and distribution of medical devices of: class I, categories 02, 03, 04, 05, 08, 09, 10,11; class Is, categories 05, 05, 06, 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, 05, 04, 05, 07, 08, 09, 10, 12, class III, categories 02, 03, 04, 05, 08, 09, 10, 12; then class: List A, List B, Self-Testing and Other – category 08, as well as class AIMD, category 01, in the territory of the Republic of Serbia. The trade in the medical devices will be carried out from the business and storage premises with the total surface area of 5,248.20 m² whereof the premises with surface area of 626.71 m² located in Belgrade, Šimanovci, 33 Dositejeva Street, are intended for the trade in medical devices. Along with the Application, the client has submitted the required evidence.

In consideration of this Application, and pursuant to Article 118, Paragraph 3, Item 2 of the Law on Medical Devices ("Official Gazette of the RS", No. 105/17), expert-in-control has been performed of the documentation, space and equipment for the location and storage of medical devices, 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: 515-04-353(6)/2021-11, dated 24 May 2021.

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", No. 105/17) and Articles 3, 8, 9, 11, 12, 13, 18, 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.

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 75, 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.

2

By the issuance of this Decision, Decision No. 515-04-7638/2020-11, dated 27 January 2021, 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 this Decision receipt date.

The applicant has paid the republic administrative fee for this Decision, pursuant to Tariff Number 145 of the Law on Republic Administrative Fees ("Official Gazette of the RS", No. 94/16).

MINISTER

(Signature)
Dr Zoran Lončar

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

Delivered to:

1. **"PHOENIX PHARMA"** d.o.o.
Belgrade-Čukarica, 2 Ilove Stankovića Street

2. Archive

Appendix 1

MARKETING AUTHORISATION FOR THE WHOLESALE TRADE OF MEDICAL DEVICES

Marketing Authorisation number:	[illegible]
Date of issue:	[illegible] May 2021

Wholesaler (name)
PHOENIX PHARMA

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

The Marketing Authorisation covers:

☒ All wholesale transactions ☒ The whole territory of the Republic of Serbia

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

☒ Registered medical devices ☒ Unregistered 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

Date of the inspection control on the basis of which the Marketing Authorisation is issued: [illegible] May 2021

	Information on the place of wholesale trade[1]	
1.	Address and contact: [illegible] Street, Contact: [illegible], E-mail: [illegible]	Name and surname, education and contact of the person responsible for wholesale trade: [illegible], BSc in Pharmacy, Personal number: [illegible]
	Delegated activities[2]	
1.	Type of activity:	
	Medical devices[3]	
1.	Type: general medical devices; **Class I**	Categories: **[illegible]**
	Type: general medical devices; **Class Is**	Categories: **[illegible]**
2.	Type: general medical devices; **Class Im**	Categories: **[illegible]**
3.	Type: general medical devices; **Class IIa**	Categories: **[illegible]**
	Type: general medical devices; **Class IIb**	Categories: **[illegible]**
4.	Type: general medical devices; **Class III**	Categories: **[illegible]**
5.	Type: in vitro diagnostic medical devices; **Class: List A, List B, self-testing, other**	Category: **[illegible]**
	Type: active implantable medical devices; **Class: AIMD**	Category: **[illegible]**

This Marketing Authorisation 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. [illegible]) and the regulations passed for its enforcement.

Delivered to: 1. "PHOENIX PHARMA" d.o.o. Belgrade-Čukarica, 7 Bore Stankovića Street; 2. Archive	Minister (Signature) Dr Zlatibor Lončar

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

The Marketing Authorisation 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 Authorisation is issued
[2] State all delegated activities
[3] State all medical devices (other than medical devices for the assessment of compliance)

I, Ljubica Bojić, Official Court Interpreter for the English language, appointed by Decision No. [illegible] dated [illegible] 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 faithful translation of the text originally composed in Serbian.

Ljubica Bojić
Official Court Interpreter for the English Language