

MARKETING AUTHORIZATION FOR THE WHOLESALE TRADE OF MEDICAL DEVICES

Marketing Authorization number:	004465146 2025 11900 008 004 530 131
Date of issue:	30 December 2025

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 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 Authorization is issued:**

24 December 2025



Information on the place of wholesale trade¹		
1.	Address and contact: Leskovac, 73 Moravska Street Contact: 016/230-920; 011/353-81-00 E-mail: office@phoenixpharma.rs	Name and surname, education and contact of the person responsible for wholesale trade: Nataša Stanić, BSc in Pharmacy Personal number: 0205969745055 063/687 005
Delegated activities²		
1.	Type of activity:	
Medical devices³		
1.	Type: general medical devices Class: I	Categories: 02, 03, 04, 05, 08, 09, 10, 11 A, B, C, D, F, G, H, K, M, N, P, Q, R, S, T, U, V, Y, Z
2.	Type: general medical devices Class: Is	Categories: 02, 03, 05, 08, 10, 11 A, B, C, D, F, G, H, K, M, N, P, Q, R, S, T, U, V, Y, Z
3.	Type: general medical devices Class: Ir	Categories: A, B, C, F, G, H, K, L, M, N, P
4.	Type: general medical devices Class: Im	Categories: 04, 05, 09 A, B, C, F, G, K, N, P, Q, R, U, V, Z
5.	Type: general medical devices Class: IIa	Categories: 02, 03, 04, 05, 07, 08, 09, 10, 11, 12 A, B, C, F, G, H, K, L, M, N, P, Q, R, S, T, U, V, Y, Z
6.	Type: general medical devices Class: IIb	Categories: 02, 03, 04, 05, 07, 08, 09, 10, 11, 12 A, B, C, F, G, H, K, L, M, N, P, Q, R, S, T, U, V, Y, Z
7.	Type: general medical devices Class: III	Categories: 02, 03, 04, 05, 07, 08, 09, 10, 11, 12 A, B, C, F, G, H, J, K, L, M, N, P, Q, R, S, T, U, V, Y, Z
8.	Type: "In vitro" diagnostic medical devices: Class: List A, List B, other, self-testing, Class: A, B, C, D	Category: 06, W
9.	Type: Active implantable medical devices Class: AIMD	Category: 01, J
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.		
		Minister (Signature) Dr Zlatibor Lončar

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

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)



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.

Delivered to:

1. **PHOENIX PHARMA DOO**
Belgrade-Čukarica,
2 Bore Stankovića Street
2. Archive

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



Coat of Arms
Republic of Serbia
MINISTRY OF HEALTH
Number: 004465146 2025 11900
008 004 530 131
Date: 30 December 2025
Belgrade, 22-26 Nemanjina Street
Tel.: 011 311 49 49
DBM

The Minister of Health of the Republic of Serbia, in consideration of the application of PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA), with its seat in Belgrade-Čukarica, at 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 RS", number 105/17), Article 37, Paragraph 1 of the Law on Inspection Control ("Official Gazette of the RS", No. 36/15, 44/18 and other law, 95/18), and Articles 136 and 184 of the Law on General Administrative Procedure ("Official Gazette of the RS", No. 18/16), renders the following

DECISION

I THE MARKETING AUTHORIZATION IS HEREBY ISSUED to PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA), with its seat in Belgrade-Čukarica, at 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 joint business and storage premises for medicines and medical devices **in Leskovac, 73 Moravska Street**, with total surface area of 4,102.83 m².

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. 515-04-3935/2020-11, dated 7 December 2020, issued by the Ministry of Health of the Republic of Serbia, IS HEREBY CANCELLED.

Statement of Reasons

PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA), with its seat in Belgrade-Čukarica, at 2 Bore Stankovića Street, holds Decision number: 515-04-3935/2020-11, dated 7 December 2020, issued by the Ministry of Health of the Republic of Serbia, for the wholesale trade – import, export, procurement, storage and distribution of medical devices in the territory of the Republic of Serbia, in particular:



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: Ila, 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 In vitro Diagnostic Medical Devices (IVD), category: 06, and Class: AIMD, category: 01, from the business and storage premises in Leskovac, 73 Moravska Street, with total surface area of 4,102.83 m². In the same space, in addition to medical devices, the wholesaler stores medicines as well.

On 6 November 2025, PHOENIX PHARMA DOO, BEOGRAD (ČUKARICA), with its seat in Belgrade-Čukarica, at 2 Bore Stankovića Street, submitted the Application for supplementing the Marketing Authorization for the wholesale of medical devices (import, export, procurement, storage and distribution) with new classes and categories of medical devices, in compliance with the classification rules according to the requirements of the EU regulation, in particular: Class: I, categories: A, B, C, D, F, G, H, K, M, N, P, Q, R, S, T, U, V, Y, Z; Class: Is, categories: A, B, C, D, F, G, H, K, M, N, P, Q, R, S, T, U, V, Y, Z; Class: Ir, categories: A, B, C, F, G, H, K, L, M, N, P; Class: Im, categories: A, B, C, F, G, K, N, P, Q, R, U, V, Z; Class: Ila, categories: A, B, C, F, G, H, K, L, M, N, P, Q, R, S, T, U, V, Y, Z; Class: Iib, categories: 11, A, B, C, F, G, H, K, L, M, N, P, Q, R, S, T, U, V, Y, Z; Class: III, categories: 05, 11, A, B, C, F, G, H, J, K, L, M, N, P, Q, R, S, T, U, V, Y, Z; Class: A, B, C, D, category: W and Class: AIMD, category: J, from the business and storage premises in Leskovac, 73 Moravska Street, with total surface area of 4,102.83 m². 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), inspection control has been performed of the documentation, space and equipment for the location and storage of medical devices at the address in Leskovac, 73 Moravska Street, in the business and storage premises with the total surface area of 4,102.83 m², 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 Record number: 004465146 2025 11900 008 004 530 131, dated 24 December 2025.

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.

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, 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. 515-04-3935/2020-11, dated 7 December 2020, issued by the Ministry of Health, is cancelled, as stated in Item IV of the operative part of this Decision.



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. 59/2024, 94/24 and 55/2025).

MINISTER
(Signature)
Dr Zlatibor Lončar

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

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Ljubica Brajer
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