

**CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH BEGINS**

/coat of arms of the Republic of Serbia/

Republic of Serbia

**MINISTRY OF HEALTH**

No.: 004902148 2025 11900

008 004 530 128

Date: December 31<sup>st</sup>, 2025

Belgrade, Nemanjina 22-26

JPM

The Minister of Health of the Republic of Serbia, deciding upon the application of the company “INO-PHARM” d.o.o., Belgrade, Bore Stankovica Str. No. 2, for the issuance of a wholesale distribution authorisation for medical devices, pursuant to Article 122, Paragraph 10 of the Medical Devices Act (“Official Gazette of the Republic of Serbia” No. 105/17) and pursuant to Article 37, Paragraph 1 of the Law on Inspection Supervision (“Official Gazette of the Republic of Serbia”, No. 36/15, 44/18 and other laws, 95/18), as well as Articles 136 and 184, Paragraph 2 of the General Administrative Procedure Act (“Official Gazette of the Republic of Serbia” No. 18/16), passes the following

**DECISION**

**I The trade and services company “INO-PHARM” DOO (Ltd.) Belgrade (Cukarica), Bore Stankovica Str. No. 2, IS GRANTED AN AUTHORISATION for the wholesale distribution of medical devices – import, export, supply, storage and distribution in the territory of the Republic of Serbia, from the office and storage space of a total area of 250.50 m<sup>2</sup> in Belgrade (Cukarica), Bore Stankovica Str. No. 2**

**II Annex 1 – the Wholesale distribution authorisation for medical devices is an integral part of this Decision.**

**III The distribution authorisation in Item I of this Decision is issued for a period of five years, starting from the date of the inspection supervision performed on December 29<sup>th</sup>, 2025.**

**IV The AUTHORISATION issued by the Ministry of Health, number 515-04-01533/2023-11 of July, 24<sup>th</sup>, 2023 IS REVOKED.**

**Grounds for the decision**

The company “INO-PHARM” DOO Belgrade (Cukarica), was issued the Decision by the Ministry of Health, number 515-04-01533/2023-11 of July 24<sup>th</sup>, 2023, with the wholesale distribution authorisation – import, export, supply, storage and distribution of medical devices from the office and storage space of a total area of 250.50 m<sup>2</sup> in Belgrade, at the address Belgrade-Cukarica, Bore Stankovica Str. No. 2, for the following medical devices: Class I, Categories: 02-Anaesthetic and respiratory medical devices, 03-Dental medical devices, 04-Electro-mechanical medical devices, 05-Hospital apparatus equipment, 08-Optical and ophthalmic medical devices, 09-Reusable medical devices, 10-Disposable medical devices, 11-Medical devices to aid people with disabilities; Class Im, Categories: 04-Electro-mechanical medical devices, 05-Hospital apparatus equipment, 09-Reusable medical devices; Class Is, 02-Anaesthetic and respiratory medical devices, 03-Dental medical devices, 05-Hospital apparatus equipment, 08-Optical and ophthalmic medical devices, 10-Disposable medical devices, 11-Medical devices to aid people with disabilities; Class IIa, 02-Anaesthetic and respiratory medical devices, 03-Dental medical devices, 04-Electro-mechanical medical devices, 05-Hospital apparatus equipment, 07-Inactive implantable medical devices, 08-Optical and ophthalmic medical devices, 09-Reusable medical devices, 10-Disposable medical devices, 11-

Medical devices to aid people with disabilities and 12-Diagnostic and therapeutic medical devices in radiology; Class IIb, 02-Anaesthetic and respiratory medical devices, 03-Dental medical devices, 04-Electro-mechanical medical devices, 05-Hospital apparatus equipment, 07-Inactive implantable medical devices, 08-Optical and ophthalmic medical devices, 09-Reusable medical devices, 10-Disposable medical devices and 12-Diagnostic and therapeutic medical devices in radiology; Class III, Categories: 02-Anaesthetic and respiratory medical devices, 03-Dental medical devices, 04-Electro-mechanical medical devices, 07-Inactive implantable medical devices, 08-Optical and ophthalmic medical devices, 09-Reusable medical devices, 10-Disposable medical devices and 12-Diagnostic and therapeutic medical devices in radiology; Classes: List A, List B, Self-testing and Other, Category 06 – “In-vitro” diagnostic medical devices and Class AIMD, Category 01-Active implantable medical devices; Medical devices which are clinically tested in accordance with the authorisation of the Medicines and Medical Devices Agency of Serbia on conducting clinical trials, in all the above-mentioned classes and categories.

On December 5<sup>th</sup>, 2025, the Trade and Services Company “INO-PHARM” DOO (Ltd.) Belgrade (Cukarica), Bore Stankovica Str. no. 2, submitted an application to the Ministry of Health for an amendment to the wholesale distribution authorisation for medical devices which are a source of ionizing radiation and for harmonisation with the new nomenclature of medical devices according to the MDR and IVDR. The amendment refers to the addition to the authorisation of medical devices of the following classes and categories: General medical devices of Classes I, Is, IIa, IIb, III (categories A-Medical devices for administration, removal and collection, B-Medical devices for haematology and haemotransfusion, C-Medical devices for the cardiovascular system, D-Disinfectants, antiseptics, sterilisation and detergents for medical devices, F-Medical devices for dialysis, G-Medical devices for the gastrointestinal tract, H-Medical devices for sutures (suture material), K-Endotherapy and electrosurgical medical devices, L-Surgical instruments for repeated use, M-Medical devices for general and special dressings, N-Medical devices for the nervous and medullar system, P-Medical devices for osteosynthesis and implantable prosthetics, Q-dental, ophthalmological and ENT medical devices, R-respiratory and aesthetic medical devices, S-Medical devices for sterilization, T-Patient protection equipment and incontinence devices, U-Medical devices for the urogenital tract, V-Other medical devices, Y-Medical devices for assisting persons with disabilities, Z-Medical equipment and accessories, software and consumables); Class Im (categories A-Medical devices for administration, removal and collection, B-Medical devices for haematology and haemotransfusion, C-Medical devices for the cardiovascular system, F-Medical devices for dialysis, G-Medical devices for the gastrointestinal tract, K-Endotherapy and electrosurgical medical devices, N-Medical devices for the nervous and medullar system, P-Medical devices for osteosynthesis and implantable prosthetics, Q-Dental, ophthalmological and ENT medical devices, R-Respiratory and aesthetic medical devices U-medical devices for the urogenital tract, V-Other medical devices, Z-Medical equipment and accessories, software and consumables); Class Ir (categories 03-Dental medical devices, 08-Optical and ophthalmic medical devices, 09-Reusable medical devices, A-Medical devices for administration, removal and collection, B-Medical devices for haematology and haemotransfusion, C-Medical devices for the cardiovascular system, F-Medical devices for dialysis, G-Medical devices for the gastrointestinal tract, H-Medical devices for sutures (suture material), K-Endotherapy and electrosurgical medical devices, L-Surgical instruments for repeated use, P-Medical devices for osteosynthesis and implantable prosthetics, M-Medical devices for general and special dressings, N-Medical devices for the nervous and medullar system, P-Medical devices for osteosynthesis and implantable prosthetics); Active implantable medical devices of Class AIMD (category J-Active implantable medical devices); In vitro diagnostic medical devices of Classes A, B, C, D, List A, List B, Self-testing, Other (categories W-In Vitro diagnostic medical devices). Together with the application, the applicant enclosed the necessary documents and provided the necessary conditions for the distribution of medical devices which are a source of ionizing radiation.

By reviewing the attached documentation, as well as on the basis of the directly established factual situation recorded in the Protocol No. 004902148 2025 11900 008 004 530 128 dated December 29<sup>th</sup>, 2025, it was determined that the prescribed requirements for performing the activity of wholesale distribution of medical devices in accordance with Articles 69, 70 and 71 of the Medical Devices Act (Official Gazette of the Republic of Serbia No. 105/17) and Articles 3, 8, 9, 10, 11, 12, 13, 16, 18, 19, 21, 25 and 26 of the Regulations on Requirements for Wholesale Distribution of Medical Devices (“Official Gazette of the Republic of Serbia”, No. 84/18), as was decided in Item I in the wording of the document. The same storage space will be used for the distribution of medicinal products, which are functionally separated from the medical devices.

The wholesale distribution authorisation given in Annex 1 is an integral part of this Decision, and in accordance with Article 73, Paragraph 4 of the Medical Devices Act (“Official Gazette of the Republic of Serbia”, No. 105/17), the authorisation is issued for a period of five years, starting from the date of the inspection supervision performed on December 29<sup>th</sup>, 2025, as was decided in Items II and III in the wording of the document.

By passing this Decision, the Decision No. 515-04-01533/2023-11 dated July 24<sup>th</sup>, 2023 is revoked, as was decided in Item IV in the wording of the document.

This Decision shall be final in the administrative procedure.

The applicant has paid the administrative fee for this Decision according to tariff No. 182 of the Republic Administrative Fees Act (Official Gazette of the Republic of Serbia No. 43/2003, No. 98/2020-other regulations, 62/2021-other regulations, 138/22, 54/23-other regulations, 59/2024, 94/24 and 55/2025).

The Decision may be disputed in the administrative proceedings initiated before the competent court within 30 (thirty) days as of the receipt hereof.

Served to:

1. **“INO-PHARM” DOO**, Belgrade (Cukarica),  
Bore Stankovica Str. no. 2
2. Archives Department

MINISTER:

Zlatibor Lončar, M.D.  
*/signed: Zlatibor Lončar/*

*/Round seal: REPUBLIC OF SERBIA, MINISTRY OF HEALTH, BELGRADE/*

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH ENDS

On this day, February 20, 2026, I, REBEKA BOŽOVIĆ, a permanent sworn-in court translator for English and Japanese, appointed on December 26, 2005 by the Decision of the Minister of Justice of the Republic of Serbia, with the registration number 740-06-638/2005-03, declare:

*“I hereby confirm that this translation fully corresponds to the original text which is written in the Serbian language.”*



**WHOLESALE DISTRIBUTION AUTHORISATION FOR MEDICAL DEVICES**

<b>Authorisation No.:</b>	<b>004902148 2025 11900 008 004 530 128</b>
<b>Date of issuance:</b>	<b>December 31<sup>st</sup>, 2025</b>

**Wholesale (name): INO-PHARM DOO (LTD.) BELGRADE**

Business name: **The trade and services company “INO-PHARM” D.O.O. (LTD.) Belgrade,  
(Cukarica)**

Registered office: **Belgrade (Cukarica), Bore Stankovica Str. No. 2**

Legal basis for issuance of the authorisation: the Medical Devices Act (Official Gazette of the Republic of Serbia No. 105/17)

The authorisation includes:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> the entire wholesale services   | <input checked="" type="checkbox"/> the entire territory of the Republic of Serbia    |
| <input type="checkbox"/> part of wholesale services, as follows:<br>import, export, procurement, storage    | <input type="checkbox"/> part of the territory of the Republic of Serbia, as follows: |
| <input checked="" type="checkbox"/> registered medical devices  | <input checked="" type="checkbox"/> unregistered medical devices                      |
| <input checked="" type="checkbox"/> medical devices for clinical trials                                     |   |
| <input checked="" type="checkbox"/> medical devices from non-EU countries                                   |   |
| <input type="checkbox"/> medical devices for conformity assessment by a notified body                       |   |
| <input checked="" type="checkbox"/> medical devices which are ionizing radiation sources                    |   |
| <input checked="" type="checkbox"/> performs marking of medical devices with labels, i.e. additional labels |   |

Date of inspection supervision which represents the basis for the issuance of an authorisation:

**December 29<sup>th</sup>, 2025**

Wholesale distribution site data		
1	<p>Address and contact details:  <b>Belgrade (Cukarica)</b>  <b>Bore Stankovica Str. No. 2</b>            011/34 62 110;            e-mail: inopharmdoo@inopharm.net</p>	<p>Full name, education and contact data of the person responsible for wholesale distribution:  <b>Ivana Tesanovic, BSc in Pharmacy</b>            064/8062 009            e-mail: inopharmdoo@inopharm.net</p>
Assigned tasks		
1	Type of task: /	Business name, registered office address and contact information of the contractor/contract recipient: /
Medical devices		
1.	Type: General medical devices; Class: <b>I</b> ,	Categories: <b>02,03,04,05,08,09,10,11,A,B,C,D,F,G,H,K,L,M,N,P,Q,R,S,T,U,V,Y,Z</b>
	Type: General medical devices; Class: <b>Is</b>	Categories: <b>02,03,05,08,10,11,A,B,C,D,F,G,H,K,L,M,N,P,Q,R,S,T,U,V,Y,Z</b>
2.	Type: General medical devices; Class: <b>Ir</b>	Categories: <b>03,08,09,A,B,C,F,G,H,K,L,M,N,P</b>
	Type: General medical devices; Class: <b>Im</b>	Categories: <b>04,05,09,A,B,C,F,G,K,N,P,Q,R,U,V,Z</b>
3.	Type: General medical devices; Classes: <b>IIa, IIb, III</b>	Categories: <b>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</b>
4.	Type: "In Vitro" - diagnostic medical devices, <b>Class: A, B, C, D, List A, List B, Self-Testing and Other</b>	Categories: <b>06, W</b>
5.	Type: Active implantable medical devices Class: <b>AIMD</b>	Category: <b>01, J</b>
<p>This authorisation confirms the fulfilment of conditions for wholesale distribution of the medical devices stipulated by the Medical Devices Act ("Official Gazette of the Republic of Serbia", No. 105/17) and its implementation regulations.</p>		

Served to: <b>1. “INO-PHARM” DOO (Ltd.)</b> <b>Belgrade,</b> Belgrade - Cukarica, Bore Stankovica Str. No. 2 <b>2. Archives Department</b>	<b>MINISTER</b> Zlatibor Lončar, M.D. <i>/signed Zlatibor Lončar/</i> <i>/Round seal: REPUBLIC OF SERBIA,</i> <i>MINISTRY OF HEALTH, BELGRADE/</i>

The wholesale distribution authorisation for medical devices is issued for a period of five years in accordance with the law governing medical devices.

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH ENDS

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*J. Božović*

