

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH BEGINS

/coat of arms of the Republic of Serbia/

Republic of Serbia

MINISTRY OF HEALTH

No.: 515-04-11533/2023-11

Date: July 24th, 2023

Belgrade, Nemanjina 22-26

MK

The Minister of Health of the Republic of Serbia, deciding upon the application of the company “INO-PHARM” d.o.o., Belgrade, Bore Stankovića Str. No. 2, for the issuance of a wholesale distribution authorisation for medical devices, pursuant to Article 122, Paragraph 10 and Article 137 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 Oversight (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, 95/18-authentic interpretation), passes the following

DECISION

I The trade and services company “INO-PHARM” d.o.o., Belgrade (Čukarica), Bore Stankovića 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 m² in Belgrade (Čukarica), Bore Stankovića Str. No. 2

II Annex 1 – 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 to a period of five years, starting from the date of the inspection oversight performed on 03/02/2022.

IV The AUTHORISATION issued by the Ministry of Health, number 515-04-11537/2021-11 of February 4th, 2022 IS REVOKED.

Grounds for the decision

The company “INO-PHARM” DOO Belgrade, was issued the Decision by the Ministry of Health, number 515-04-11537/2021-11 of February 4th, 2022, with the wholesale distribution authorisation – import, export, supply, storage and distribution of medical devices from the office and storage space in Belgrade, at the address Belgrade-Čukarica, Bore Stankovića Str. No. 2.

On February 14th, 2023, the company “INO-PHARM” DOO Belgrade, Bore Stankovića Str. No. 2, due to the change of the responsible person for the wholesale distribution of medical devices, whereby Ana Nićiforović, a BSc. in Pharmacy, is deleted, and Ivana Tešanović, a BSc. in Pharmacy, is recorded, submitted a request to the Ministry of Health for the issuance of a wholesale distribution authorisation – import, export, supply, storage and distribution of

medical devices on the territory of the Republic of Serbia, from the office and storage premises with a total area of 250.50 m² in Belgrade (Čukarica), Bore Stankovića 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 that 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.

By reviewing the attached documentation, as well as on the basis of the directly established factual situation recorded in the Protocol No. 515-04-11537/2021-11 dated February 3rd, 2022, 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. Medicinal products will also be stored in the same space, but they will be organizationally separated.

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 oversight performed on 03/02/2022, as was decided in Item III in the wording of the document.

By passing this Decision, the Decision No. 515-04-11537/2021-11 dated February 4th, 2022 is revoked.

This Decision shall be final in the administrative procedure.

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

The applicant paid the administrative fee for this application according to tariff No. 182 of the Administrative Fees Act (Official Gazette of the Republic of Serbia No. 98/2020, 144/20, 60/21).

MINISTER

Prof. Danica Grujičić, M.D.

(signed and sealed)

Served to:

1. **“INO-PHARM” DOO Belgrade,**
Belgrade (Čukarica), Bore Stankovića Str. No. 2
2. Archives Department



WHOLESALE DISTRIBUTION AUTHORISATION FOR MEDICAL DEVICES

Authorisation No.:	515-04-01533/2023-11
Date of issuance:	July 24th, 2023

Wholesale (name):
“INO-PHARM” DOO Belgrade

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

Registered office: **Belgrade, Bore Stankovića 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:

- | | |
|---|---|
| ☒ all wholesale services
☐ part of wholesale services, as follows:
☒ registered medical devices
☒ medical devices for clinical trials
☒ medical devices from non-EU countries
☐ medical devices for conformity assessment by a notified body
☐ medical devices which are ionizing radiation sources
☒ performs marking of medical devices with labels, i.e. additional labels | ☒ the entire territory of the Republic of Serbia
☐ part of the territory of the Republic of Serbia, as follows:
☒ unregistered medical devices |
|---|---|

Date of inspection oversight

which represents the basis for the issuance of an authorisation: February 3rd, 2022

Wholesale distribution site data		
1.	Address and contact details: Belgrade, Čukarica, Bore Stankovića Str. No. 2 011/34 62 123; e-mail: inopharmdoo@inopharm.net	Full name, education and contact data of the person responsible for wholesale distribution: Ivana Tešanović, BSc in Pharmacy 011/34 62 110 e-mail: inopharmdoo@inopharm.net

Assigned tasks	
1.	Type of task: /

Medical devices		
1.	Type: General medical devices Class I Class Im Class Is Class Ia Class Ib Class III	Categories: 02,03,04,05,08,09,10,11 04,05,09 02,03,05,08,10,11 02,03,04,05,07,08,09,10,11,12 02,03,04,05,07,08,09,10,12 02,03,04,07,08,09,10,12
2.	Type: "In Vitro" – diagnostic medical devices, Class: List A, List B, Self-Testing and Other	Category: 06
3.	Type: Active implantable medical devices Class: AIMD	Category: 01

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	
Served to: 1. "INO-PHARM" DOO Belgrade, Belgrade - Čukarica, Bore Stankovića Str. No. 2 2. Archives Department	MINISTER Prof. Danica Grujičić, M.D. <i>/signed and sealed/</i>

CERTIFIED TRANSLATION FROM SERBIAN INTO ENGLISH ENDS

On this day, September 15, 2023, I, REBEKA BOZOVIC, 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."

