



Republic of Serbia

**MINISTRY OF HEALTH**

No.: 515-04-07672/2020-11

Date: November 12<sup>th</sup>, 2020

Belgrade, Nemanjina 22-26

VV

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 (RS Official Gazette 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 state 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" d.o.o., 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 in Belgrade, Peke Dapčevića Boulevard No. 17.**

**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 5 years.**

**IV The AUTHORISATION issued by the Ministry of Health, number 515-04-05417/2019-11 of October 10<sup>th</sup>, 2019 IS REVOKED.**

**Grounds for the decision**

The company "INO-PHARM" DOO Belgrade, was issued the Decision by the Ministry of Health, number 515-04-05417/2019-11 of October 10<sup>th</sup>, 2019 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 Milosev Kladenac No. 9v.

On October 22<sup>nd</sup>, 2020, the company "INO-PHARM" DOO Belgrade, Bore Stankovića Str. No. 2, due to the relocation of its storage facilities to the new address, 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



360.35 m<sup>2</sup> in Belgrade, Peke Dapčevića Boulevard No. 17, 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 instruments, 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 instruments; 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 Ia, 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 instruments, 10-Disposable medical devices, 11-Medical devices to aid people with disabilities and 12-Diagnostic and therapeutic 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 instruments, 10-Disposable medical devices and 12-Diagnostic and therapeutic agents 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 instruments, 10-Disposable medical devices and 12-Diagnostic and therapeutic means 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. 515-04-07672/2020-11 dated November 5<sup>th</sup> and November 10<sup>th</sup>, 2020, 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, as was decided in Item III in the wording of the document.

By passing this Decision, the Decision No. 515-04-05417/2019-11 dated October 10<sup>th</sup>, 2019 is revoked.

This Decision shall be final in the administrative procedure.



Certified translation from the Serbian language

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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. 38/2019).

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,  
Belgrade (Čukarica), Bore Stankovića No. 2
2. Archives Department

**MINISTER**

Zlatibor Lončar, M.D.

*(signed and sealed)*

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Certified in full conformity with the original text in Serbian by Milan Vurdelja, Sworn Court Translator by appointment of the Ministry of Justice, Belgrade (#740-06-773/98-04).

Number: 072-1/20  
Date: 02/12/2020



Milan Vurdelja