

WHOLESALE DISTRIBUTION AUTHORISATION FOR MEDICAL DEVICES

Authorisation No.:	515-04-07672/2020-11
Date of issuance:	November 12 th , 2020

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

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

Registered office: **Belgrade, Bore Stankovića 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"/> all wholesale services | <input checked="" type="checkbox"/> the entire territory of the Republic of Serbia |
| <input type="checkbox"/> part of wholesale services, as follows: | <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 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 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 oversight which represents the basis for the issuance of an authorisation:

05/11 and 10/11/2020



Wholesale distribution site data		
1.	Address and contact details: Belgrade, Peke Dapčevića Boulevard No. 17 011/34 62 123; e-mail: inopharmdoo@inopharm.net	Full name, education and contact data of the person responsible for wholesale distribution: Ana Nićiforović, BSc in Pharmacy 011/34 62 123; 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 IIa Class IIb 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 <u>its implementation regulations</u>	
Served to: 1. "INO-PHARM" DOO, Belgrade, Belgrade (Čukarica), Bore Stankovića No. 2 2. Archives Department	MINISTER Zlatibor Lončar, M.D. <i>(signed and sealed)</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 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: 073/20
Date: 02/12/2020

Milan Vurdelja