



ADDRESSEE  
INVE Medical, s.r.o.

ADDRESS OF SERVICE:  
Kralická 950/1  
100 00 Prague 10 - Strašnice

File no. sukls173657/2017  
Ref. no. suk178924/2017

Attended by/phone  
MVDr. Květa Pelikánová/430

Date: 24 July 2017

Dispatched on the day of delivery for the purpose of mailing service marked on the envelope by an operator of postal services, date of transmitting a data message from a data box of the State Institute for Drug Control, or date of delivery to the addressee in case of personal service.

## DECISION

The State Institute for Drug Control with its registered office in Prague 10, Šrobárova 48, as an authority competent to decide pursuant to section 13, subsec. 2, item a) 2 of the Act no. 378/2007 Coll., on Pharmaceuticals and on amendments to some related acts (hereinafter "Act on Pharmaceuticals"), as amended, has decided pursuant to sec. 67 of the Act no. 500/2004 Coll., the Code of Administrative Procedure, as amended (hereinafter "Code of Administrative Procedure")

as follows:

The State Institute for Drug Control, pursuant to sec. 76 and sec. 63, subsec. 1 of the Act no. 378/2007 Coll., on Pharmaceuticals and on amendments to some related acts (hereinafter "Act on Pharmaceuticals"), as amended (hereinafter "Act on Pharmaceuticals"), based on request of the company INVE Medical, s.r.o., with its registered office Kralická 950/1, 100 00 Prague 10 - Strašnice, Company Id. No. 242 20 701,

### **changes the decision on permission to distribute pharmaceutical products issued under the file no. sukls104312/2012 on 25 May 2012**

as follows:

1. The scope of permission for distribution of pharmaceuticals in the Attachment no. 1 shall be amended by section 3.1.1 Pharmaceutical products from blood.
2. The individual places for distribution (approved storage places) with specification of the scope of distribution activities are specified in the Attachment no. 1.

The facts specified in this decision and its attachments correspond to the document Compilation of Community Procedures on Inspection and Exchange of Information (Soubor postupů Společenství pro inspekce a výměnu informací) as amended with effect from 2 January 2013.

### **Statement of Reasoning**

The company INVE Medical, s.r.o., with its registered office at Kralická 950/1, 100 00 Prague 10 - Strašnice, Company Id. No. 242 20 701, has submitted an application for change of the permission for distribution of pharmaceutical products on 13 July 2017. Submission of the application has started an administrative procedure kept under the file no. sukls173657/2017. The State Institute for Drug Control (hereinafter "Institute") has assessed, whether the requirements determined by the Act on Pharmaceuticals and its implementing legislation have been met in the specified case. After the procedure executed, the Institute states that it is possible to comply with the application, and therefore it decided on change in the permission for distribution of pharmaceutical products, as specified in the statement of this decision.

The permission for distribution of pharmaceutical products issued by INVE Medical, s.r.o., with its registered office at Kralická 950/1, 100 00 Prague 10, Strašnice, Company Id. No. 242 20 701, under the file no. sukls104312/2012 dated 25 May 2012, as amended by the decision on change, file no. sukls194060/2013 dated 12 December 2013, after the decision on change of permission for distribution of pharmaceutical products enters into force, is in the following scope:

Name and surname for an individual / business name of legal person	INVE Medical, s.r.o.
Place of business/registered office	Kralická 950/1, 100 00 Prague 10 - Strašnice
Company Id. No.	242 20 701
Scope of activity	Distribution of pharmaceutical products
Addresses of storage area and name of a competent person	Bělá pod Bezdězem 1521, 294 21 Bělá pod Bezdězem (One hall on the ground floor of the building with the area of 220 m <sup>2</sup> ) Mgr. Ladislava Tothová
Addresses of contractual distribution points and names of competent persons	---

#### Instructions on Appeal

It is possible to file an appeal against the Decision pursuant to provision of sect. 81 et seq. of the Act no. 500/2004 Coll., the Administrative Procedure Act, as amended, with the State Institute for Drug Control, within 15 days from service of the Decision. The Ministry of Health of the Czech Republic decides on the appeal.

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PharmDr. Ivan Buzek  
Director of Pharmacy and Distribution

Attachment no. 1 – Scope of permission to distribute pharmaceuticals (1 page)

## SCOPE OF PERMISSION TO DISTRIBUTE PHARMACEUTICALS

Name and address of the place of distribution:

INVE Medical, s.r.o., Bělá pod Bezdězem 1521, 294 21 Bělá pod Bezdězem

### 1. PHARMACEUTICAL PRODUCTS

- 1.1 With the decision on registration in a country/countries of EEA  
 1.2 Without decision on registration in EEA and determined for EEA market\*  
 1.3 Without decision on registration in EEA and determined for export

### 2. PERMITTED DISTRIBUTION ACTIVITIES

- 2.1 Purchase/Procurement  
 2.2 Storage  
 2.3 Delivery  
 2.4 Export  
 2.5 Other activities: ---

### 3. PHARMACEUTICAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1 Pharmaceutical products according to art. 83 of the Directive 2001/83/EC<sup>1</sup>  
     3.1.1 Pharmaceutical products from blood  
     3.1.2 Immunological pharmaceutical products  
     3.1.3 Radiopharmaceuticals (including radionuclide kits)  
 3.2 Healing gases  
 3.3 Cold chain preparations (requiring handling at low temperatures)  
 3.4 Other preparations: ---

Any limitations or explaining notes or determination of the conditions related to the scope of distribution activity:

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\*art. 5 of the Directive 2001/83/EC or no. 83 of the Regulation EC/726/2004

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PharmDr. Ivan Buzek  
Director of Pharmacy and Distribution

<sup>1</sup> For distribution of pharmaceutical products with content of narcotics and psychotropic drugs it is necessary to obtain not only this permission, but also permission for handling issued by the Ministry of Health of Czech Republic according to the Act no. 167/1998 Coll., on Habit-forming Matters and on changes of some acts, as amended.