

**State Institute for Drug Control**

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION  
(MEDICINAL PRODUCTS FOR HUMAN USE)**

1. Authorisation Number : sukls213433/2016
2. Name of Authorisation Holder : mcePharma s. r. o.
3. Legally registered address of Authorisation Holder : Budovatelská 1178/35, Bílovec, 743 01, Czech Republic
4. Address(es) of Site(s) : Budovatelská 1178/35, Bílovec, 743 01, Czech Republic
5. Scope of authorisation (complete for each site under 4) : ANNEX 1
6. Legal basis of authorisation : Art.77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation : Confidential, Confidential
8. Signature :
9. Date : 2016-11-07
10. Annexes attached : Annex 1 Scope of wholesale distribution authorisation  
Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number  
Annex 3 (Optional) Name(s) of responsible person(s)  
Annex 4 (Optional) Date of Inspection on which authorisation was granted  
Annex 5 (Optional) Additional provisions based on national requirements

**ANNEX 1**

**SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION**

**Name and address of the site:** mcePharma s. r. o., Budovatelská 1178/35, Bílovec, 743 01, Czech Republic

**1. MEDICINAL PRODUCTS**

1.1 with a Marketing Authorisation in EEA country(s)

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.4 Export

\*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

\*\*Without prejudice to further authorisations as may be required according to national legislation

EudraGMDP