

**Bezirksregierung Köln**

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

1. Authorisation Number : DE\_NW\_04\_WDA\_2021-0111-02
2. Name of Authorisation Holder : Plasmaconcept AG
3. Legally registered address of Authorisation Holder : Breite Str. 2-4, Köln, 50667, Germany
4. Address(es) of Site(s) : Breite Str. 2-4, Köln, 50667, Germany
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 : 2021-01-18
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:** Plasmaconcept AG, Breite Str. 2-4, Köln, 50667, Germany

**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

**3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

3.1 Products according to Art. 83 of 2001/83/EC \*\*  
3.1.2 Medicinal products derived from blood

**Any restrictions or clarifying remarks (for all users):** Wholesale with blood coagulation factors.  
Großhandel mit Gerinnungsfaktoren.

\*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