

Bezirksregierung Düsseldorf

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

1. Authorisation Number : DE_NW_03_WDA_2018_0007/24.05.05.01-Orly
2. Name of Authorisation Holder : Orly Pharma GmbH
3. Legally registered address of Authorisation Holder : An der Kleinbahn 18, Nettetal-Kaldenkirchen, 41334, Germany
4. Address(es) of Site(s) : An der Kleinbahn 14, Nettetal-Kaldenkirchen, 41334, 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 : 2018-01-17
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: Orly Pharma GmbH, An der Kleinbahn 14, Nettetal-Kaldenkirchen, 41334, Germany

<p>1. MEDICINAL PRODUCTS</p> <p>1.1 with a Marketing Authorisation in EEA country(s)</p>
<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1 Products according to Art. 83 of 2001/83/EC ** 3.1.3 Immunological medicinal products</p>

Any restrictions or clarifying remarks (for all users): Licence includes storage of human medicinal products in the site above. Storage between 2°C to 8°C and 15°C to 25°C.
Erlaubnis umfasst die Lagerung von Arzneimitteln in der oben genannten Betriebsstätte, die für eine Lagerung im Bereich von 2°C-8°C (Kühlware) sowie im Bereich von 15-25°C geeignet ist.

*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