




Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit
UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION
(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number : G3-5423/INOPHA/07/27.04.2016
2. Name of Authorisation Holder : INOPHA GmbH
3. Legally registered address of Authorisation Holder : Genshagener Str. 37a, Ludwigsfelde, Brandenburg, 14974, Deutschland
4. Address(es) of Site(s) : Genshagener Str. 37a, Ludwigsfelde, Brandenburg, 14974, Deutschland
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 : Anja Brandt, +49 3318683 854
8. Signature : 
9. Date : 2016-04-27
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: INOPHA GmbH, Genshagener Str. 37a, Ludwigsfelde, Brandenburg, 14974, Deutschland

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

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
3.1.3 Immunological medicinal products
3.3 Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): The wholesale is carried out on the premises in accordance with the present site plans from 18th march 2016 (Genshagener Str. 37a) and from 14th march 2016 (Märkersteig12-16) .

Der Großhandel wird in den Räumen gem. den vorliegenden Lageplänen vom 18.03.2016 (Genshagener Str. 37a) und vom 14.03.2016 (Märkersteig12-16) durchgeführt.

*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

