Landesamt für soziale Dienste Schleswig-Holstein UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

- 1. Authorisation Number
- 2. Name of Authorisation Holder
- 3. Legally registered address of Authorisation Holder
- 4. Address(es) of Site(s)
- 5. Scope of authorisation (complete for each site under 4)
- 6. Legal basis of authorisation
- 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation
- 8. Signature
- 9. Date
- 10. Annexes attached

- : DE_SH_01_WDA_2021_0018
- : JUERS Pharma Import-Export GmbH
- : Kiebitzhörn 5-9, Barsbüttel, 22885, Germany
- : Kiebitzhörn 5-9, Barsbüttel, 22885, Germany
- : ANNEX 1
- : Art. 77(1) of Directive 2001/83/EC
- : Confidential, Confidential
- :

2021-10-29

: 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: JUERS Pharma Import-Export GmbH , Kiebitzhörn 5-9, Barsbüttel, 22885, Germany

1. MEDICINAL PRODUCTS

- 1.1 with a Marketing Authorisation in EEA country(s)
- 1.2 without a Marketing Authorisation in the EEA and intended for EEA market*
- 1.3 without a Marketing Authorisation in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

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

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 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): National legal basis of authorisation: § 52a Section 1 of German Drug Law (Arzneimittelgesetz)

§ 52a Section 1 of German Drug Law (Arzneimitteigesetz)

*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