

State Agency of Medicines

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products and Veterinary medicinal products

1. Authorisation Number : 87
2. Name of Authorisation Holder : osäühing KALVERTON
3. Address(es) of Site(s) : Vinkli tn 3, Tartu linn, Tartu Linn, 50411, Estonia
4. Legally registered address of Authorisation Holder : Rukki tn 44, Tartu linn, Tartu linn, Tartu maakond, 50407, Estonia
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
Art. 99 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation : Confidential, Confidential
8. Signature :
9. Date : 2014-11-01
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: Kalverton OÜ
(ORG-100024727 / LOC-100033907)
, Vinkli tn 3, Tartu linn, Tartu Linn, 50411, Estonia

Human medicinal products
Veterinary medicinal products

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

- 3.1.1. Narcotic or psychotropic products
- 3.1.2. Medicinal products derived from blood
- 3.1.3. Immunological medicinal products
- 3.3. Cold chain products(requiring low temperature handling)

*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