

**Agency for medicinal products and medical devices of the Republic of  
Slovenia**

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

1. Authorisation Number : 801-41/2020-15
2. Name of Authorisation Holder : Rhei life, trgovina in storitve, d.o.o.
3. Legally registered address of Authorisation Holder : Dunajska cesta 136, Ljubljana, 1000, Slovenia
4. Address(es) of Site(s) : Brodišče 12, Trzin, 1236, Slovenia
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 : 2021-04-19
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:** Rhei life, trgovina in storitve, d.o.o.-warehouse at MEDICAL INTERTRADE, d.o.o., promet z zdravili in sanitetnim materialom, Brodišče 12, Trzin, 1236, Slovenia

#### **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

2.5 Other activities(s): Entry of medicinal products from EU to RS, Outwards of medicinal products from RS to EU

#### **3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

3.1 Products according to Art. 83 of 2001/83/EC \*\*

3.1.3 Immunological medicinal products

3.3 Cold chain products(requiring low temperature handling)

**Any restrictions or clarifying remarks (for all users):** Cold chain products: 2-8 °C.

WDA is issued for wholesale distribution only to other holders of wholesale distribution authorisation for a restricted scope of customers, which covers the wholesale distribution of medicinal products that may be placed on the market in accordance with Medicinal Products Act (ZZdr-2).

\*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