


Federal Agency for Medicines and Health Products

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

- | | |
|--|---|
| 1. Authorisation Number | : 1641 H |
| 2. Name of Authorisation Holder | : Nadimed |
| 3. Legally registered address of Authorisation Holder | : Prins Boudewijnlaan 7b Bus 18, Kontich, 2550, Belgium |
| 4. Address(es) of Site(s) | : Prins Boudewijnlaan 7b Bus 18, Kontich, 2550, Belgium |
| 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 | : Xavier De Cuyper, +32 2 5284000
on behalf Philippe De Buck,
DG Inspection - Head of Division Authorisations |
| 8. Signature | :  Digitally signed by Philippe De Buck (Signature)
Date: 2022.05.30 10:49:15 +02'00' |
| 9. Date | : 2022-05-11 |
| 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: Nadimed, Prins Boudewijnlaan 7b Bus 18, Kontich, 2550, Belgium

Human medicinal products

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

3.1.2 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): 3.3 Authorized temperature for the cold chain : 2-8 °C

3.3 Toegestane temperatuur voor de koude bewaring : 2-8 °C

*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