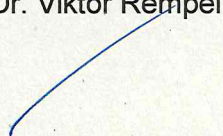




Bezirksregierung Düsseldorf

“English Translation/Original in German”
UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

- | | |
|--|--|
| 1. Authorisation number | DE_NW_03_WDA_2020_0020/ 24.05.05.01-
Paesel & Lorei |
| 2. Name of authorisation holder | Paesel & Lorei GmbH & Co. KG
Biochemika, Diagnostika und Pharmazeutika |
| 3. Legally registered address
of authorisation holder | Nordring 11
47495 Rheinberg |
| 4. Address(es) of site(s) | Nordring 11
47495 Rheinberg |
| 5. Scope of authorisation (complete for
each site under 4) | Annex 1 |
| 6. Legal basis of authorisation | Sect 52a para 1 Arzneimittelgesetz (German
Drug Law) |
| 7. Name of responsible officer of the
competent authority of the member state
granting the wholesale authorisation | Dr. Viktor Rempel |
| 8. Signature |  |
| 9. Date | 24.08.2020 |
| 10. Annexes attached | <input checked="" type="checkbox"/> Annex 1 Scope of wholesale distribution
authorisation |

This translation complies with the original document bearing the signature of the competent authority.

Annex 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of site: Paesel & Lorei GmbH & Co. KG
Biochemika, Diagnostika und Pharmazeutika
Nordring 11
47495 Rheinberg

MEDICINAL PRODUCTS

- Medicinal products for human use Medicinal Products for Veterinary Use
- 1.1 with a Marketing Authorisation in EEA country/countries
- 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

AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.4 Export
- 2.5 Other activities(s): /

MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1 Products according to Art. 83 of 2001/83/EC¹
- Products according to Art. 67 of 2001/82/EG
- 3.1.1 Narcotic or psychotropic products
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.2 Medicinal gases
- 3.3 Cold chain products (requiring low temperature handling)
- 3.4 Other products: /

Any restrictions or clarifying remarks related to the scope of these wholesaling operations:

To 1.2: cannabis flowers and cannabis extract from EU/EWR-states
To 3.1.1: subject to a corresponding authorisation under § 3 BtMG
To 3.1.2: no blood plasma

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*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

¹Without prejudice to further authorisations as may be required according to national legislation