




"English Translation/Original in German"

## UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION (MEDICINAL PRODUCTS FOR HUMAN USE AND/OR VETERINARY USE: PLEASE NOTE ANNEX)

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|--|---|
| 1. Authorisation number  | DE_BY_04_WDA_2022/ROB-55Ph-2677.Ph_2-345-23-18  |
| 2. Name of authorisation holder  | Medizone Germany GmbH   |
| 3. Legally registered address of authorisation holder  | Keltenring 15<br>82041 Oberhaching  |
| 4. Address(es) of site(s)<br><i>(All sites should be listed, if not covered by separate authorisations)</i>          | Keltenring 15<br>82041 Oberhaching  |
| 5. Scope of authorisation<br><i>(complete for each site under 4)</i>   | See Annex 1   |
| 6. Legal basis of authorisation  | § 52 a (1) of the Medicinal Products Act (AMG) in current version   |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | Lisa Köhnlein   |
| 8. Signature   |   |
| 9. Date  | 10.05.2022  |
| 10. Annexes attached   | <input checked="" type="checkbox"/> Annex 1 Scope of wholesale distribution authorisation                                       |
|  | <input type="checkbox"/> Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number |
|  | <input checked="" type="checkbox"/> Annex 3 (Optional) Name(s) of responsible person(s)   |
|  | <input type="checkbox"/> Annex 4 (Optional) Date of Inspection on which authorisation was granted                               |
|  | <input checked="" type="checkbox"/> Annex 5 (Optional) Additional provisions based on national requirements                     |



**SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION**

Name and address of the site:

Medizone Germany GmbH  
Keltenring 15  
82041 Oberhaching

**MEDICINAL PRODUCTS**

- Medicinal Products for Human Use     Medicinal Products for Veterinary Use
- 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

**AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

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

**Medicinal products with additional requirements**

- 3.1 Products according to Art. 83 of 2001/83/EC<sup>1</sup>
- Products according to Art. 67 of 2001/82/EC
- 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: (please specify here or make a reference to Annex 5)

Any restrictions or clarifying remarks related to the scope of these wholesaling operations  
 Regarding 1.2: Individual import as described in § 73 (2) AMG  
 Regarding 2.2: Holding is carried out by C.P.M. Contract Pharma GmbH (note annex 5)  
 Regarding 3.4: Chilled medicinal products

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

<sup>1</sup>Without prejudice to further authorisations as may be required according to national legislation

**ANNEX 5 (Optional)**

Additional provisions based on national requirements

External service provider:

C.P.M. Contract Pharma GmbH  
Rösnerstraße 24  
83052 Bruckmühl

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

**ANNEX 3 (Optional)**

Name(s) of responsible person(s)

Felix Wagnmüller

Medizone Germany GmbH

Keltenring 15

82041 Oberhaching

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