
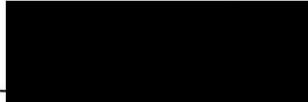
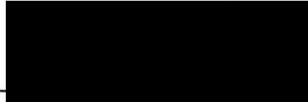


# Regierung von Oberbayern

"English Translation/Original in German"

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

- |  |   |  |   |                                  |  |   |   |                                  |  |                                  |   |
|--|---|--|---|----------------------------------|--|---|---|----------------------------------|--|----------------------------------|---|
| 1. Authorisation number  | DE_BY_04_WDA_2023/ROB-55Ph-2677.Ph_2-345-30-14  |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 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<br><br>Rösnerstr. 24<br>83052 Bruckmühl  |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 5. Scope of authorisation<br><i>(complete for each site under 4)</i>   | See Annex 1   |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 6. Legal basis of authorisation  | Sect 52a Arzneimittelgesetz (German Drug Law) in current version  |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | <br>   |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 8. Signature   |   |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 9. Date  | 20.11.2023  |  |   |                                  |  |   |   |                                  |  |                                  |   |
| 10. Annexes attached   | <table><tbody><tr><td><input checked="" type="checkbox"/> Annex 1a, 1b</td><td>Scope of wholesale distribution authorisation</td></tr><tr><td><input type="checkbox"/> Annex 2</td><td>(Optional) Address(es) of contract wholesale distribution sites and their authorisation number</td></tr><tr><td><input checked="" type="checkbox"/> Annex 3</td><td>(Optional) Name(s) of responsible person(s)</td></tr><tr><td><input type="checkbox"/> Annex 4</td><td>(Optional) Date of Inspection on which authorisation was granted</td></tr><tr><td><input type="checkbox"/> Annex 5</td><td>(Optional) Additional provisions based on national requirements</td></tr></tbody></table> | <input checked="" type="checkbox"/> Annex 1a, 1b | 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 type="checkbox"/> Annex 5 | (Optional) Additional provisions based on national requirements |
| <input checked="" type="checkbox"/> Annex 1a, 1b   | Scope of wholesale distribution authorisation   |  |   |                                  |  |   |   |                                  |  |                                  |   |
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| <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 type="checkbox"/> Annex 5   | (Optional) Additional provisions based on national requirements   |  |   |                                  |  |   |   |                                  |  |                                  |   |



**Scope of wholesale distribution authorisation**

Name and address of the site:

Name of the site

Medizone Germany GmbH

Street, House number

Keltenring 15

Postcode, City

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<sup>1</sup>
- 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: *(please specify)*

**Medicinal products with additional requirements**

- 3.1  Products according to Art. 83 of 2001/83/EC<sup>2</sup>
- 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)*
- Medicinal products for veterinary use
- 3.1.5  Narcotic or psychotropic products
- 3.1.6  Medicinal products for food-producing animals
- 3.1.7  Prescription medicinal products for veterinary use
- 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 (3) AMG

Regarding 3.4: Chilled medicinal products

<sup>1</sup> Art. 5 of Directive 2001/83/EC or Art. 83 of Regulation EC/726/2004<sup>2</sup> Without prejudice to further authorisations as may be required according to national legislation

## Scope of wholesale distribution authorisation

Name and address of the site:

Name of the site

Medizone Germany GmbH

Street, House number

Rösnerstr. 24

Postcode, City

83052 Bruckmühl

### 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<sup>1</sup>
- 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: *(please specify)*

### Medicinal products with additional requirements

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- 3.1.6  Medicinal products for food-producing animals
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<sup>2</sup> Without prejudice to further authorisations as may be required according to national legislation

Name(s) of responsible person(s)

Name Wagmüller	First name Felix
Name of site Medizone Germany GmbH	
Street, House number. Keltenring 15	Postcode, City 82041 Oberhaching
Name Wagmüller	First name Felix
Name of site Medizone Germany GmbH	
Street, House number Rösnerstr. 24	Postcode, City 83052 Bruckmühl
Name	First name
Name of site	
Street, House number.	Postcode, City