

## Authorisation for the wholesale of pharmaceuticals

1. Number of the authorisation	DE_BY_04_WDA_2018/ ROB-55Ph-2677.Ph_2-345-7-5
2. Authorisation holder's name	Medizone Germany GmbH
3. Authorisation holder's registered address	Keltenring 15 82041 Oberhaching
4. Authorisation holder's address/es of the business premises <i>(All business premises should be indicated, unless they are covered by any separate authorisations).</i>	Keltenring 15 82041 Oberhaching
5. Authorisation scope <i>(Please specify for each business premises mentioned under no. 4).</i>	see annex 1
6. Legal basis of the authorisation	Article 52 a subparagraph 1 of the German Law on Trade in Medicinal Products ( <i>German Pharmaceutical Products Act</i> ) as amended from time to time
7. Name of the responsible person at the competent authority in the member state granting the authorisation	
8. Signature	[Signature]
9. Date	09/07/2018
10. Attached annexes	Authorisation scope
<input checked="" type="checkbox"/> Annex 1a Annex 1b	
<input type="checkbox"/> Annex 2	Address/es and authorisation number/s of the business premises of the wholesalers commissioned
<input checked="" type="checkbox"/> Annex 3	Name(s) of the responsible person(s)
<input type="checkbox"/> Annex 4	Date of the inspection on the basis of which the authorisation was granted
<input type="checkbox"/> Annex 5	Any further regulations based on national legislation

[Seal]

**Authorisation scope** (Please mark with a cross where applicable  or complete)

Name and address of the business premises:

Name of the business premises

Medizone Germany GmbH

Street, house number

Keltenring 15

Postal code, place

82041 Oberhaching

**Pharmaceuticals**

- Human pharmaceuticals  Veterinary pharmaceuticals
- 1.1 with a marketing authorisation in any state of the European Economic Area
- 1.2 with no marketing authorisation in any state of the European Economic Area (EEA) that are placed on the market in the EEA (exemption from the authorisation obligation)<sup>1</sup>
- 1.3 with no marketing authorisation in any state of the European Economic Area (EEA) that are **not** placed on the market in the EEA (Pharmaceuticals for third countries)

**Authorised activities**

- 2.1 Procurement
- 2.2 Storage
- 2.3 Delivery (dispensing)
- 2.4 Export
- 2.5 Other activities: (please specify)

**Pharmaceuticals with special requirements**

- 3.1 Pharmaceuticals pursuant to Article 83 of the directive 2001/83/EC<sup>2</sup>
- Pharmaceuticals pursuant to Article 67 of the directive 2001/82/EC
- 3.1.1 Narcotics or psychotropic substances
- 3.1.2 Pharmaceuticals from blood
- 3.1.3 Immunological pharmaceuticals
- 3.1.4 Radiopharmaceuticals (including radionuclide kits)
- 3.2 Medicinal gases
- 3.3 Temperature-controlled pharmaceuticals (storage and transportation at low temperatures)
- 3.4 Other activities: (please specify or refer to annex 5)

Any restrictions or clarification with regard to the authorisation scope (publicly accessible)

For 3.4: Temperature-controlled pharmaceuticals

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<sup>1</sup> Article 5 of the directive 2001/83/EC or Article 83 of the regulation 726/2004/EC

<sup>2</sup> Without prejudice to any further authorisations on grounds of national legislation

**Authorisation scope** (Please mark with a cross where applicable  or complete)

**Name and address of the business premises:**

Name of the business premises

C.P.M. Contract Pharma GmbH & Co. KG

Street, house number

Rösnerstr. 24

Postal code, place

83052 Bruckmühl

**Pharmaceuticals**

- Human pharmaceuticals  Veterinary pharmaceuticals
- 1.1 with a marketing authorisation in any state of the European Economic Area
- 1.2 with no marketing authorisation in any state of the European Economic Area (EEA) that are placed on the market in the EEA (exemption from the authorisation obligation)<sup>1</sup>
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<sup>2</sup> Without prejudice to any further authorisations on grounds of national legislation

**Annex 3**

Authorisation for the wholesale of pharmaceuticals

**Name(s) of the responsible person(s)**

Name  
Hörl

Given name  
Gerhard

Name of the business premises  
Medizone Germany GmbH

Street, house number  
Keltenring 15

Postal code, place  
82041 Oberhaching

Name

Given name

Name of the business premises

Street, house number

Postal code, place

Name

Given name

Name of the business premises

Street, house number

Postal code, place

[Seal]

This is to confirm that the translation was carried out by me, a professionally registered translator, authorized by the President of the Higher Regional Court of Hamm (Germany). This is to certify that I am authorized to translate from the German language into English and that the translation produced is true and accurate.

Verl, 16 July 2018

*[Handwritten signature]*  
[Faint stamp]  
Germany

Die Richtigkeit und Vollständigkeit vorstehender  
Übersetzung aus der englischen/deutschen Sprache  
wird bescheinigt.

*[Handwritten signature]*  
Ort Datum

Durch den Präsidenten des Oberlandesgerichts Hamm  
ermächtigte Übersetzerin für die englische Sprache