Certified translation from the German language

<<stamp of the Ministry of Social Affairs, Health, Women and Family of Saarland>>
<<coat of arms of the Federal State of Saarland>>

SAARLAND

Ministerium für Soziales, Gesundheit, Frauen und Familie
[Ministry of Social Affairs, Health, Women and Family]

AUTHORISATION FOR WHOLESALE DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

1. Authorisation number/file number
   DE_SL_01_WDA_2020_0002/5011-060

2. Name of authorisation holder
   1az Pharm GmbH

3. Registered address of authorisation holder
   Am Nusskopf 35
   66578 Schiffweiler

4. Address(es) of sites of the authorisation holder
   see Appendix 1

5. Scope of authorisation
   see Appendix 1

6. Legal basis of authorisation
   Section 52 a subsection 1 of *Gesetz über den Verkehr mit Arzneimitteln* (*Arzneimittelgesetz - AMG*) [German Drugs Act] as amended from time to time

7. Name of the responsible clerk of the competent authority of the member state granting the authorisation
   Stefan Stein

8. Signature
   <<signature illegible>>
   <<stamp of the Ministry of Social Affairs, Health, Women and Family of Saarland>>

9. Date
   Saarbücken, this 19 February 2020

10. Enclosed appendices:

☒ Appendix1	Scope of authorisation
☐ Appendix 2	(optional) Address(es) of contract wholesale distribution sites and their authorisation number(s)
☒ Appendix 3	(optional) Name(s) of responsible person(s)
☒ Appendix 4	(optional) Date of inspection that served as the basis for the granting of this authorisation
☐ Appendix 5	(optional) Further provisions based on national regulations

APPENDIX 1

SCOPE OF AUTHORISATION

Name and address of the site:

1az Pharm GmbH
Am Nusskopf 35
66578 Schiffweiler

1. PHARMACEUTICAL PRODUCTS

☒ Pharmaceutical products for human use ☐ Pharmaceutical products for veterinary use

1.1 ☒ with marketing authorisation in a country of the European Economic Area

1.2 ☐ without marketing authorisation in a country of the European Economic Area (EEA) that are placed on the market in the EEA (exemption from the marketing authorisation requirement)*

1.3 ☐ without marketing authorisation in a country of the European Economic Area that are NOT placed on the market in the EEA (pharmaceutical products for third countries)

2. AUTHORISED OPERATIONS

2.1 ☒ Procurement

2.2 ☒ Storage

2.3 ☒ Delivery (supply)

2.4 ☒ Export

2.5 ☐ other operations (please specify)

3. PHARMACEUTICAL PRODUCTS WITH SPECIAL REQUIREMENTS

3.1 ☒ Pharmaceutical products according to section 83 of Directive 2001/83/EC[1]

☐ Pharmaceutical products according to section 67 of Directive 2001/82/EC

3.1.1 ☒ Narcotics or psychotropic agents

3.1.2 ☒ Pharmaceutical products derived from blood

3.1.3 ☒ Immunological pharmaceutical products

3.1.4 ☐ Radioactive pharmaceutical products (including radionuclide kits)

3.2 ☐ Medicinal gases

3.3 ☒ Cold chain pharmaceutical products (storage and transport at low temperatures)

3.4 ☐ Other operations: (please specify or refer to Appendix 5)

Restrictions or explanations regarding the scope of authorisation (publicly available)

ad 3.1.1: The authorisation for wholesale distribution comprises narcotic agents produced by the manufacturers Mundipharma, Hexal, and Hameln, as well as the products Bedrocan, Bediol and Bedrolite by Bedrocan B.V. (bought from Eucan GmbH company).

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

[1] Notwithstanding further authorisations due to national regulations

APPENDIX 3 (optional)

Name(s) of the responsible person(s) Mr Thomas Engler

APPENDIX 4 (optional)

Date of inspection that served as the basis for the granting of this authorisation	21 August 2018

Authentication

I have examined the German original/photocopy/facsimile, and this is a true translation of the same into English.

Barbara Wohanka, registered translator for the English language at the District Court of Landshut, Germany

Geisenhausen, 24 April 2020