Certified translation from the German language into the English language

District Government Cologne

PERMIT FOR PHARMACEUTICAL WHOLESALING

1. Permit number/reference	DE_NW_04_WDA_2019-0105-03
2. Name of the permit holder	Siliris GmbH
3. Permit holder's registered address	Frankfurter Str. 22 a D-53721 Siegburg
4. Address of the permit holder's business premises	Frankfurter Str. 22a D-53721 Siegburg (office) Am Turm 38 c D-53721 Siegburg (warehouse)
5. Scope of permit (please state for each site listed under no. 4)	Annex 1
6. Legal basis of granting of permit	Section 52 a paragraph 1 German Act on Trading in Pharmaceuticals (Arzneimittelgesetz – AMG) in its applicable version
7. Name of the person responsible of the competent authority of the Member State issuing the permit	Sonja Haske *[Stamp: District Government Cologne, 170, logo]*
8. Signature	*[signed by hand: Sonja Haske]*
9. Date	27th September 2019
10. Enclosed annexes: ☒	Annex 1 Scope of permit

ANNEX 1

SCOPE OF PERMIT

Name and address of business premises:
Siliris GmbH
Frankfurter Str. 22 a
D-53721 Siegburg (office)

Am Turm 38 c
D-53721 Siegburg (warehouse)

1. PHARMACEUTICALS

☒ medicinal products for human use ☐ veterinary medicinal products

1.1 ☒ with an authorisation to place the products on the market in a state of the European Economic Area

1.2 ☐ without an authorisation to place the products on the market in a state of the European Economic Area (EEA) which will be placed on the market in the EEA (exemption from the obligation to obtain prior authorisation)*

1.3 ☒ without an authorisation to place the products on the market in a state of the European Economic Area which will NOT be placed on the market in the EEA (pharmaceuticals for third countries)

2. PERMITTED ACTIVITIES

2.1 ☒ Procurement
2.2 ☒ Storage
2.3 ☒ Supply (dispensing)
2.4 ☒ Export
2.5 ☐ Other activities: (please specify)

3. PHARMACEUTICALS WITH SPECIAL REQUIREMENTS

3.1 ☐ Pharmaceuticals according to Art. 83 of Directive 2001/83/EC[1]
☐ Pharmaceuticals according to Art. 67 of Directive 2001/82/EC
3.1.1 ☐ anaesthetics or psychotropic substances
3.1.2 ☐ pharmaceuticals derived from blood
3.1.3 ☐ immunological pharmaceutical products
3.1.4 ☐ radiopharmaceuticals (including radionuclide kits)
3.2 ☐ Medicinal gases
3.3 ☒ Pharmaceuticals requiring refrigerated transport (storage and transport at low temperatures)
3.4 ☐ Other activities: (please specify or make a reference to Annex 5)

Any restrictions or clarifying remarks related to the scope of this permit (publicly accessible)
None.

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

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[1] without prejudice to further authorisations as may be required according to national legislation

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[Signed by hand: Sonja Haske]

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Seal/Signature

In my capacity as translator for the English and German language appointed and sworn in the Federal State of Bavaria I hereby certify that foregoing translation of the presented original document in German is correct and complete.

Munich, this 10th October 2019

Eva Schalk

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ÜZM GmbH
München, den 10.10.2019
PC73547

Staatlich geprüfte, öffentlich bestellte und beeidigte Übersetzerin für Deutsch und Englisch
Eva Schalk
State certified, publicly appointed and sworn translator for German and English