Certified Translation from German to English

[Emblem]

Baden-Württemberg

REGIERUNGSPRÄSIDIUM TÜBINGEN

[REGIONAL COUNCIL OF TÜBINGEN]

LEITSTELLE ARZNEIMITTELÜBERWACHUNG

[CENTRE FOR DRUG MONITORING]

WHOLESALE DISTRIBUTION AUTHORISATION FOR MEDICINAL PRODUCTS

1. Authorisation number/reference number
   DE_BW_01_WDA_2021_0001_Bodensee Pharma
2. Name of authorisation holder
   Bodensee Pharma GmbH
3. Legally registered address of authorisation holder
   Gewerbestr. 10
   78244 Gottmadingen
4. Address(es) of site(s) of authorisation holder
   See item 3
5. Scope of authorisation
   See Annex 1
6. Legal basis of authorisation
   Section 52 a subsection 1 of the Act on Medicinal Products (Arzneimittelgesetz - AMG *[Medicinal Products Act]*) as amended
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation
   Muna Khosrof
8. Signature
   [Illegible signature]

   [Seal:]
   REGIERUNGSPRÄSIDIUM
   TÜBINGEN
   [REGIONAL COUNCIL OF TÜBINGEN]
9. Date
   09 June 2021
10. Annexes attached:
    Annex 1 Scope of authorisation

Street address: Konrad-Adenauer-Str. 20 · 72072 Tübingen · Telephone 07071 757-0 · Fax 07071 757-3190

[Emblem]

Baden-Württemberg
REGIERUNGSPRÄSIDIUM TÜBINGEN
[REGIONAL COUNCIL OF TÜBINGEN]
LEITSTELLE ARZNEIMITTELÜBERWACHUNG
[CENTRE FOR DRUG MONITORING]

ANNEX 1

SCOPE OF AUTHORISATION

Name and address of site:

Bodensee Pharma GmbH, Gewerbestr. 10, 78244 Gottmadingen

1.	**MEDICINAL PRODUCTS**	
	☒ **Medicinal Products for Human Use**	☒ **Medicinal Products for Veterinary Use**
1.1	☒	with a Marketing Authorisation in EEA country (countries)
1.2	☐	without a Marketing Authorisation in the EEA and intended for EEA market (exemption from the requirement of marketing authorisation)*
1.3	☐	without a Marketing Authorisation in the EEA and NOT intended for EEA market (medicinal products for third countries)
2.	**AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**	
2.1	☒	Procurement
2.2	☒	Holding
2.3	☒	Supply
2.4	☒	Export
2.5	☐	Other activities: (please specify)
3.	**MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**	
3.1	☒	Medicinal products according to Art. 83 of Directive 2001/83/EC[1]
	☐	Medicinal products according to Art. 67 of Directive 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 or make a reference to Annex 5)

Any restrictions or clarifying remarks related to the scope of these wholesaling operations (for all users):
Item 3.1.1: cannabis

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

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

[Seal:]
REGIERUNGSPRÄSIDIUM TÜBINGEN
[REGIONAL COUNCIL OF TÜBINGEN]

Certification of Translation:

In my capacity as a translator of English, sworn and officially appointed by the Regional Court of Karlsruhe (Germany), I hereby certify that the foregoing is a true and complete English translation of the German document presented to me, a copy of which is attached hereto.

Ettlingen (Germany), 06 July 2021

Marianne Rosner

Öffentlich best. u. beeid. Urkundenübersetzerin d. span. u. engl. Sprache
Allgem. beeid. Verhandlungsdolmetscherin d. span. Sprache
Marianne Rosner
Im Albgrün 2
76275 Ettlingen
Tel. 07243/30620
für die Gerichte des Landes Baden-Württemberg