

MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_BW_01_MIA_2023_0081/ DE_BW_01_Biochem
2. Name of authorisation holder	Biochem Labor Für Biologische Und Chemische Analytik GmbH (LOC-100021870)
3. Address(es) of manufacturing site(s)	Biochem Labor Für Biologische Und Chemische Analytik GmbH Daimlerstraße 5b 76185 Karlsruhe (LOC-100021870)
4. Legally registered address of authorisation holder	Daimlerstraße 5b 76185 Karlsruhe
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Miriam Schnitzler
8. Signature	
9. Date	14/08/2023
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

Biochem Labor Für Biologische Und Chemische Analytik GmbH, Daimlerstraße 5b, 76185 Karlsruhe

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.6 Quality control testing**

	<i>1.6.1 Microbiological: sterility</i>
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	<i>1.6.2 Microbiological: non-sterility</i>
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	<i>1.6.3 Chemical/Physical</i>
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	<i>1.6.4 Biological</i>
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

The quality control also includes the testing of sterile and non-sterile raw and starting materials, active pharmaceutical ingredients and packaging materials.

SCOPE OF AUTHORISATION**Annex 2**

Name and address of the site:

Biochem Labor Für Biologische Und Chemische Analytik GmbH, Daimlerstraße 5b, 76185 Karlsruhe

Investigational Medicinal Products for Human Use
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AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

The quality control also includes the testing of sterile and non-sterile raw and starting materials, active pharmaceutical ingredients and packaging materials.

Address(es) of Contract Laboratories

Tentamus Pharma & Med Deutschland GmbH
Columbiestraße 14
97688 Kissingen
Instrumental analytics

SGS Analytics Germany GmbH
Auf der Hüls 183
52068 Aachen
Instrumental analytics

Evonik Operations GmbH
Paul-Baumann-Strasse 1
45772 Marl
Instrumental analytics

Evonik Operations GmbH - Labor Product Line Analytics
Rodenbacher Chaussee 4
63457 Hanau
Instrumental analytics