MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_RP_01_MIA_2022_0048
2. Name of authorisation holder	HWI pharma services GmbH (LOC-100006965)
3. Address(es) of manufacturing site(s)	HWI pharma services GmbH Rheinzaberner Straße 8 76761 Rülzheim (LOC-100006965)
4. Legally registered address of authorisation holder	Rheinzaberner Strasse 8 76761 Rülzheim
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. 88 of Regulation (EU) 2019/6 and Sect 28 para 1 German Veterinary Medicinal Products 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. Burkhard Trapp
8. Signature	On behalf
9. Date	10/11/2022
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories)

Annex 5 (Name of Qualified Person)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
HWI pharma services GmbH, Rheinzaberner Straße 8, 76761 Rülzheim

Human Medicinal Products Veterinary Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.6 Human or animal extracted products
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
HWI pharma services GmbH, Rheinzaberner Straße 8, 76761 Rülzheim

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Date of Inspection on which authorisation was granted	21/09/2022
Scope of last Inspection	General GMP Inspection

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

Die Liste der Produkte ist dem Landesamt bekannt.