



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_2021_0020
2. Name of authorisation holder	HWI pharma services GmbH
3. Address(es) of manufacturing site(s)	HWI pharma services GmbH Rheinzaberner Strasse 8 76761 Rülzheim
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)
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	06/09/2021
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)





SCOPE OF AUTHORISATION

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
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.2 Batch certification</i>
	1.3.2.6 Human or animal extracted products
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>





SCOPE OF AUTHORISATION

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

26/09/2019

Scope of last Inspection

General GMP Inspection

