MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_HE_01_MIA_2023_0051/V4 - 18 L 18.01 / 1894-B
2. Name of authorisation holder	HWI pharma services GmbH (LOC-100006965)
3. Address(es) of manufacturing site(s)	HWI pharma services GmbH Weismüllerstraße 50 60314 Frankfurt am Main (LOC-100053214)
4. Legally registered address of authorisation holder	Rheinzaberner Str. 8 76761 Rülzheim
5. Scope of authorisation and dosage forms	ANNEX 2
6. Legal basis of authorisation	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	
8. Signature	On behalf
9. Date	09/10/2023
10. Annexes attached	Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 8 (Manufactured products authorised)

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
HWI pharma services GmbH, Weismüllerstraße 50, 60314 Frankfurt am Main

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**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.5 Liquids for external use
	1.2.1.6 Liquids for internal use
	1.2.1.11 Semi-solids
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products
	1.3.1.5 Biotechnology products
	1.3.2 Batch certification
	1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of:
	1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.5 Liquids for external use
	1.5.1.6 Liquids for internal use
	1.5.1.11 Semi-solids

Quality control testing
1.6.3 Chemical/Physical

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

refer to 1.2.1.11 and 1.5.1.11: gel and ointment,
refer to 1.1 till 1.5: for list of products and manufacturing steps see current annex 8,
refer to 1.6.3: Partial testing in contract laboratories according to sect 14 para 4 German Medicinal Product Act (refer to annex 4).