




## IMPORTER'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_2023_0034
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 72 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 72 para 2a AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	
8. Signature	On behalf
9. Date	08/08/2023
10. Annexes attached	Annex 1 and Annex 2 Annex 5 (Name of Qualified Person) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)





**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

HWI pharma services GmbH, Rheinzaberner Straße 8, 76761 Rülzheim

Human Medicinal Products

**AUTHORISED OPERATIONS**

Importation of Medicinal Products (according to part 2)

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**2.1 Quality control testing of imported medicinal products**

*2.1.3 Chemical/Physical*

**2.2 Batch certification of imported medicinal products**

*2.2.2 Non-sterile products*





**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**

Importation of Investigational Medicinal Products (according to part 2)

**Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS**

**2.1 Quality control testing of imported investigational medicinal products**

*2.1.3 Chemical/Physical*

**2.2 Batch certification of imported investigational medicinal products**

*2.2.2 Non-sterile products*

