



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_2022_0049
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	Dr. Burkhard Trapp
8. Signature	On behalf
9. Date	10/11/2022
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)





Annex 8 (Imported products authorised)





SCOPE OF AUTHORISATION

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

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





Date of Inspection on which
authorisation was granted

21/09/2022

