IMPORTER 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_2025_0036
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 Str. 8 76761 Rülzheim
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	
8. Signature	On behalf
9. Date	25/09/2025
10. Annexes attached	Annex 1 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 **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
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

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

Regarding 2.3.2: aseptic manufactured biotechnology bulkproduct (vials and prefilled syringes)

Date of Inspection on which authorisation was granted	03/07/2025