MANUFACTURER / 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_0016/3112-0069/20250626
2. Name of authorisation holder	Popack Logistik GmbH (LOC-100021394)
3. Address(es) of manufacturing site(s)	Popack Logistik GmbH Achardstraße 1 55127 Mainz (LOC-100021394)
4. Legally registered address of authorisation holder	Achardstraße 1 55127 Mainz
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) Sect 72 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG 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	[redacted]
8. Signature	On behalf
9. Date	26/06/2025

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
Name and address of the site:
Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

Annex 1

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packing

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:
Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.5	**Packaging**
	1.5.2 Secondary packing

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Annex 5

Name(s) of Qualified Person(s)

[redacted]

Annex 7

Date of Inspection on which authorisation was granted	08/05/2025
Scope of last Inspection	General GMP-Inspection (details see inspection report)