

MANUFACTURER / IMPORTER AUTHORISATION

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

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| 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 | Dr. Ilka Petry |
| 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

Annex 1

Name and address of the site:

Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

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
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	1.5.2 Secondary packing
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

Popack Logistik GmbH, Achardstraße 1, 55127 Mainz

Investigational Medicinal Products for Human Use
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AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
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	1.5.2 Secondary packing
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Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Name(s) of Qualified Person(s)

Mrs. Dr. Christel Schmelzer

Mrs. Dr. Cathrin Pauly

deputy qualified person

Annex 7

Date of Inspection on which
authorisation was granted

08/05/2025

Scope of last Inspection

General GMP-Inspection (details see inspection report)