

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_HE_01_MIA_2022_0001
2. Name of authorisation holder DHL Supply Chain Operations GmbH
3. Address(es) of manufacturing site(s) DHL Supply Chain Operations GmbH, In der Au 9, Florstadt, Hessen, 61197, Germany
4. Legally registered address of authorisation holder Heinemannstrasse 11-13, Bonn, Hessen, 53175, Germany
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2022-01-05
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3 (Addresses of Contract Manufacturing Site(s))
Annex 4 (Addresses of Contract laboratories)
Annex 5 (Name of Qualified Person)
Annex 6 (Name of responsible persons)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)³

¹ The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : DHL Supply Chain Operations GmbH, In der Au 9, Florstadt,
Hessen, 61197, Germany

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
	<i>1.5.2 Secondary packaging</i>

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 : DHL Supply Chain Operations GmbH, In der Au 9, Florstadt,
Hessen, 61197, Germany

Human Investigational 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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	<i>1.5.2 Secondary packaging</i>
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.3	Other importation activities
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	2.3.1 Site of physical importation
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