

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_NW_03_MIA_2021_0001
2. Name of authorisation holder PS Pharma Service GmbH
3. Address(es) of manufacturing site(s) PS Pharma Service GmbH, Lise-Meitner-Str. 10, Meerbusch, Nordrhein-Westfalen, 40670, Germany
PS Pharma Service GmbH, Mollsfeld 3, Meerbusch, Nordrhein-Westfalen, 40670, Germany
4. Legally registered address of authorisation holder Lise-Meitner-Str. 10, Meerbusch, Nordrhein-Westfalen, 40670, 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
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2021-01-13
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 : PS Pharma Service GmbH, Lise-Meitner-Str. 10, Meerbusch,
Nordrhein-Westfalen, 40670, Germany

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.17 Other non-sterile medicinal products: herbal drugs, oils and extracts(en)
	<i>1.5.2 Secondary packaging</i>
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

**Any restrictions or clarifying remarks related to the scope of these Importation operations
(for Public users)**

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SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : PS Pharma Service GmbH, Mollsfeld 3, Meerbusch,
Nordrhein-Westfalen, 40670, Germany

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

To 1.5.2: Secondary packaging of cold chain products.