MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_NW_03_MIA_2018_0005
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
4. Legally registered address of authorisation holder	Lise-Meitner-Str. 10, Meerbusch, Nordrhein-Westfalen, 40670, Germany
5. Scope of authorisation and dosage forms [2]	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	2018-03-20
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	
1.5	**Packaging**
	1.5.2 Secondary packing

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

Secondary packaging includes batch release acc. pragraph 16 AMWHV. 1.5.2: - Capsules, hard shell (with powder for inhalation) - Tablets - Ampules - Transdermal patches - liquids (solutions, drops)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

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

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