

# MANUFACTURER'S AUTHORISATION<sup>1, 2</sup>

1. Authorisation Number 39452
2. Name of authorisation holder GMPack ApS
3. Address(es) of manufacturing site(s) GMPack ApS, Plastvænget 9, Hadsund, 9560, Denmark
4. Legally registered address of authorisation holder Plastvænget 9, Hadsund, 9560, Denmark
5. Scope of authorisation and dosage forms<sup>2</sup> ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 13 of Directive 2001/20/EC  
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 2020-04-16
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)<sup>3</sup>

<sup>1</sup> 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.

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

<sup>3</sup> 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 : GMPack ApS, Plastvænget 9, Hadsund, 9560, Denmark

Human Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.2 Capsules, soft shell
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i>

**SCOPE OF AUTHORISATION****ANNEX 2**

Name and address of the site : GMPack ApS, Plastvænget 9, Hadsund, 9560, Denmark

Human Investigational Medicinal Products

**Authorised Operations**

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.2 Capsules, soft shell
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 Microbiological: non-sterility