

## Manufacturer/Importer Authorisation <sup>1</sup>

1. Authorisation Number MIAE-CH-511566-102728127
2. Name of authorisation holder Fisher Clinical Services GmbH (ORG-100012942 / LOC-100021959)
3. Address(es) of manufacturing site(s) Fisher Clinical Services GmbH (ORG-100012942 / LOC-100053878), Ringstrasse 9, Allschwil, 4123, Switzerland  
Fisher Clinical Services GmbH (ORG-100012942 / LOC-100021959), Steinbühlweg 69, Allschwil, 4123, Switzerland
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Steinbühlweg 69, Allschwil, 4123, Switzerland
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms <sup>1</sup> ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Issued under the provisions of the Mutual Recognition Agreement between the European Union and Switzerland
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2024-05-21
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>1</sup> Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

## SCOPE OF AUTHORISATION

## ANNEX 1

Name and address of the site: Fisher Clinical Services GmbH, Ringstrasse 9, Allschwil, 4123, Switzerland

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

<b>Authorised Operations</b>
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.5	Packaging
	1.5.2 Secondary packaging

## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : Fisher Clinical Services GmbH, Ringstrasse 9, Allschwil, 4123, Switzerland

Additional Details:

Human Investigational Medicinal Products
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### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

### Part 1 - MANUFACTURING OPERATIONS

<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</i>

## SCOPE OF AUTHORISATION

## ANNEX 1

Name and address of the site: Fisher Clinical Services GmbH, Steinbühlweg 69, Allschwil,  
4123, Switzerland

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

### Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>

## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : Fisher Clinical Services GmbH, Steinbühlweg 69, Allschwil,  
4123, Switzerland

Additional Details:

Human Investigational Medicinal Products
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### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
1.2	<b>Non-sterile investigational medicinal products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.17 Other: Other non-sterile medicinal product: overencapsulation(en)
	<i>1.2.2 Batch certification</i>
1.5	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.3 Chewing gums 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>

### Update operation comments in english

replaced by updated MIA entry (new issued authorisation)