

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

1. Authorisation Number FIMEA/2021/003430
2. Name of authorisation holder Biovian Oy (ORG-100015607 / LOC-100024349)
3. Address(es) of manufacturing site(s) Biovian Oy (ORG-100015607 / LOC-100024349), Tykistökatu 6 A ja B, Turku, FI-20520, Finland  
Biovian Oy, laboratory (ORG-100015607 / LOC-100053529), Itäinen Pitkätie 4, Turku, FI-20520, Finland
4. Legally registered address of authorisation holder Tykistökatu 6 A ja B Turku 20520, Finland
5. Scope of authorisation and dosage forms<sup>2</sup> 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  
Art. 44 of Directive 2001/82/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2021-05-26
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: Biovian Oy, Tykistökatu 6 A ja B, Turku, FI-20520, Finland

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products 1.3.1.4 Gene therapy products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.4 Gene therapy products
<b>1.4</b>	<b>Other products or manufacturing activity</b>
	<i>1.4.1 Manufacture of</i> 1.4.1.3 Other: Manufacture of biological active substances(en)
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

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

1.1.1.4. Injections, 1.1.2.3. Injections, 1.3.1.2 and 1.3.2.2 only for veterinary products

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## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : Biovian Oy, Tykistökatu 6 A ja B, Turku, FI-20520, Finland

Human Investigational Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

#### Part 1 - MANUFACTURING OPERATIONS

<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products 1.3.1.4 Gene therapy products 1.3.1.5 Biotechnology products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products
<b>1.4</b>	<b>Other products or manufacturing activity</b>
	<i>1.4.1 Manufacture of</i> 1.4.1.3 Other: Manufacture of biological active substances(en)
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

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

1.1.1.4. injections; concentrate for solution for injection; concentrate for solution for infusion, including cytotoxics; oral solutions 1.1.2.3. injections; diluents for parenteral use

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## SCOPE OF AUTHORISATION

## ANNEX 1

Name and address of the site: Biovian Oy, laboratory, Itäinen Pitkätatu 4, Turku, FI-20520, Finland

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

### Part 1 - MANUFACTURING OPERATIONS

<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

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

Name and address of the site : Biovian Oy, laboratory, Itäinen Pitkätatu 4, Turku, FI-20520, Finland

Human Investigational Medicinal Products
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**Authorised Operations**

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

<b>1.6</b>	<b>Quality control testing</b>
	1.6.3 Chemical/Physical
	1.6.4 Biological