MANUFACTURER'S AUTHORISATION [1] , [2]

1. Authorisation Number	FIMEA/2023/002840
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 Pitkäkatu 4, Turku, FI-20520, Finland
4. Legally registered address of authorisation holder	Tykistoekatu 6 A Ja B, Turku, 20520, Finland
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 Art. 88 of Regulation (EU) 2019/6 Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2023-05-17
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: 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)

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

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

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

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

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Biovian Oy, laboratory, Itäinen Pitkäkatu 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	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

SCOPE OF AUTHORISATION **ANNEX 2**

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

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological