

## *Finnish Medicines Agency*

CERTIFICATE NUMBER: **FIMEA/2022/004584**

# **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

### **Part 1**

Issued following an inspection in accordance with :  
Art. 111(5) of Directive 2001/83/EC as amended  
Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Finland confirms the following:

The manufacturer: **Biovian Oy**

Site address: **Tykistöekatu 6 A Ja B, Turku, 20520, Finland**

OMS Organisation Id. / OMS Location Id.: **ORG-100015607 / LOC-100024349**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **FIMEA/2021/003430** in accordance with Art. 40 of Directive 2001/83/EC and Art. 88 of Regulation (EU) 2019/6.

Is an active substance manufacturer that has been inspected in accordance with Art. 123(6) of Regulation (EU) 2019/6 and Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-10-14**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569<sup>3</sup>
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC<sup>3</sup>
- The principles of GMP for active substances<sup>3</sup> referred to in and Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

<sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC, 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>These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products
Veterinary Medicinal Products

<b>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: 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>

Clarifying remarks (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***

2022-11-23

Name and signature of the authorised person of the  
Competent Authority of Finland

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