Finnish Medicines Agency

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

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :
Art. 63 of Regulation (EU) 536/2014

The competent authority of Finland confirms the following:
The manufacturer: ***Biovian Oy***
Site address: ***Tykistoekatu 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. 61 of Regulation (EU) No 536/2014.

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 [3]

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.

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[1] *The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC, 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] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

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: biological active substances(en)
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

Clarifications: 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

2022-11-23

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

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Confidential
Finnish Medicines Agency
Tel:***Confidential***
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