Health And Youth Care Inspectorate

CERTIFICATE NUMBER: ***NL/H 23/2049436***

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

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended
Art. 63 of Regulation (EU) 536/2014

The competent authority of Netherlands confirms the following:
The manufacturer: ***Eurofins Bactimm B.V.***
Site address: ***Middenkampweg 19, Nijmegen, 6545 CH, Netherlands, GPS: 51.843059, 5.806297***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012332*** / ***LOC-100021251***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***6475 F*** in accordance with Art. 61 of Regulation (EU) No 536/2014 and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-07-06 00:00:00.0***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

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

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility
	2.1.2 Microbiological: non-sterility

Clarifying remarks (for public users)

This document also encompasses CTD IMP's

2023-10-17 00:00:00.0

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

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