Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	6475 F
2. Name of authorisation holder	Eurofins Bactimm B.V., NIJMEGEN
3. Address(es) of manufacturing site(s)	Eurofins Bactimm B.V. (ORG-100012332 / LOC-100021251), Middenkampweg 19, Nijmegen, 6545 CH, Netherlands
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Middenkampweg 19, NIJMEGEN, 6545CH, Netherlands
4.a Additional details on units inspected of legally registered address	
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. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2025-04-01
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 as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be*

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required for imports coming from third countries into a Member State.

[2]Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

[3]The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).

SCOPE OF AUTHORISATION — ANNEX 1

Name and address of the site: Eurofins Bactimm B.V., Middenkampweg 19, Nijmegen, 6545 CH, Netherlands

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.3 Moist heat
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

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

1.6.3 Chemical and psychical testing for water quality

Part 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*

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SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Eurofins Bactimm B.V., Middenkampweg 19, Nijmegen, 6545 CH, Netherlands

Additional Details:

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.3 Moist heat
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

1.6.3 Chemical and psychical testing for water quality

Part 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

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