

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 3003-F
2. Name of authorisation holder Eurofins Bactimm B.V. (ORG-100012332 / LOC-100021251)
3. Address(es) of manufacturing site(s) Eurofins Bactimm B.V. (ORG-100012332 / LOC-100021251),
Middenkampweg 19, Nijmegen, 6545 CH, Netherlands
4. Legally registered address of authorisation holder Middenkampweg 19, Nijmegen, 6545 CH, Netherlands
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 88 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2023-09-18
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 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:

Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS_(according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS_(according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.2 Microbiological: non-sterility</i>

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
	<i>2.1.1 Microbiological: sterility</i>
	<i>2.1.2 Microbiological: non-sterility</i>