# Manufacturer/Importer Authorisation [1, 2]

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|---|---|
| 1. Authorisation Number | 6444 F |
| 2. Name of authorisation holder | Eurofins Spinnovation Analytical B.V., OSS |
| 3. Address(es) of manufacturing site(s) | Eurofins Spinnovation Analytical B.V. (ORG-100012378 / LOC-100023177), Kloosterstraat 9, Oss, 5349 AB, Netherlands |
| 3.a Additional details on units inspected of manufacturing site(s) address(es) | |
| 4. Legally registered address of authorisation holder | Kloosterstraat 9, Oss, 5349 AB, 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<br>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 | 2021-09-14 |
| 10. Annexes attached | Annex 1 and/or Annex 2<br>Optional Annexes as required:<br>Annex 3(Addresses of Contract Manufacturing Site(s))<br>Annex 4(Addresses of Contract laboratories)<br>Annex 5(Name of Qualified Person)<br>Annex 6(Name of responsible persons)<br>Annex 7(Date of inspection on which authorisation granted, scope of last inspection)<br>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 Spinnovation Analytical B.V., Kloosterstraat 9, Oss, 5349 AB, Netherlands

Additional Details:

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|---|
| Human 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** |
| | *1.6.3 Chemical/Physical* |
| **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS** | |
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.3 Chemical/Physical* |

**SCOPE OF AUTHORISATION** **ANNEX 2**

Name and address of the site : Eurofins Spinnovation Analytical B.V., Kloosterstraat 9, Oss, 5349 AB, Netherlands

Additional Details:

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|---|
| Human Investigational Medicinal Products |

**Authorised Operations**

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

| **Part 1 - MANUFACTURING OPERATIONS** | |
|---|---|
| **1.6** | **Quality control testing** |
| | 1.6.3 Chemical/Physical |
| **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS** | |
| **2.1** | **Quality control testing of imported medicinal products** |
| | 2.1.3 Chemical/Physical |