Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	4577 F
2. Name of authorisation holder	Eurofins Biopharma Product Testing Leiden B.V. (ORG-100011886 / LOC-100021977)
3. Address(es) of manufacturing site(s)	Eurofins Biopharma Product Testing Leiden B.V. (ORG-100011886 / LOC-100021977), Archimedesweg 25, Leiden, Zuid-Holland, 2333 CM, Netherlands Eurofins Biopharma Product Testing Leiden B.V. (ORG-100011886 / LOC-100021255), Darwinweg 24, Leiden, Zuid-Holland, 2333 CR, Netherlands
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Archimedesweg 25, Leiden, Zuid-Holland, 2333 CM, 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. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2026-03-20
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)

[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 Biopharma Product Testing Leiden B.V., Archimedesweg 25, Leiden, Zuid-Holland, 2333 CM, 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**

	1.6.3 Chemical/Physical *1.6.4 Biological*
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Eurofins Biopharma Product Testing Leiden B.V., Archimedesweg 25, Leiden, Zuid-Holland, 2333 CM, 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	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids 1.1.1.5 Solids and implants
	1.1.3 Batch certification
1.2	**Non-sterile investigational medicinal products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms
	1.5.2 Secondary packaging
1.6	**Quality control testing**

	1.6.3 Chemical/Physical 1.6.4 Biological
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical 2.1.4 Biological

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Eurofins Biopharma Product Testing Leiden B.V., Darwinweg 24, Leiden, Zuid-Holland, 2333 CR, 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	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological
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
	2.1.3 Chemical/Physical
	2.1.4 Biological

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Eurofins Biopharma Product Testing Leiden B.V., Darwinweg 24, Leiden, Zuid-Holland, 2333 CR, 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	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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
	2.1.3 Chemical/Physical
	2.1.4 Biological