MANUFACTURER'S AUTHORISATION [1] , [2]

1. Authorisation Number	2022_197_1_2_10
2. Name of authorisation holder	Eurofins Pharma Quality Control (ORG-100011502 / LOC-100019504)
3. Address(es) of manufacturing site(s)	Eurofins Pharma Quality Control (ORG-100011502 / LOC-100020938), Zone Industrielle De Courtaboeuf9 Avenue De Laponie, Les Ulis, 91940, France
4. Legally registered address of authorisation holder	Site De La Geraudiere, Rue Pierre Adolphe Bobierre, Nantes, 44300, France
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	2022-08-30
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 and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Eurofins Pharma Quality Control, Zone Industrielle De Courtaboeuf9 Avenue De Laponie, Les Ulis, 91940, France

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**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.3 Other: holding of samples for on-going stability studies(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

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

Manufacturer (Article R.5124-2 1° of the French Public Health Code)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical* *2.1.4 Biological*

Any restrictions or clarifying remarks related to the scope of these Importation operations

(for Public users)

Importer (Article R.5124-2 2° of the French Public Health Code) --- Signatory: Mrs Mme Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Eurofins Pharma Quality Control, Zone Industrielle De Courtaboeuf9 Avenue De Laponie, Les Ulis, 91940, France

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**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.3 Other: holding of samples for on-going stability studies(en)
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

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

Manufacturer (Article R.5124-2 1° of the French Public Health Code)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility 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 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

Importer (Article R.5124-2 2° of the French Public Health Code) --- This site is not authorised for blinding operations --- Signatory: Mrs Mme Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department. The ANSM does not issue hard copy of this authorisation.