MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	2021_179_1_2
2. Name of authorisation holder	EUROFINS PHARMA QUALITY CONTROL
3. Address(es) of manufacturing site(s)	EUROFINS PHARMA QUALITY CONTROL, 16 rue Clément Ader, SAINTE CROIX EN PLAINE, 68127, France
4. Legally registered address of authorisation holder	Site de la Géraudière, 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. 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	2021-10-18
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 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, 16 rue Clément Ader, SAINTE CROIX EN PLAINE, 68127, France

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

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) --- 1.6.3: chemical/physical quality control testing limited to the measure of the total organic carbon in water and of the particulate contamination (sub-visible particles) in injectable finished products --- 1.6.4: limited to bacterial endotoxin testing

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

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) --- 2.1.3: chemical/physical quality control testing limited to the measure of the total organic carbon in water and of the particulate contamination (sub-visible particles) in injectable finished products --- 2.1.4: limited to bacterial endotoxin testing --- Signatory: Mr Said Ioughlissen, deputy 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, 16 rue Clément Ader, SAINTE CROIX EN PLAINE, 68127, 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	
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	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) --- 1.6.3: chemical/physical quality control testing limited to the measure of the total organic carbon in water and of the particulate contamination (sub-visible particles) in injectable finished products --- 1.6.4: limited to bacterial endotoxin testing

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

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) --- 2.1.3: chemical/physical quality control testing limited to the measure of the total organic carbon in water and of the particulate contamination (sub-visible particles) in injectable finished products --- 2.1.4: limited to bacterial endotoxin testing --- Signatory: Mr Said Ioughlissen, deputy head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copy of this authorisation.