

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 2022_149_1_2
2. Name of authorisation holder Laboratoire Icare (ORG-100033884 / LOC-100053417)
3. Address(es) of manufacturing site(s) Laboratoire Icare (ORG-100033884 / LOC-100053417), Biopole Clermont Limagne Rue Emile Duclaux, Saint Beauzire, 63360, France
4. Legally registered address of authorisation holder Biopole Clermont Limagne, Rue Emile Duclaux, Saint Beauzire, 63360, France
5. Scope of authorisation and dosage forms² 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 2022-07-01
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

¹The 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.

²Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³The 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: Laboratoire Icare, Biopole Clermont Limagne Rue Emile
Duclaux, Saint Beauzire, 63360, 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	
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.4 Biological</i>

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) --- 1.6.4 : limited to testing for bacterial endotoxins.

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> <i>2.1.4 Biological</i>

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) --- 2.1.4 ; limited to testing for bacterial endotoxins. Signatory: Mrs 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 : Laboratoire Icare, Biopole Clermont Limagne Rue Emile
Duclaux, Saint Beuzire, 63360, 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
	1.6.4 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) --- 1.6.4 : limited to testing for bacterial endotoxins.

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
	2.1.4 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) --- 2.1.4 ; limited to testing for bacterial endotoxins. Signatory: Mrs Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue hard copy of this authorisation.