

## Manufacturer/Importer Authorisation <sup>1, 2</sup>

1. Authorisation Number 2024\_273\_1\_2
2. Name of authorisation holder Cryoport France (ORG-100040164 / LOC-100065361)
3. Address(es) of manufacturing site(s) Cryoport France (ORG-100040164 / LOC-100066929), Rue De Chambussiere, Pont Du Chateau, 63430, France
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder 8 Rue Jacqueline Auriol, Clermont Ferrand, 63100, France
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms<sup>2</sup> 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 2024-10-18
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)<sup>3</sup>

<sup>1</sup>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.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

<sup>3</sup>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: Cryoport France, Rue De Chambussiere, Pont Du Chateau,  
63430, France

Additional Details:

Human Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.7 Tissue engineered products
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</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)

<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i>

	2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological medicinal products</i> 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products 2.2.3.7 Tissue engineered products
<b>2.3</b>	<b>Other importation activities</b>
	2.3.1 <i>Site of physical importation</i> 2.3.2 <i>Importation of intermediate which undergoes further processing</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) --- 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 : Cryoport France, Rue De Chambussiere, Pont Du Chateau,  
63430, France

Additional Details:

Human Investigational Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile investigational medicinal products</b>
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.7 Tissue engineered products
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packaging</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) --- This site is not authorised for blinding operations.

<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>

	<p>2.2.3 <i>Biological medicinal products</i></p> <p>2.2.3.2 Immunological products</p> <p>2.2.3.3 Cell therapy products</p> <p>2.2.3.4 Gene therapy products</p> <p>2.2.3.5 Biotechnology products</p> <p>2.2.3.7 Tissue engineered products</p>
<b>2.3</b>	<b>Other importation activities</b>
	<p>2.3.1 Site of physical importation</p> <p>2.3.2 Importation of intermediate which undergoes further processing</p>

**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 Florence Descamps-Delesalle, head of pharmaceutical product inspection and counterfeiting fight department  
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