

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 2023_186_1
2. Name of authorisation holder Ionisos (ORG-100018490 / LOC-100054722)
3. Address(es) of manufacturing site(s) Ionisos (ORG-100018490 / LOC-100027290), Parc Dombes Cotiere Activites, 176 Route De Balan, Dagneux, 01120, France
4. Legally registered address of authorisation holder Zone Dactivite Du Pontet, 13 Chemin Du Pontet, Civrieux D Azergues, 69380, 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. 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 2023-07-11
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: Ionisos, Parc Dombes Cotiere Activites, 176 Route De Balan,
Dagneux, 01120, France

Additional Details:

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.5 Gamma irradiation

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) --- Signatory: Mrs Mélanie Cachet, deputy director - Inspection division --- The ANSM does not issue hard copy of this authorisation.

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Ionisos, Parc Dombes Cotiere Activites, 176 Route De Balan,
Dagneux, 01120, France

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.4	Other products or manufacturing activity
	<i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.5 Gamma irradiation

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) --- Signatory: Mrs Mélanie Cachet, deputy director - Inspection division --- The ANSM does not issue hard copy of this authorisation.