

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 58032
2: Name of authorisation holder	RENTSCHLER ATMP LIMITED
3: Address(es) of manufacturing site(s)	RENTSCHLER ATMP LIMITED, MODULE 12, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM RENTSCHLER ATMP LIMITED, SYCAMORE HOUSE, LEYDEN ROAD, STEVENAGE, SG1 2BP, UNITED KINGDOM
4: Legally registered address of authorisation holder	RENTSCHLER ATMP LIMITED, 4 FLEET PLACE, LONDON, EC4M 7RD, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	14/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RENTSCHLER ATMP LIMITED, MODULE 12, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.4] Gene therapy products [1.3.1.5] Biotechnology products [1.4] Other investigational medicinal products or manufacturing activity

<p>[1.4.1] Manufacture of:</p> <p>[1.4.1.3] Other</p> <p>Environmental monitoring or process simulation (media fill) to support sterile manufacture</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p> <p>[1.6.4] Biological</p>
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SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RENTSCHLER ATMP LIMITED, SYCAMORE HOUSE, LEYDEN ROAD, STEVENAGE, SG1 2BP, UNITED KINGDOM

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.6] Quality control testing</p> <p>[1.6.2] Microbiological: non-sterility</p> <p>[1.6.3] Chemical/Physical</p> <p>[1.6.4] Biological</p>
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