Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 46113 **AUTOLUS LIMITED** 2: Name of authorisation holder

> AUTOLUS LIMITED MODULE 4, MODULE 4, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD,

STEVENAGE, SG1 2FX, UNITED KINGDOM

AUTOLUS LIMITED THE NUCLEUS, THE NUCLEUS, MARSHGATE,

STEVENAGE, SG1 1FR, UNITED KINGDOM

AUTOLUS LIMITED, 5TH FLOOR THE MEDIAWORKS, 191 WOOD 4: Legally registered address of authorisation holder

LANE, LONDON, W12 7FP, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 6: Legal Basis of authorisation

[SI 2004/1031]

7: Name of responsible officer of the competent

authority of the member state granting the

3: Address(es) of manufacturing site(s)

manufacturing authorisation

Confidential

8: Authorisation Date 21/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

AUTOLUS LIMITED MODULE 4, MODULE 4, 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

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

Special Requirements

Live Cells

Issue Date: 21 Oct 2025 Manufacturer's Authorisation: UK MIA(IMP) 46113

[1.1.1.4] Small volume liquids **Special Requirements** Live Cells [1.1.1.6] Other aseptically prepared products Gene Therapies **Special Requirements** Live Cells [1.1.3] Batch certification [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.4] Gene therapy products **Special Requirements** Live Cells [1.3.2] Batch certification [1.3.2.4] Gene therapy products Special Requirements Live Cells [1.5] Packaging [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

AUTOLUS LIMITED THE NUCLEUS, THE NUCLEUS, MARSHGATE, STEVENAGE, SG1 1FR, UNITED KINGDOM

Human Investigational Medicinal Products

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Special Requirements

Live Cells

[1.1.1.6] Other aseptically prepared products

Gene therapies

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

Issue Date: 21 Oct 2025

[1.3.1.4] Gene therapy products
Special Requirements
Live Cells
[1.3.2] Batch certification
[1.3.2.4] Gene therapy products
Special Requirements
Live Cells
[1.5] Packaging
[1.5.2] Secondary packaging
[1.6.1 Quality control testing
[1.6.1] Microbiological: sterility
[1.6.2] Microbiological: non-sterility
[1.6.4] Biological

