

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 46113

2: Name of authorisation holder

AUTOLUS LIMITED

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

AUTOLUS LIMITED MODULE 4, MODULE 4, CELL & GENE THERAPY
CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD,
STEVENAGE, SG1 2FX, UNITED KINGDOM

4: Legally registered address of authorisation holder

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

5: Scope of authorisation and dosage forms

AUTOLUS LIMITED, 5TH FLOOR THE MEDIWORKS, 191 WOOD
LANE, LONDON, W12 7FP, UNITED KINGDOM

6: Legal Basis of authorisation

ANNEX 1 and/ or ANNEX 2
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

27/01/2026

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

- [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
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
 - [1.1.1.4] Small volume liquids
 - 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

[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] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological