

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 46113
2: Name of authorisation holder	AUTOLUS LIMITED AUTOLUS LIMITED MODULE 3, MODULE 3, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM
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 AUTOLUS LIMITED THE NUCLEUS, THE NUCLEUS, MARSHGATE, STEVENAGE, SG1 1FR, UNITED KINGDOM
4: Legally registered address of authorisation holder	AUTOLUS LIMITED, THE MEDIWORKS, 191 WOOD LANE, LONDON, W12 7FP, 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	15/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

AUTOLUS LIMITED MODULE 3, MODULE 3, 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)

[1.1.1.6] Other aseptically prepared products

Ex Vivo Viral Vector

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

Special Requirements

Ex Vivo Viral Vector

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

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