

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

**4: Legally registered address of authorisation holder** AUTOLUS LIMITED, 5TH FLOOR THE MEDIAWORKS, 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** 24/02/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids <b>Special Requirements</b> 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
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1)
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**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