

# 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<br><br>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  | 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)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.1 ] Large volume liquids<br><b>Special Requirements</b><br>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)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.1 ] Large volume liquids<br><b>Special Requirements</b><br>Live Cells<br>[ 1.1.1.4 ] Small volume liquids<br><b>Special Requirements</b><br>Live Cells<br>[ 1.1.1.6 ] Other aseptically prepared products<br>Gene therapies<br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 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