

# 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  AUTOLUS LIMITED MODULE 3, MODULE 3, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM
4: Legally registered address of authorisation holder	AUTOLUS LIMITED, 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	18/03/2024
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

**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)
<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 <b>Special Requirements</b> 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

**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)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.1.1.6 ] Other aseptically prepared products               <ul style="list-style-type: none"> <li>Ex Vivo Viral Vector</li> </ul> </li> </ul> </li> </ul> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.3.1 ] Biological medicinal products           <ul style="list-style-type: none"> <li>[ 1.3.1.4 ] Gene therapy products</li> </ul> </li> </ul> <p><b>Special Requirements</b></p> <p>Ex Vivo Viral Vector</p> <p><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b></p> <ul style="list-style-type: none"> <li>[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:           <ul style="list-style-type: none"> <li>[ 1.4.2.1 ] Filtration</li> </ul> </li> </ul>