

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 46113
<b>2: Name of authorisation holder</b>	AUTOLUS LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	AUTOLUS LIMITED THE NUCLEUS, THE NUCLEUS, MARSHGATE, STEVENAGE, SG1 1FR, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	AUTOLUS LIMITED, 5TH FLOOR THE MEDIAWORKS, 191 WOOD LANE, LONDON, W12 7FP, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	24/02/2025
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile 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 therapy

**Special Requirements**

Live Cells

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological 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