# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 46113 AUTOLUS LIMITED

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

AUTOLUS LIMITED, 5TH FLOOR THE MEDIAWORKS, 191
WOOD LANE, LONDON, W12 7FP, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

21/10/2025

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)

## Part 1 - MANUFACTURING OPERATIONS

## [ 1.1 ] Sterile 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

Issue Date: 21 Oct 2025

[ 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

