

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 48152
<b>2: Name of authorisation holder</b>	CELL AND GENE THERAPY CATAPULT
<b>3: Address(es) of manufacturing site(s)</b>	CELL AND GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CELL AND GENE THERAPY CATAPULT, 12TH FLOOR TOWER WING, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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>	24/05/2019
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CELL AND GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, 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 Advanced Therapy Medicinal Products

[ 1.1.1.4 ] Small volume liquids

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.1.1.6 ] Other aseptically prepared products

Cell based therapies and viral vectors

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.3 ] Cell therapy products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.1.4 ] Gene therapy products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.1.5 ] Biotechnology products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.1.6 ] Human or animal extracted products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.1.8 ] Other biological medicinal products

Viral vectors

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.2 ] Batch certification

[ 1.3.2.3 ] Cell therapy products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.2.4 ] Gene therapy products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.2.5 ] Biotechnology products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.2.6 ] Human or animal extracted products

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

[ 1.3.2.8 ] Other biological medicinal products

Viral vectors

**Special Requirements**

Live Cells

Advanced Therapy Medicinal Products

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological