

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 25224
<b>2: Name of authorisation holder</b>	NHS BLOOD AND TRANSPLANT  NHSBT ADVANCED THERAPIES UNIT, 14 ESTUARY BANKS, SPEKE, LIVERPOOL, L24 8RB, UNITED KINGDOM  BIRMINGHAM BLOOD CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2SG, UNITED KINGDOM  CLINICAL BIOTECHNOLOGY CENTRE, BRISTOL INST FOR TRANSFUSION SCIENCES, UNIVERSITY OF BRISTOL, LANGFORD HOUSE, LOWER LANGFORD, BRISTOL, BS40 5DU, UNITED KINGDOM  FILTON BLOOD CENTRE, NORTH BRISTOL PARK, NORTHWAY, FILTON, BRISTOL, BS34 7QH, UNITED KINGDOM  BARNSELY BLOOD CENTRE, NHSBT BARNSELY BLOOD CENTRE, UNIT D, CAPITOL WAY, DODWORTH, BARNSELY, S75 3FG, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	
<b>4: Legally registered address of authorisation holder</b>	NHS BLOOD AND TRANSPLANT, PLYMOUTH GROVE, MANCHESTER, M13 9LL, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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>	17/01/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**NHSBT ADVANCED THERAPIES UNIT**, 14 ESTUARY BANKS, SPEKE, LIVERPOOL, L24 8RB, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.4 ] Small volume liquids
  - [ 1.1.1.5 ] Solids and implants

**[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.3 ] Cell therapy products
  - [ 1.3.1.7 ] Tissue Engineered Products

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

- [ 1.4.1 ] Manufacture of:
  - [ 1.4.1.3 ] Other Biologically Active Starting materials
- [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
  - [ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**BIRMINGHAM BLOOD CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2SG, UNITED KINGDOM**

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.4 ] Small volume liquids

**[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.3 ] Cell therapy products
  - [ 1.3.1.7 ] Tissue Engineered Products

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

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

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**CLINICAL BIOTECHNOLOGY CENTRE, BRISTOL INST FOR TRANSFUSION SCIENCES, UNIVERSITY OF BRISTOL, LANGFORD HOUSE, LOWER LANGFORD, BRISTOL, BS40 5DU, UNITED KINGDOM**

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.4 ] Small volume liquids

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.8 ] Other biological medicinal products

Recombinant Proteins

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

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.4 ] Biological

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

- [ 2.2.3 ] Biological medicinal products
  - [ 2.2.3.4 ] Gene therapy products
  - [ 2.2.3.5 ] Biotechnology products
  - [ 2.2.3.8 ] Other biological medicinal products
    - Recombinant Proteins

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**FILTON BLOOD CENTRE, NORTH BRISTOL PARK, NORTHWAY, FILTON, BRISTOL, BS34 7QH, UNITED KINGDOM**

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)  
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

### Part 1 - MANUFACTURING OPERATIONS

#### [ 1.1 ] Sterile Investigational Medicinal Products

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.4 ] Small volume liquids

#### [ 1.3 ] Biological investigational medicinal products

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.3 ] Cell therapy products
  - [ 1.3.1.4 ] Gene therapy products
  - [ 1.3.1.5 ] Biotechnology products
  - [ 1.3.1.7 ] Tissue Engineered Products
  - [ 1.3.1.8 ] Other biological medicinal products
    - Recombinant Proteins/Enucleated non-replicating Human cells

#### [ 1.4 ] Other investigational medicinal products or manufacturing activity

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

#### [ 1.5 ] Packaging

- [ 1.5.2 ] Secondary packaging

#### [ 1.6 ] Quality control testing

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

### Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

#### [ 2.1 ] Quality control testing of imported medicinal products

- [ 2.1.4 ] Biological

#### [ 2.2 ] Batch certification of imported medicinal products

- [ 2.2.1 ] Sterile Products

- [ 2.2.1.1 ] Aseptically prepared
- [ 2.2.3 ] Biological medicinal products
  - [ 2.2.3.4 ] Gene therapy products
  - [ 2.2.3.5 ] Biotechnology products
  - [ 2.2.3.8 ] Other biological medicinal products
    - Recombinant Proteins/Enucleated non-replicating Human cells
- [ 2.3 ] Other Importation Activities**
  - [ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**BARNSELY BLOOD CENTRE**, NHSBT BARNSELY BLOOD CENTRE, UNIT D, CAPITOL WAY, DODWORTH, BARNSELY, S75 3FG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

- [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
  - [ 1.1.1.4 ] Small volume liquids
  - [ 1.1.1.6 ] Other aseptically prepared products
    - Virally transduced cellular product

**[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.3 ] Cell therapy products
    - Special Requirements**
    - Live Cells
  - [ 1.3.1.4 ] Gene therapy products
    - Special Requirements**
    - Live Cells
  - [ 1.3.1.7 ] Tissue Engineered Products
    - Special Requirements**
    - Live Cells

**[ 1.4 ] Other investigational medicinal 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**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological