

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 44168
<b>2: Name of authorisation holder</b>	INSTIL BIO (UK) LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	INSTIL BIO (UK) LIMITED, 46 GRAFTON STREET, MANCHESTER, M13 9NT, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	INSTIL BIO (UK) LIMITED, UNIVERSITY OF MANCHESTER INNOVATION CENTRE, BIOINCUBATOR BUILDING, 48 GRAFTON STREET, MANCHESTER, M13 9XX, 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>	12/03/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**INSTIL BIO (UK) LIMITED**, 46 GRAFTON STREET, MANCHESTER, M13 9NT, 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) [ 1.1.1.4 ] Small volume liquids [ 1.1.1.6 ] Other aseptically prepared products Autologous cell therapies using cells extracted from human tissues prior to manipulation. The final product is made up as a cell suspension for re-infusion

[ 1.1.3 ] Batch certification  
**[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.4 ] Gene therapy products
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.4 ] Gene therapy products

**[ 1.5 ] Packaging**

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.6 ] Liquids for internal use
- [ 1.5.2 ] Secondary packaging

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**INSTIL BIO (UK) LIMITED**, UNIVERSITY OF MANCHESTER INNOVATION CENTRE, BIOINCUBATOR BUILDING, 48 GRAFTON STREET, MANCHESTER, M13 9XX, 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)
  - [ 1.1.1.6 ] Other aseptically prepared products
    - Autologous cellular therapies for direct infusion. Allogenic cell therapies
- [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)
  - [ 1.1.2.3 ] Small volume liquids
- [ 1.1.3 ] Batch certification

**[ 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
  - [ 1.3.1.8 ] Other biological medicinal products
    - Autologous cellular therapies using cells extracted from human tissue prior to manipulation. The final product is made up as a cell suspension for re-infusion. Allogeneic cell therapies
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.3 ] Cell therapy products
  - [ 1.3.2.4 ] Gene therapy products
  - [ 1.3.2.8 ] Other biological medicinal products
    - Autologous cellular therapies using cells extracted from human tissue prior to manipulation. The final product is made up as a cell suspension for re-infusion. Allogeneic cell therapies

**[ 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

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological