

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 3473
<b>2: Name of authorisation holder</b>	NHS NATIONAL SERVICES SCOTLAND  NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICcartON, CURRIE, EH14 4BE, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	INSTITUTE FOR REGENERATION AND REPAIR - NORTH, GMP CELLULAR THERAPY FACILITY, SCOTTISH CENTRE FOR REGENERATIVE MEDICINE, EDINBURGH BIOQUARTER, 5 LITTLE FRANCE DRIVE, EDINBURGH, EH16 4UU, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICcartON, CURRIE, EH14 4BE, 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>	07/01/2025
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**NHS NATIONAL SERVICES SCOTLAND**, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICcartON, CURRIE, EH14 4BE, 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)

- [ 1.1.1.6 ] Other aseptically prepared products  
Human derived ATMPs as stipulated in 1394/2007. Cell banking of cells of human origin.

**[ 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  
Human derived ATMPs as stipulated in 1394/2007. Cell banking of cells of human origin.

**[ 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

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**INSTITUTE FOR REGENERATION AND REPAIR - NORTH**, GMP CELLULAR THERAPY FACILITY, SCOTTISH CENTRE FOR REGENERATIVE MEDICINE, EDINBURGH BIOQUARTER, 5 LITTLE FRANCE DRIVE, EDINBURGH, EH16 4UU, 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  
Human derived ATMPs as stipulated in 1394/2007

**[ 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
  - [ 1.3.1.6 ] Human or animal extracted products
  - [ 1.3.1.8 ] Other biological medicinal products  
Cell banking of cells of human origin

**[ 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

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