

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 3473

**2: Name of authorisation holder** NHS NATIONAL SERVICES SCOTLAND

**3: Address(es) of manufacturing site(s)** NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICCARTON, CURRIE, EH14 4BE, UNITED KINGDOM

**4: Legally registered address of authorisation holder** 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

**5: Scope of authorisation and dosage forms** NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICCARTON, CURRIE, EH14 4BE, UNITED KINGDOM

**6: Legal Basis of authorisation** ANNEX 1 and/ or ANNEX 2

**7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

**8: Authorisation Date** Confidential

**9: Annexes attached** 16/09/2025

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

|                                                                                                                                                                                                |
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| Human Investigational Medicinal Products                                                                                                                                                       |
| Authorised Operations                                                                                                                                                                          |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                 |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 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

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| Human Investigational Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.6 ] Other aseptically prepared products<br>Human derived ATMPs as stipulated in 1394/2007<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.3 ] Cell therapy products<br>[ 1.3.1.4 ] Gene therapy products<br>[ 1.3.1.6 ] Human or animal extracted products<br>[ 1.3.1.8 ] Other biological medicinal products<br>Cell banking of cells of human origin<br><b>[ 1.5 ] Packaging</b><br>[ 1.5.1 ] Primary packaging<br>[ 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

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