

# 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<br>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 |
| 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                                                                  | NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICCARTON, CURRIE, EH14 4BE, UNITED KINGDOM                                                                                   |
| 5: Scope of authorisation and dosage forms                                                                             | ANNEX 1 and/ or ANNEX 2                                                                                                                                                                                                                     |
| 6: Legal Basis of authorisation                                                                                        | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]                                                                                                                                                     |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Confidential                                                                                                                                                                                                                                |
| 8: Authorisation Date                                                                                                  | 21/07/2025                                                                                                                                                                                                                                  |
| 9: Annexes attached                                                                                                    | Annex 1 and/or Annex 2                                                                                                                                                                                                                      |

### 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)                                                                                                                                                 |
| <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

### [ 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

## 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)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.1.1.6 ] Other aseptically prepared products</li> <li>Human derived ATMPs as stipulated in 1394/2007. Cell banking of cells of human origin.</li> </ul> </li> </ul> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.3.1 ] Biological medicinal products           <ul style="list-style-type: none"> <li>[ 1.3.1.3 ] Cell therapy products</li> <li>[ 1.3.1.4 ] Gene therapy products</li> <li>[ 1.3.1.8 ] Other biological medicinal products</li> <li>Human derived ATMPs as stipulated in 1394/2007. Cell banking of cells of human origin.</li> </ul> </li> </ul> <p><b>[ 1.5 ] Packaging</b></p> <ul style="list-style-type: none"> <li>[ 1.5.1 ] Primary packaging           <ul style="list-style-type: none"> <li>[ 1.5.1.6 ] Liquids for internal use</li> </ul> </li> </ul> |

[ 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