

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
NHS NATIONAL SERVICES SCOTLAND, THE JACK COPLAND CENTRE, 52 RESEARCH AVENUE NORTH, HERIOT-WATT RESEARCH PARK, RICCARTON, CURRIE, EH14 4BE, UNITED KINGDOM

3: Address(es) of manufacturing site(s) 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

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 16/09/2025

9: Annexes attached 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)
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. 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