

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 45803

2: Name of authorisation holder ROSLIN CELL THERAPIES LIMITED

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

BIO CUBE 2, BIOCUBE 2, 11 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM

ROSLINCT - SHAWFAIR, 2 WESTER SHAWFAIR, DANDERHALL, DALKEITH, EH22 1FD, UNITED KINGDOM

4: Legally registered address of authorisation holder ROSLIN CELL THERAPIES LIMITED, 9 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, 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 15/02/2024

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

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) |

- [1.1.1.4] Small volume liquids
- [1.1.1.6] Other aseptically prepared products
cellular therapy products (ATMPs), Master cell banks
- [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
 - [1.3.1.6] Human or animal extracted products
 - [1.3.1.7] Tissue Engineered Products

Special Requirements

Live Cells

- [1.3.2] Batch certification
 - [1.3.2.3] Cell therapy products
 - [1.3.2.4] Gene therapy products
 - [1.3.2.7] Tissue Engineered Products

Special Requirements

Live Cells

[1.5] Packaging

- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BIO CUBE 2, BIOCUBE 2, 11 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM

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| 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)
 - [1.1.1.4] Small volume liquids
 - [1.1.1.6] Other aseptically prepared products
Cellular therapy products (ATMPs), Master cell banks
- [1.1.3] Batch certification

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

Live Cells

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

[1.3.1.6] Human or animal extracted products

[1.3.1.7] Tissue Engineered Products

Special Requirements

Live Cells

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

[1.3.2.4] Gene therapy products

Special Requirements

Live Cells

[1.3.2.7] Tissue Engineered Products

Special Requirements

Live Cells

[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:

ROSLINCT - SHAWFAIR, 2 WESTER SHAWFAIR, DANDERHALL, DALKEITH, EH22 1FD, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.3] Cell therapy products Special Requirements Live Cells |

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

[1.3.1.6] Human or animal extracted products

Special Requirements

Live Cells