

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 45803

2: Name of authorisation holder ROSLIN CELL THERAPIES LIMITED

3: Address(es) of manufacturing site(s) ROSLINCT - SHAWFAIR, 2 WESTER SHAWFAIR, DANDERHALL, DALKEITH, EH22 1FD, UNITED KINGDOM

4: Legally registered address of authorisation holder ROSLINCT- BIOCUBE 2 , BIOCUBE 2, 11 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 Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 25/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.3] Biological medicinal products [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

[1.3.2.6] Human or animal extracted products

Special Requirements

Live Cells

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ROSLINCT- BIOCUBE 2 , BIOCUBE 2, 11 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.6] Other aseptically prepared products

Cellular therapy products (ATMPs), Master cell banks

Special Requirements

Live Cells

[1.1.3] Batch certification

[1.3] Biological 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

[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

[1.3.2.6] Human or animal extracted 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