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)	ROSLINCT- BIOCUBE 2 , BIOCUBE 2, 11 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM ROSLINCT 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 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	18/06/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

[1.1.1.4] 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

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

[1.3.2.7] 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 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)

[1.1.1.4] 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:

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

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.3] Biological investigational 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