

# 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** 19/06/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological medicinal products</b> [ 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