

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 45803
<b>2: Name of authorisation holder</b>	ROSLIN CELL THERAPIES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	ROSLINCT - SHAWFAIR, 2 WESTER SHAWFAIR, DANDERHALL, DALKEITH, EH22 1FD, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	BIO CUBE 2, BIOCUBE 2, 11 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ROSLIN CELL THERAPIES LIMITED, 9 LITTLE FRANCE ROAD, EDINBURGH BIOQUARTER, EDINBURGH, EH16 4UX, UNITED KINGDOM
<b>6: Legal Basis of authorisation</b>	ANNEX 1 and/ or ANNEX 2
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>8: Authorisation Date</b>	Confidential
<b>9: Annexes attached</b>	20/05/2024
	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> [ 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:

**BIO CUBE 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