# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA 54923

ADVENT BIOSERVICES LTD

ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK, SAWSTON, CAMBRIDGE, CB22 3JG, UNITED KINGDOM

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ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

27/02/2025

Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK, SAWSTON, CAMBRIDGE, CB22 3JG, 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

[ 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

Issue Date: 27 Feb 2025

[ 1.3.2 ] Batch certification
[ 1.3.2.3 ] Cell therapy products
Special Requirements
Live Cells

## [ 1.5 ] Packaging

[1.5.2] Secondary packaging

## [ 1.6 ] Quality control testing

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.4 ] Biological

