

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 54923
<b>2: Name of authorisation holder</b>	ADVENT BIOSERVICES LTD
<b>3: Address(es) of manufacturing site(s)</b>	ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK, SAWSTON, CAMBRIDGE, CB22 3JG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK, SAWSTON, CAMBRIDGE, CB22 3JG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	20/12/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 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 <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products

[ 1.3.1.3 ] Cell therapy products

**Special Requirements**

Live Cells

[ 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

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 1.1 ] Sterile Investigational Medicinal 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 investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.3 ] Cell therapy products

**Special Requirements**

Live Cells

[ 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

**[ 2.3 ] Other Importation Activities**

[ 2.3.4 ] Other

Importation of QP-certified IMPs from a country on the approved country for import list'