

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 54923

2: Name of authorisation holder ADVENT BIOSERVICES LTD

3: Address(es) of manufacturing site(s) ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK,
SAWSTON, CAMBRIDGE, CB22 3JG, UNITED KINGDOM

4: Legally registered address of authorisation holder ADVENT BIOSERVICES LTD, SAWSTON BUSINESS PARK,
SAWSTON, CAMBRIDGE, CB22 3JG, 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 23/03/2023

9: Annexes attached 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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.6] 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