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(IMP) 54923

ADVENT BIOSERVICES LTD

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

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

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

Confidential

21/02/2025

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)

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

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[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



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