Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 43821

2: Name of authorisation holder ADAPTIMMUNE LIMITED

ADAPTIMMUNE LIMITED, MODULE 5, CELL & GENE THERAPY
CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD,

STEVENAGE, SG1 2FX, UNITED KINGDOM

OTEVERNOE, GOT ZI X, GIVITED KINGDOW

ADAPTIMMUNE LIMITED, 60 JUBILEE AVENUE, MILTON PARK, MILTON,

ABINGDON, OX14 4RX, UNITED KINGDOM

4: Legally registered address of authorisation

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

holder

ADAPTIMMUNE LIMITED, 60 JUBILEE AVENUE, MILTON PARK, MILTON,

ABINGDON, OX14 4RX, 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 31/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ADAPTIMMUNE LIMITED, MODULE 5, CELL & GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, 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

Ex vivo viral vector

[1.3] Biological investigational medicinal products

Issue Date: 31 Oct 2024

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

Special Requirements

Ex vivo viral vectors

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ADAPTIMMUNE LIMITED, 60 JUBILEE AVENUE, MILTON PARK, MILTON, ABINGDON, OX14 4RX, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products



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