

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 18480

2: Name of authorisation holder

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED

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

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, 1 UNION
SQUARE, CENTRAL PARK, DARLINGTON, DL1 1GL, UNITED
KINGDOM

4: Legally registered address of authorisation holder

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED,
BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM

5: Scope of authorisation and dosage forms

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED,
BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM
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

22/12/2025

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, 1 UNION SQUARE, CENTRAL PARK, DARLINGTON, DL1 1GL, 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

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Manufacturing of recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, master/working cell banks and master/working non-pathogenic viral banks/seed lots, storage of these and samples for testing

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, cell banks and non-pathogenic viral banks for further processing

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, BELASIS AVENUE, BILLINGHAM, TS23 1LH, 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

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Manufacturing of recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, master/working cell banks and master/working non-pathogenic viral banks/seed lots, storage of these and samples for testing

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, cell banks and non-pathogenic viral banks for further processing