

# 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** 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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