

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

**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** 28/10/2025

**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**, BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM

|                                                                                                                                                                                                                                 |
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| Human Investigational Medicinal Products                                                                                                                                                                                        |
| Authorised Operations                                                                                                                                                                                                           |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                       |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products<br>[ 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

**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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| Human Investigational Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products<br>[ 1.3.1.4 ] Gene therapy products<br>[ 1.3.1.5 ] Biotechnology products<br>[ 1.3.1.8 ] Other biological medicinal products<br>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<br><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b><br><b>[ 2.3 ] Other Importation Activities</b><br>[ 2.3.2 ] Importation of Intermediate which undergoes further processing<br>[ 2.3.4 ] Other<br>Recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, cell banks and non-pathogenic viral banks for further processing |