

# 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,  
BELASIS AVENUE, BILLINGHAM, TS23 1LH, 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** 13/12/2023

**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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<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 [ 1.3.1.5 ] Biotechnology products [ 1.3.1.8 ] Other biological medicinal products Manufacturing of recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, cell bank manufacturing, storage of (non-pathogenic) baculovirus seed bank for insect cell culture <b>[ 1.6 ] Quality control testing</b>

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological