

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 18480
<b>2: Name of authorisation holder</b>	FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	13/12/2023
<b>9: Annexes attached</b>	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

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