

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)
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, cell bank manufacturing, storage of (non-pathogenic) baculovirus seed bank for insect cell culture [1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological