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