Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 18480 1: Authorisation Number

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED 2: Name of authorisation holder

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED. 4: Legally registered address of authorisation holder

BELASIS AVENUE, BILLINGHAM, TS23 1LH, UNITED

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 24/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological 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, master/working cell banks and master/working non-pathogenic viral banks/seed lots, storage of these and samples for testing

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[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

[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

[1.3] Biological 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, master/working cell banks and master/workin<mark>g no</mark>n-p<mark>at</mark>hog<mark>en</mark>ic viral banks/seed lots, storage of these and samples for testing

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

[2.3] Other Importation Activities

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Recombinant protein and nucleotide intermediates and active pharmaceutical ingredients, cell banks and non-pathogenic viral banks for further processing



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