

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 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>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<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>	25/02/2026
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological 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, master/working cell banks and master/working non-pathogenic 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

**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/working non-pathogenic 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