

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 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** Regulation 17 of The Human Medicines Regulations 2012 (SI  
2012/1916)

**7: Name of responsible officer of the competent authority of the  
member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 29/07/2025

**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
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Authorised Operations
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IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
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#### [ 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 testing
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