# 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** | 13/12/2023 |
| **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)

**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, cell bank manufacturing, storage of (non-pathogenic) baculovirus seed bank for insect cell culture

**[ 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