

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 31644

**2: Name of authorisation holder** CLINIGEN HEALTHCARE LIMITED

**3: Address(es) of manufacturing site(s)** CLINIGEN HEALTHCARE LIMITED, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, UNITED KINGDOM

CLINIGEN HEALTHCARE LIMITED, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, UNITED KINGDOM

**4: Legally registered address of authorisation holder** CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, 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** 19/03/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CLINIGEN HEALTHCARE LIMITED**, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, 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>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>

**[ 2.2 ] Batch certification of imported medicinal products**

**[ 2.2.1 ] Sterile Products**

**[ 2.2.1.1 ] Aseptically prepared**

**[ 2.2.1.2 ] Terminally sterilised**

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**CLINIGEN HEALTHCARE LIMITED**, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, 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**

**[ 1.1 ] Sterile Products**

**[ 1.1.3 ] Batch certification**

**[ 1.2 ] Non-sterile products**

**[ 1.2.2 ] Batch certification**

**[ 1.5 ] Packaging**

**[ 1.5.2 ] Secondary packaging**

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.2 ] Batch certification of imported medicinal products**

**[ 2.2.1 ] Sterile Products**

**[ 2.2.1.1 ] Aseptically prepared**

**[ 2.2.1.2 ] Terminally sterilised**

**[ 2.3 ] Other Importation Activities**

**[ 2.3.1 ] Site of Physical Importation**