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	03/03/2026
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)
Part 1 - MANUFACTURING OPERATIONS **[1.1] Sterile Products** [1.1.3] Batch certification **[1.2] Non-sterile products** [1.2.2] Batch certification Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

MHRA-GMDP MHRA-GMDP MHRA

[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

MHRA-GMDP MHRA-GMDP MHRA MHRA