

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 31644
2: Name of authorisation holder	CLINIGEN HEALTHCARE LIMITED CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM
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	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	20/11/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products

<ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.2.3] Biological medicinal products <ul style="list-style-type: none"> [2.2.3.2] Immunological products [2.2.3.5] Biotechnology products
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SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CLINIGEN HEALTHCARE LIMITED, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, UNITED KINGDOM

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.1] Sterile Investigational Medicinal Products</p> <ul style="list-style-type: none"> [1.1.3] Batch certification <p>[1.2] Non-sterile investigational medicinal products</p> <ul style="list-style-type: none"> [1.2.2] Batch certification <p>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</p> <p>[2.2] Batch certification of imported medicinal products</p> <ul style="list-style-type: none"> [2.2.1] Sterile Products <ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal 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

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Importation of QP certified IMPs from a country on the 'approved country for import list'.