

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 31644
<b>2: Name of authorisation holder</b>	CLINIGEN HEALTHCARE LIMITED CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	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
<b>4: Legally registered address of authorisation holder</b>	CLINIGEN HEALTHCARE LIMITED, PITCAIRN HOUSE, CROWN SQUARE, FIRST AVENUE, BURTON-ON-TRENT, DE14 2WW, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	20/11/2024
<b>9: Annexes attached</b>	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 ] <b>Batch certification of imported medicinal products</b> [ 2.2.1 ] Sterile Products

<ul style="list-style-type: none"> <li>[ 2.2.1.1 ] Aseptically prepared</li> <li>[ 2.2.1.2 ] Terminally sterilised</li> <li>[ 2.2.2 ] Non-sterile products</li> <li>[ 2.2.3 ] Biological medicinal products <ul style="list-style-type: none"> <li>[ 2.2.3.2 ] Immunological products</li> <li>[ 2.2.3.5 ] Biotechnology products</li> </ul> </li> </ul>
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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
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MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.3 ] Batch certification</li> </ul> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.2.2 ] Batch certification</li> </ul> <p><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b></p> <p><b>[ 2.2 ] Batch certification of imported medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 2.2.1 ] Sterile Products <ul style="list-style-type: none"> <li>[ 2.2.1.1 ] Aseptically prepared</li> <li>[ 2.2.1.2 ] Terminally sterilised</li> </ul> </li> <li>[ 2.2.2 ] Non-sterile products</li> </ul>
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**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
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MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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**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'.