

# 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, UNIT 3, CANADA ROAD, BYFLEET, WEST BYFLEET, KT14 7JL, UNITED KINGDOM CLINIGEN HEALTHCARE LIMITED, IDIS HOUSE, CHURCHFIELD ROAD, WEYBRIDGE, KT13 8DB, 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>	21/08/2023
<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

- [ 2.2.1.1 ] Aseptically prepared
- [ 2.2.1.2 ] Terminally sterilised
- [ 2.2.2 ] Non-sterile products
- [ 2.2.3 ] Biological medicinal products
  - [ 2.2.3.2 ] Immunological products
  - [ 2.2.3.5 ] Biotechnology products

**SCOPE OF AUTHORISATION**

**Annex 2**

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<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>[ 1.5 ] Packaging</b></p> <ul style="list-style-type: none"> <li>[ 1.5.2 ] Secondary packaging</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> <li>[ 2.2.3 ] Biological medicinal products           <ul style="list-style-type: none"> <li>[ 2.2.3.1 ] Blood products</li> <li>[ 2.2.3.2 ] Immunological products</li> <li>[ 2.2.3.3 ] Cell therapy products</li> <li>[ 2.2.3.4 ] Gene therapy products</li> <li>[ 2.2.3.5 ] Biotechnology products</li> <li>[ 2.2.3.6 ] Human or animal extracted products</li> </ul> </li> </ul> <p><b>[ 2.3 ] Other Importation Activities</b></p> <ul style="list-style-type: none"> <li>[ 2.3.1 ] Site of Physical Importation</li> <li>[ 2.3.4 ] Other Importation of QP certified IMPs from a country on the 'approved country for import list'.</li> </ul>

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Human Investigational 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 Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 2.2.1 ] Sterile Products [ 2.2.1.1 ] Aseptically prepared [ 2.2.1.2 ] Terminally sterilised [ 2.2.2 ] Non-sterile products