

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 11387
<b>2: Name of authorisation holder</b>	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST  GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, PHARMACY PRODUCTION UNIT, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM  RADIOPHARMACY UNIT, RADIOPHARMACY UNIT, NUCLEAR MEDICINE, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM  GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, THE FMT LABORATORY, CENTRE FOR CLINICAL INFECTION AND DIAGNOSTIC RESEARCH, NORTH WING, FLOOR 5, ST THOMAS'S HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM  CLINICAL PET CENTRE, ST THOMAS HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM  GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, CLINICAL RESEARCH FACILITY, 15TH FLOOR, TOWER WING, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	
<b>4: Legally registered address of authorisation holder</b>	GUY'S AND ST THOMAS' NHS FOUNDATION TRUST, PHARMACY MANUFACTURING UNIT, 13TH FLOOR, GUY'S TOWER, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, 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>	10/01/2025
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Investigational Medicinal Products</b></p> <p>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)</p> <p>[ 1.1.2.1 ] Large volume liquids</p> <p>[ 1.1.2.2 ] Semi-solids</p> <p>[ 1.1.2.3 ] Small volume liquids</p> <p>[ 1.1.3 ] Batch certification</p> <p><b>[ 1.2 ] Non-sterile investigational medicinal products</b></p> <p>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[ 1.2.1.1 ] Capsules, hard shell</p> <p>[ 1.2.1.5 ] Liquids for external use</p> <p>[ 1.2.1.6 ] Liquids for internal use</p> <p>[ 1.2.1.11 ] Semi-solids</p> <p>[ 1.2.1.13 ] Tablets</p> <p>[ 1.2.2 ] Batch certification</p> <p><b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b></p> <p>[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:</p> <p>[ 1.4.2.3 ] Moist heat</p> <p><b>[ 1.5 ] Packaging</b></p> <p>[ 1.5.1 ] Primary packaging</p> <p>[ 1.5.1.1 ] Capsules, hard shell</p> <p>[ 1.5.1.5 ] Liquids for external use</p> <p>[ 1.5.1.6 ] Liquids for internal use</p> <p>[ 1.5.1.11 ] Semi-solids</p> <p>[ 1.5.1.13 ] Tablets</p> <p>[ 1.5.1.15 ] Other non-sterile medicinal products</p> <p>Solid non-sterile including powders and granules</p> <p>[ 1.5.2 ] Secondary packaging</p> <p><b>[ 1.6 ] Quality control testing</b></p> <p>[ 1.6.2 ] Microbiological: non-sterility</p> <p>[ 1.6.3 ] Chemical/Physical</p>

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**RADIOPHARMACY UNIT**, RADIOPHARMACY UNIT, NUCLEAR MEDICINE, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids [ 1.1.1.6 ] Other aseptically prepared products Radiopharmaceuticals [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.8 ] Other biological medicinal products Radiopharmaceuticals; Nano-antibodies <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.1 ] Filtration <b>[ 1.5 ] Packaging</b> [ 1.5.2 ] Secondary packaging <b>[ 1.6 ] Quality control testing</b> [ 1.6.2 ] Microbiological: non-sterility [ 1.6.3 ] Chemical/Physical

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**GUY'S AND ST THOMAS' NHS FOUNDATION TRUST**, THE FMT LABORATORY, CENTRE FOR CLINICAL INFECTION AND DIAGNOSTIC RESEARCH, NORTH WING, FLOOR 5, ST THOMAS'S HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

- [ 1.2.1.1 ] Capsules, hard shell
- [ 1.2.1.6 ] Liquids for internal use
- [ 1.2.1.15 ] Other non-sterile medicinal products
  - Faecal Microbiota for transplantation (FMT)

### [ 1.3 ] Biological investigational medicinal products

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.6 ] Human or animal extracted products
  - [ 1.3.1.8 ] Other biological medicinal products
    - Faecal Microbiota for transplantation (FMT)
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.6 ] Human or animal extracted products
  - [ 1.3.2.8 ] Other biological medicinal products
    - Faecal Microbiota for transplantation (FMT)

### [ 1.5 ] Packaging

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.6 ] Liquids for internal use
  - [ 1.5.1.15 ] Other non-sterile medicinal products
    - Faecal Microbiota for transplantation (FMT)

### [ 1.6 ] Quality control testing

- [ 1.6.2 ] Microbiological: non-sterility

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**CLINICAL PET CENTRE**, ST THOMAS HOSPITAL, WESTMINSTER BRIDGE ROAD, LONDON, SE1 7EH, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> <ul style="list-style-type: none"> <li>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.1.1.4 ] Small volume liquids</li> </ul> </li> </ul> <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> <ul style="list-style-type: none"> <li>[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:           <ul style="list-style-type: none"> <li>[ 1.4.2.1 ] Filtration</li> </ul> </li> </ul> <b>[ 1.6 ] Quality control testing</b> <ul style="list-style-type: none"> <li>[ 1.6.3 ] Chemical/Physical</li> </ul>

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**GUY'S AND ST THOMAS' NHS FOUNDATION TRUST**, CLINICAL RESEARCH FACILITY, 15TH FLOOR, TOWER WING, GUY'S HOSPITAL, GREAT MAZE POND, LONDON, SE1 9RT, UNITED KINGDOM

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> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.4 ] Small volume liquids <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.3 ] Cell therapy products <b>Special Requirements</b> ATMPs [ 1.3.1.4 ] Gene therapy products <b>Special Requirements</b> ATMPs [ 1.3.1.5 ] Biotechnology products [ 1.3.1.8 ] Other biological medicinal products Autologous or allogeneic cell therapies for intravenous or solid tissue <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.1 ] Filtration <b>[ 1.6 ] Quality control testing</b> [ 1.6.1 ] Microbiological: sterility [ 1.6.3 ] Chemical/Physical [ 1.6.4 ] Biological <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 2.2.3 ] Biological medicinal products [ 2.2.3.3 ] Cell therapy products [ 2.2.3.4 ] Gene therapy products