# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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| **1: Authorisation Number** | UK MIA(IMP) 14523 |
| **2: Name of authorisation holder** | KING'S COLLEGE LONDON |
| **3: Address(es) of manufacturing site(s)** | RAYNE CELL THERAPY SUITE (RCTS), THE RAYNE INSTITUTE, KING'S COLLEGE HOSPITAL & KING'S COLLEGE LONDON, DEPARTMENT OF HAEMATOLOGICAL AND EXPERIMENTAL MEDICINE, THE RAYNE INSTITUTE, 123 COLDHARBOUR LANE, LONDON, SE5 9NU, UNITED KINGDOM<br><br>KING'S COLLEGE LONDON - KING'S CTU, NIHR-WELLCOME TRUST CLINICAL RESEARCH FACILITY , KING'S CTU, NIHR-WELLCOME TRUST CLINICAL RESEARCH FACILITY, KING'S COLLEGE HOSPITAL, DENMARK HILL, LONDON, SE5 9RS, UNITED KINGDOM |
| **4: Legally registered address of authorisation holder** | KING'S COLLEGE LONDON, DEPARTMENT OF HAEMATOLOGY & MOLECULAR MEDICINE, THE RAYNE INSTITUTE KING'S COLLEGE HOSPITAL AND KINGS COLLEGE, 123 COLDHARBOUR LANE, LONDON, SE5 9NU, 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** | 07/10/2026 |
| **9: Annexes attached** | Annex 1 and/or Annex 2 |

### SCOPE OF AUTHORISATION

**Annex 2**

Name and address of the site:

**RAYNE CELL THERAPY SUITE (RCTS), THE RAYNE INSTITUTE, KING'S COLLEGE HOSPITAL & KING'S COLLEGE LONDON**, DEPARTMENT OF HAEMATOLOGICAL AND EXPERIMENTAL MEDICINE, THE RAYNE INSTITUTE, 123 COLDHARBOUR LANE, LONDON, SE5 9NU, UNITED KINGDOM

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|---|
| Human Investigational Medicinal Products |
| Authorised Operations |

MHRA-GMDP MHRA

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

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Investigational Medicinal Products**

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[ 1.1.1.4 ] Small volume liquids

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.3 ] Cell therapy products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.2 ] Batch certification

[ 1.3.2.1 ] Blood products

[ 1.3.2.2 ] Immunological products

[ 1.3.2.3 ] Cell therapy products

[ 1.3.2.4 ] Gene therapy products

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.6 ] Human or animal extracted products

**[ 1.4 ] Other investigational medicinal products or manufacturing activitiy**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

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

[ 2.2.3 ] 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

[ 2.2.3.8 ] Other biological medicinal products

Tissue Engineered Products

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**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**KING'S COLLEGE LONDON - KING'S CTU, NIHR-WELLCOME TRUST CLINICAL RESEARCH FACILITY** , KING'S CTU, NIHR-WELLCOME TRUST CLINICAL RESEARCH FACILITY, KING'S COLLEGE HOSPITAL, DENMARK HILL, LONDON, SE5 9RS, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal Products**

[ 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

Encapsulated (alginate) human cells from donated human tissues such as human hepatocyes.

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.1 ] Blood products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.3 ] Cell therapy products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.1.8 ] Other biological medicinal products

Encapsulated (alginate) human cells from donated human tissues such as human hepatocyes

[ 1.3.2 ] Batch certification

[ 1.3.2.1 ] Blood products

[ 1.3.2.2 ] Immunological products

[ 1.3.2.3 ] Cell therapy products

[ 1.3.2.4 ] Gene therapy products

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.6 ] Human or animal extracted products

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[ 1.3.2.8 ] Other biological medicinal products

Encapsulated (alginate) human cells from donated human tissues such as human hepatocyes

**[ 1.4 ] Other investigational medicinal products or manufacturing activitiy**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

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

[ 2.2.3 ] 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**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of Intermediate which undergoes further processing

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