

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 17479

**2: Name of authorisation holder** OXFORD BIOMEDICA (UK) LIMITED

**3: Address(es) of manufacturing site(s)** OXFORD BIOMEDICA (UK) LIMITED, UNIT 5, OXFORD INDUSTRIAL PARK, MEAD ROAD, YARNTON, KIDLINGTON, OXFORD, OX5 1QU, UNITED KINGDOM

OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM

OXFORD BIOMEDICA (UK) LIMITED, COUNTY TRADING ESTATE, WATLINGTON ROAD, OXFORD, OX4 6LX, UNITED KINGDOM

OXFORD BIOMEDICA (UK) LIMITED, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, UNITED KINGDOM

**4: Legally registered address of authorisation holder** OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, WATLINGTON ROAD, OXFORD, OX4 6LT, 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** 26/05/2023

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**OXFORD BIOMEDICA (UK) LIMITED**, UNIT 5, OXFORD INDUSTRIAL PARK, MEAD ROAD, YARNTON, KIDLINGTON, OXFORD, OX5 1QU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b>

**[ 1.1 ] Sterile Investigational Medicinal Products**

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal 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

[ 1.3.2 ] Batch certification

[ 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

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

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Biological active starting materials

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**OXFORD BIOMEDICA (UK) LIMITED**, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.6 ] Quality control testing</b> [ 1.6.3 ] Chemical/Physical [ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**OXFORD BIOMEDICA (UK) LIMITED** , COUNTY TRADING ESTATE, WATLINGTON ROAD, OXFORD, OX4 6LX, 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> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal 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 [ 1.3.2 ] Batch certification [ 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 <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> [ 1.4.1 ] Manufacture of: [ 1.4.1.3 ] Other Biological active starting materials <b>[ 1.6 ] Quality control testing</b> [ 1.6.2 ] Microbiological: non-sterility

## SCOPE OF AUTHORISATION

### Annex 2

Name and address of the site:

**OXFORD BIOMEDICA (UK) LIMITED**, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, 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 [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal 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

[ 1.3.2 ] Batch certification

[ 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

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

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Biological active starting materials

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical