

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 17479

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

**3: Address(es) of manufacturing site(s)** OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT,  
TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM  
OXFORD BIOMEDICA (UK) LIMITED, UNIT 5, OXFORD INDUSTRIAL  
PARK, MEAD ROAD, YARNTON, KIDLINGTON, OXFORD, OX5 1QU,  
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,  
TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM

**5: Scope of authorisation and dosage forms** ANNEX 1 and/ or ANNEX 2

**6: Legal Basis of authorisation** Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

**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 1

Name and address of the site:

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

Human 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

**SCOPE OF AUTHORISATION****Annex 1**

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 Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological 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 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 1**

Name and address of the site:

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

Human Medicinal Products
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Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

  

<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological 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 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
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## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

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

Human Medicinal Products
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Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

  

<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile 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 medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products
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- [ 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 products or manufacturing activity**

- [ 1.4.1 ] Manufacture of:
  - [ 1.4.1.3 ] Other
    - Biological active starting materials
  - [ 1.4.1.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- [ 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