

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 42803

**2: Name of authorisation holder** TC BIOPHARM LIMITED

**3: Address(es) of manufacturing site(s)** TC BIOPHARM LIMITED - CLINICAL MANUFACTURING FACILITY, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, UNITED KINGDOM

**4: Legally registered address of authorisation holder** TC BIOPHARM LIMITED, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, 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** 18/03/2024

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

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**TC BIOPHARM LIMITED - CLINICAL MANUFACTURING FACILITY, MAXIM 1, 2 PARKLANDS WAY, HOLYTOWN, MOTHERWELL, ML1 4WR, UNITED KINGDOM**

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| Human Investigational Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.4 ] Small volume liquids<br><b>Special Requirements</b><br>Live Cells<br>[ 1.1.3 ] Batch certification<br><b>[ 1.3 ] Biological investigational medicinal products</b> |

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.3 ] Cell therapy products

**Special Requirements**

Live Cells

Cell Banking

[ 1.3.2 ] Batch certification

[ 1.3.2.3 ] Cell therapy products

**Special Requirements**

Live Cells

Cell Banking

**[ 1.5 ] Packaging**

[ 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

[ 1.6.4 ] Biological