

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 46616
<b>2: Name of authorisation holder</b>	REPLIMUNE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, 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>	21/04/2026
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**REPLIMUNE LIMITED**, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, 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>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products

[ 1.3.1.4 ] Gene therapy products

**Special Requirements**

Selectively replication competent Herpes simplex virus that contain various transgenes intended to simulate immune responses.

These products are administered by direct tumour injection into suitable non-neurological solid tumours

[ 1.3.2 ] Batch certification

[ 1.3.2.4 ] Gene therapy products

**Special Requirements**

Selectively replication competent Herpes simplex virus that contain various transgenes intended to simulate immune responses.

These products are administered by direct tumour injection into suitable non-neurological solid tumours

[ 1.3.2.5 ] Biotechnology products

**Special Requirements**

According to the commercial product SmPC

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological