Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 46616
REPLIMUNE LIMITED

REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM

REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

Confidential

22/10/2025

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)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

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