Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 19437
2: Name of authorisation holder	MEDIMMUNE UK LIMITED
3: Address(es) of manufacturing site(s)	MEDIMMUNE UK LIMITED, PLOT 6 RENAISSANCE WAY, LIVERPOOL, L24 9JW, UNITED KINGDOM
4: Legally registered address of authorisation holder	MEDIMMUNE UK LIMITED, PLOT 6 RENAISSANCE WAY, BOULEVARD INDUSTRY PARK, SPEKE, LIVERPOOL, L24 9JW, 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	23/04/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MEDIMMUNE UK LIMITED, PLOT 6 RENAISSANCE WAY, LIVERPOOL, L24 9JW, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.6] Other aseptically prepared products

Sterile Monovalent Virus Harvest Bulk Product

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.2] Batch certification

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[1.3.2.2] Immunological products

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.3] Biological medicinal products

[2.2.3.8] Other biological medicinal products

Vaccine Products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

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