Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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	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	23/04/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human 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 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 medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.5] Biotechnology products

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[1.3.1.8] Other biological medicinal products
Vaccine Products. Monoclonal Antibody Products
[1.3.2] Batch certification
[1.3.2.2] Immunological products
[1.3.2.5] Biotechnology products
[1.3.2.8] Other biological medicinal products
Vaccine Products. Monoclonal Antibody Products

[1.4] Other products or manufacturing activity

[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
[2.2.3.2] Immunological products
[2.2.3.5] Biotechnology products
[2.2.3.8] Other biological medicinal products
Vaccine Products. Monoclonal Antibody Products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

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