

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 23/01/2025

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

- [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