Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 16209
2: Name of authorisation holder	MEDIMMUNE LIMITED
3: Address(es) of manufacturing site(s)	MEDIMMUNE LTD (PART OF THE ASTRAZENECA GROUP), AARON KLUG BUILDING, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6ET, UNITED KINGDOM
4: Legally registered address of authorisation holder	MEDIMMUNE LIMITED, MILSTEIN BUILDING, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6GH, 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	21/12/2021
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MEDIMMUNE LTD (PART OF THE ASTRAZENECA GROUP), AARON KLUG BUILDING, GRANTA PARK, GREAT ABINGTON, CAMBRIDGE, CB21 6ET, 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

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

MHRA-GMDP MHRA

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.8] Other biological medicinal products

Biological active starting materials(when required by national legislation)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.2] Immunological products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.8] Other biological medicinal products

Biological active starting materials(when required by national legislation)

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list

MHRA-GMDP MHRA