

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 18606
2: Name of authorisation holder	LONZA BIOLOGICS PLC
3: Address(es) of manufacturing site(s)	LONZA BIOLOGICS PLC, 228 BATH ROAD, SLOUGH, SL1 4DX, UNITED KINGDOM
4: Legally registered address of authorisation holder	LONZA BIOLOGICS PLC, 228 BATH ROAD, SLOUGH, SL1 4DX, 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	03/10/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

LONZA BIOLOGICS PLC, 228 BATH ROAD, SLOUGH, SL1 4DX, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products [1.3.1.5] Biotechnology products [1.4] Other investigational medicinal products or manufacturing activity [1.4.1] Manufacture of: [1.4.1.3] Other Monoclonal antibodies, other proteins manufactured with recombinant DNA technology and Biological active starting materials [1.6] Quality control testing [1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

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