

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 22/04/2025

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

