Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 18606

LONZA BIOLOGICS PLC

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

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

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations

2012 (SI 2012/1916)

Confidential

22/04/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.5] Biotechnology products

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Biological active starting materials

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

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