

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 60304

2: Name of authorisation holder MODERNA BIOTECH MANUFACTURING UK LTD

3: Address(es) of manufacturing site(s) MODERNA TECHNOLOGY CENTRE - HARWELL (MTC-H),
PERIMETER ROAD, HARWELL OXFORD, DIDCOT, OX11 0GN,
UNITED KINGDOM

4: Legally registered address of authorisation holder MODERNA BIOTECH MANUFACTURING UK LTD, 54 PORTLAND
PLACE, LONDON, W1B 1DY, 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 11/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MODERNA TECHNOLOGY CENTRE - HARWELL (MTC-H), PERIMETER ROAD, HARWELL OXFORD, DIDCOT, OX11 0GN,
UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products Special Requirements Manf. of low bioburden drug substance (mRNA) and low bioburden Intermediates (mRNA Lipid Nanoparticle (LNP)) products

[1.3.1.5] Biotechnology products

Special Requirements

Manf. of low bioburden drug substance (mRNA) and low bioburden Intermediates (mRNA Lipid Nanoparticle (LNP)) products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

Special Requirements

Manf. of low bioburden drug substance (mRNA) and low bioburden Intermediates (mRNA Lipid Nanoparticle (LNP)) products

[1.3.2.5] Biotechnology products

Special Requirements

Manf. of low bioburden drug substance (mRNA) and low bioburden Intermediates (mRNA Lipid Nanoparticle (LNP)) products

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological