

# 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** 19/06/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products <b>Special Requirements</b> 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**

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological