

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 54440
<b>2: Name of authorisation holder</b>	CENTRE FOR PROCESS INNOVATION LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	RNA CENTRE OF EXCELLENCE, 3 JOHN WILLIAMS BOULEVARD SOUTH, DARLINGTON, DL1 1FN, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CENTRE FOR PROCESS INNOVATION LIMITED, 1 UNION SQUARE, CENTRAL PARK, DARLINGTON, DL1 1GL, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	18/04/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**RNA CENTRE OF EXCELLENCE**, 3 JOHN WILLIAMS BOULEVARD SOUTH, DARLINGTON, DL1 1FN, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products [ 1.3.1.8 ] Other biological medicinal products Low bioburden RNA and RNA-LNP bulk drug substance <b>[ 1.6 ] Quality control testing</b> [ 1.6.3 ] Chemical/Physical [ 1.6.4 ] Biological