# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 54440

CENTRE FOR PROCESS INNOVATION LIMITED 2: Name of authorisation holder

RNA CENTRE OF EXCELLENCE, 3 JOHN WILLIAMS BOULEVARD SOUTH, DARLINGTON, DL1 1FN, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

CENTRE FOR PROCESS INNOVATION LIMITED, 1 UNION 4: Legally registered address of authorisation holder

SQUARE, CENTRAL PARK, DARLINGTON, DL1 1GL, UNITED

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) 6: Legal Basis of authorisation

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 18/06/2025

9: Annexes attached 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)

#### Part 1 - MANUFACTURING OPERATIONS

# [ 1.3 ] Biological investigational medicinal products

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.8 ] Other biological medicinal products

Low bioburden RNA and RNA-LNP bulk drug substance

### [ 1.6 ] Quality control testing

[ 1.6.3 ] Chemical/Physical

[1.6.4] Biological

Issue Date: 18 Jun 2025