

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 54440

2: Name of authorisation holder CENTRE FOR PROCESS INNOVATION LIMITED

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

4: Legally registered address of authorisation holder CENTRE FOR PROCESS INNOVATION LIMITED, 1 UNION SQUARE, CENTRAL PARK, DARLINGTON, DL1 1GL, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) 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 13/01/2025

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