

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 58849
<b>2: Name of authorisation holder</b>	NOVEAYR RESPIRATORY SERVICES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	NOVEAYR RESPIRATORY SERVICES LIMITED, 9 ARKWRIGHT ROAD, ASTMOOR INDUSTRIAL ESTATE, RUNCORN, WA7 1NU, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NOVEAYR RESPIRATORY SERVICES LIMITED, 9 ARKWRIGHT ROAD, ASTMOOR INDUSTRIAL ESTATE, RUNCORN, WA7 1NU, 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>	07/11/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**NOVEAYR RESPIRATORY SERVICES LIMITED, 9 ARKWRIGHT ROAD, ASTMOOR INDUSTRIAL ESTATE, RUNCORN, WA7 1NU, UNITED KINGDOM**

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.9 ] Pressurised preparations [ 1.2.2 ] Batch certification <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging [ 1.5.1.9 ] Pressurised preparations

[ 1.5.2 ] Secondary packaging  
[ 1.6 ] **Quality control testing**  
[ 1.6.3 ] Chemical/Physical

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA