

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 32917
<b>2: Name of authorisation holder</b>	SARTORIUS STEDIM BIOOUTSOURCE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	SARTORIUS STEDIM BIOOUTSOURCE LIMITED, 2ND FLOOR, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	SARTORIUS STEDIM BIOOUTSOURCE LIMITED, 1 TECHNOLOGY TERRACE, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, 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>	17/04/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**SARTORIUS STEDIM BIOOUTSOURCE LIMITED**, 2ND FLOOR, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, 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 [ 1.3.1.8 ] Other biological medicinal products Mammalian Cell banks - MCB and WCB [ 1.3.2 ] Batch certification [ 1.3.2.8 ] Other biological medicinal products Mammalian Cell banks - MCB and WCB

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

MHRA-GMDP

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