Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 32917
2: Name of authorisation holder	SARTORIUS STEDIM BIOOUTSOURCE LIMITED
3: Address(es) of manufacturing site(s)	SARTORIUS STEDIM BIOOUTSOURCE LIMITED, 2ND FLOOR, BIOCITY SCOTLAND, BO'NESS ROAD, MOTHERWELL, ML1 5UH, UNITED KINGDOM
4: Legally registered address of authorisation holder	SARTORIUS STEDIM BIOOUTSOURCE LIMITED, 1 TECHNOLOGY TERRACE, TODD CAMPUS, WEST OF SCOTLAND SCIENCE PARK, GLASGOW, G20 0XA, 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	23/02/2026
9: Annexes attached	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)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological investigational medicinal products

[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

MHRA-GMDP MHRA MHRA-GMDP MHRA

[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