

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 16/12/2024

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

[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