Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 17724
2: Name of authorisation holder	POLAR SPEED DISTRIBUTION LIMITED
3: Address(es) of manufacturing site(s)	POLAR SPEED DISTRIBUTION LIMITED, CHARTMOOR ROAD 15A, LEIGHTON BUZZARD, LU7 4WG, UNITED KINGDOM
4: Legally registered address of authorisation holder	POLAR SPEED DISTRIBUTION LIMITED, UNIT 8, CHARTMOOR ROAD, LEIGHTON BUZZARD, LU7 4WG, 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	12/10/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

POLAR SPEED DISTRIBUTION LIMITED, CHARTMOOR ROAD 15A, LEIGHTON BUZZARD, LU7 4WG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS **[1.5] Packaging** [1.5.2] Secondary packaging Part 2 - IMPORTATION OF MEDICINAL PRODUCTS **[2.2] Batch certification of imported medicinal products** [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised

MHRA-GMDP MHRA

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP-certified IMPs from a country on the approved country for import list

MHRA-GMDP MHRA MHRA-GMDP MHRA