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

POLAR SPEED DISTRIBUTION LIMITED, CHARTMOOR ROAD 15A, LEIGHTON BUZZARD, LU7 4WG, UNITED 3: Address(es) of manufacturing site(s)

KINGDOM

POLAR SPEED DISTRIBUTION LIMITED, UNIT 8, 4: Legally registered address of authorisation holder

CHARTMOOR ROAD, LEIGHTON BUZZARD, LU7 4WG

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) 6: Legal Basis of authorisation

Confidential

Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

8: Authorisation Date 14/10/2025

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

Issue Date: 14 Oct 2025

[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



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