

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 741

2: Name of authorisation holder MAWDSLEY-BROOKS & COMPANY LIMITED

3: Address(es) of manufacturing site(s) MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 22, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, UNITED KINGDOM

4: Legally registered address of authorisation holder MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 3, SOUTH LANGWORTHY ROAD, PO BOX 18, SALFORD, M50 2PW, 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 09/08/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 22, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, 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

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

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