

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 45001

2: Name of authorisation holder QMED PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) QMED PHARMACEUTICALS LIMITED, UNIT 4, THORNHAM GROVE INDUSTRIAL ESTATE, LONDON, E15 1DN, UNITED KINGDOM

4: Legally registered address of authorisation holder QMED PHARMACEUTICALS LIMITED, 168 PEMBROKE ROAD, ILFORD, IG3 8PG, UNITED KINGDOM

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

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 19/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

QMED PHARMACEUTICALS LIMITED, UNIT 4, THORNHAM GROVE INDUSTRIAL ESTATE, LONDON, E15 1DN, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.2] Batch certification [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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation