

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 57761

2: Name of authorisation holder QMED CLINICAL SERVICES LIMITED

3: Address(es) of manufacturing site(s) QMED CLINICAL SERVICES, UNIT 4, THORNHAM GROVE, LONDON, E15 1DN, UNITED KINGDOM

4: Legally registered address of authorisation holder QMED CLINICAL SERVICES LIMITED, UNIT 4, THORNHAM GROVE, LONDON, E15 1DN, 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 19/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

QMED CLINICAL SERVICES, UNIT 4, THORNHAM GROVE, LONDON, E15 1DN, 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 [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.15] Other non-sterile medicinal products Filling of hard-shell capsules to manufacture [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell

[1.5.1.13] Tablets

[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

[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