Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 25298

2: Name of authorisation holder BROWN & BURK UK LIMITED

BROWN AND BURK UK LIMITED, MICRO HOUSE, BURY

STREET, RUISLIP, HA4 7TL, UNITED KINGDOM

BROWN & BURK UK LIMITED, MICRO HOUSE, 5 MARRYAT

CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM

4: Legally registered address of authorisation holder

CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM

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

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

6: Legal Basis of authorisation

3: Address(es) of manufacturing site(s)

06/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BROWN AND BURK UK LIMITED, MICRO HOUSE, BURY STREET, RUISLIP, HA4 7TL, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

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

Issue Date: 06 Jun 2024

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BROWN & BURK UK LIMITED, MICRO HOUSE, 5 MARRYAT CLOSE, HOUNSLOW, TW4 5DQ, UNITED KINGDOM

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MHRA: GMDY MHRA

Manufacturer's Authorisation: UK MIA 25298 Page 2 of 2 Issue Date: 06 Jun 2024