

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 20072 |
| 2: Name of authorisation holder | AMDIPHARM UK LIMITED |
| 3: Address(es) of manufacturing site(s) | AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, 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 | 06/03/2025 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification 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

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