

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 20072
<b>2: Name of authorisation holder</b>	AMDIPHARM UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	AMDIPHARM UK LIMITED, CAPITAL HOUSE, 85 KING WILLIAM STREET, LONDON, EC4N 7BL, UNITED KINGDOM AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	AMDIPHARM UK LIMITED, DASHWOOD HOUSE, 69 OLD BROAD STREET, LONDON, EC2M 1QS, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	23/11/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**AMDIPHARM UK LIMITED**, CAPITAL HOUSE, 85 KING WILLIAM STREET, LONDON, EC4N 7BL, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> [ 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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### Annex 1

Name and address of the site:

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

##### [ 1.1 ] 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