

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 20894
<b>2: Name of authorisation holder</b>	BRUNEL HEALTHCARE MANUFACTURING LIMITED BRUNEL HEALTHCARE MANUFACTURING LIMITED, UNIT 2, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	BRUNEL HEALTHCARE MANUFACTURING LIMITED, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM  BRUNEL HEALTHCARE MANUFACTURING LIMITED, WILLIAM NADIN WAY, SWADLINCOTE, DERBYSHIRE, DE11 0BB, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	BRUNEL HEALTHCARE MANUFACTURING LIMITED, WILLIAM NADIN WAY, SWADLINCOTE, DERBYSHIRE, DE11 0BB, 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>	22/03/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BRUNEL HEALTHCARE MANUFACTURING LIMITED, UNIT 2, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM**

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging

- [ 1.5.1.1 ] Capsules, hard shell
- [ 1.5.1.2 ] Capsules, soft shell
- [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

**BRUNEL HEALTHCARE MANUFACTURING LIMITED**, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"><li>[ 1.2.1.1 ] Capsules, hard shell</li><li>[ 1.2.1.13 ] Tablets</li></ul> [ 1.2.2 ] Batch certification <b>[ 1.4 ] Other products or manufacturing activity</b> [ 1.4.1 ] Manufacture of: <ul style="list-style-type: none"><li>[ 1.4.1.1 ] Herbal products</li><li>[ 1.4.1.3 ] Other Licenced for Traditional Herbal Medicinal Products</li></ul> <b>[ 1.5 ] Packaging</b> <ul style="list-style-type: none"><li>[ 1.5.1 ] Primary packaging</li><li>[ 1.5.1.2 ] Capsules, soft shell</li><li>[ 1.5.2 ] Secondary packaging</li></ul> <b>[ 1.6 ] Quality control testing</b> <ul style="list-style-type: none"><li>[ 1.6.3 ] Chemical/Physical</li></ul>