

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 20894

**2: Name of authorisation holder** BRUNEL HEALTHCARE MANUFACTURING LIMITED

**3: Address(es) of manufacturing site(s)** BRUNEL HEALTHCARE MANUFACTURING LIMITED, UNIT 2, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM

**4: Legally registered address of authorisation holder** BRUNEL HEALTHCARE MANUFACTURING LIMITED, WILLIAM NADIN WAY, SWADLINCOTE, DERBYSHIRE, DE11 0BB, 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** 22/03/2024

**9: Annexes attached** 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)
<div> <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)                [ 1.2.1.1 ] Capsules, hard shell                [ 1.2.1.13 ] Tablets            [ 1.2.2 ] Batch certification  <b>[ 1.4 ] Other products or manufacturing activity</b>            [ 1.4.1 ] Manufacture of:                [ 1.4.1.1 ] Herbal products                [ 1.4.1.3 ] Other                    Licenced for Traditional Herbal Medicinal Products  <b>[ 1.5 ] Packaging</b>            [ 1.5.1 ] Primary packaging                [ 1.5.1.2 ] Capsules, soft shell            [ 1.5.2 ] Secondary packaging  <b>[ 1.6 ] Quality control testing</b>            [ 1.6.3 ] Chemical/Physical         </div>