

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, 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 22/04/2025

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