

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, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM

4: Legally registered address of authorisation holder BRUNEL HEALTHCARE MANUFACTURING LIMITED, UNIT 2, 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 29/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BRUNEL HEALTHCARE MANUFACTURING LIMITED, 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) [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:

[1.4.1.1] Herbal products

[1.4.1.3] Other

Licensed for Traditional Herbal Medicinal Products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.2] Capsules, soft shell

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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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