

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	15/11/2024
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)
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)
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<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile products</p> <p>[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)</p> <p>[1.2.1.1] Capsules, hard shell</p> <p>[1.2.1.13] Tablets</p> <p>[1.2.2] Batch certification</p> <p>[1.4] Other products or manufacturing activity</p> <p>[1.4.1] Manufacture of:</p> <p>[1.4.1.1] Herbal products</p> <p>[1.4.1.3] Other</p> <p>Licensed for Traditional Herbal Medicinal Products</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.2] Capsules, soft shell</p> <p>[1.5.2] Secondary packaging</p> <p>[1.6] Quality control testing</p> <p>[1.6.3] Chemical/Physical</p>
