

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 20894 |
| 2: Name of authorisation holder | BRUNEL HEALTHCARE MANUFACTURING LIMITED BRUNEL HEALTHCARE MANUFACTURING LIMITED, UNIT 2, WILLIAM NADIN WAY, SWADLINCOTE, DE11 0BB, UNITED KINGDOM |
| 3: Address(es) of manufacturing site(s) | 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 |
| 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 | 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

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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 |

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| [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

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| Human Medicinal Products |
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| Authorised Operations |
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| 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> |
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