

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 48145 |
| 2: Name of authorisation holder | CRESCENT MEDICAL UK LIMITED |
| 3: Address(es) of manufacturing site(s) | CRESCENT MEDICAL UK LIMITED, ALLENBURY LABORATORIES, WIGAN ROAD, WESTHOUGHTON, BOLTON, BL5 2AL, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | CRESCENT MEDICAL UK LIMITED, ALLENBURY LABORATORIES, WIGAN ROAD, WESTHOUGHTON, BOLTON, BL5 2AL, 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 | 31/01/2025 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CRESCENT MEDICAL UK LIMITED, ALLENBURY LABORATORIES, WIGAN ROAD, WESTHOUGHTON, BOLTON, BL5 2AL, 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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Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.13] Tablets

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

MHRA-GMDP

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