

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 12845 |
| 2: Name of authorisation holder | SPRINGDEW LIMITED |
| 3: Address(es) of manufacturing site(s) | SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, 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 | 12/07/2023 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SPRINGDEW LIMITED, UNITS 11/12, WOODLANDS BUSINESS PARK, YSTRADGYNLAIS, SWANSEA, SA9 1JW, 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

[1.2.2] Batch certification

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical