

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 28255 |
| 2: Name of authorisation holder | RUTLAND BIODYNAMICS LIMITED |
| 3: Address(es) of manufacturing site(s) | RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, 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 | 23/04/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [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 [1.2.1.11] Semi-solids [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

Manufacture API's

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products