

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 10414

2: Name of authorisation holder DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED

3: Address(es) of manufacturing site(s) DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED, UNIT 18, ARKWRIGHT ROAD INDUSTRIAL ESTATE, ARKWRIGHT ROAD, BEDFORD, MK42 0LQ, UNITED KINGDOM

4: Legally registered address of authorisation holder DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED, NORTH SUITE, LOMOND COURT, THE CASTLE BUSINESS PARK, STIRLING, FK9 4TU, UNITED KINGDOM

5: Scope of authorisation and dosage forms DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED, UNIT 2, BROADLEYS ROAD, SPRINGKERSE INDUSTRIAL ESTATE, STIRLING, FK7 7ST, UNITED KINGDOM

6: Legal Basis of authorisation DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED, NORTH SUITE, LOMOND COURT, THE CASTLE BUSINESS PARK, STIRLING, FK9 4TU, UNITED KINGDOM

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation ANNEX 1 and/ or ANNEX 2

8: Authorisation Date Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

9: Annexes attached Confidential

10: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation 30/01/2025

11: Authorisation Date Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

DOLBY MEDICAL HOME RESPIRATORY CARE LIMITED, UNIT 18, ARKWRIGHT ROAD INDUSTRIAL ESTATE, ARKWRIGHT ROAD, BEDFORD, MK42 0LQ, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

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

[1.2.1.7] Medicinal gases

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.7] Medicinal gases

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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