Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)

UK MIA 50143 MOBIUS LABORATORIES LIMITED

UNITED KINGDOM

2012/1916)

Confidential

29/11/2024

ANNEX 1 and/ or ANNEX 2

Annex 1 and/or Annex 2

MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS, UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ, UNITED KINGDOM

MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS,

UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ,

Regulation 17 of The Human Medicines Regulations 2012 (SI

- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

SCOPE OF AUTHORISATION

Annex 1 Name and address of the site:

MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS, UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation