Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 50143
2: Name of authorisation holder	MOBIUS LABORATORIES LIMITED
3: Address(es) of manufacturing site(s)	MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS, UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ, UNITED KINGDOM
4: Legally registered address of authorisation holder	MOBIUS LABORATORIES LIMITED, UNIT 7, BOURNE END MILLS, UPPER BOURNE END LANE, HEMEL HEMPSTEAD, HP1 2UJ, 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	10/11/2026
9: Annexes attached	Annex 1 and/or Annex 2

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

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[2.1.2] Microbiological: non-sterility

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

MHRA-GMDP MHRA MHRA-GMDP MHRA