Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 19054
2: Name of authorisation holder	ALIUM MEDICAL LIMITED
3: Address(es) of manufacturing site(s)	ALIUM MEDICAL LIMITED, UNIT 7, CAPITAL BUSINESS PARK, MANOR WAY, BOREHAMWOOD, WD6 1GW, UNITED KINGDOM
4: Legally registered address of authorisation holder	ALIUM MEDICAL LIMITED, UNIT 7, CAPITAL BUSINESS PARK, MANOR WAY, BOREHAMWOOD, WD6 1GW, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	18/11/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALIUM MEDICAL LIMITED, UNIT 7, CAPITAL BUSINESS PARK, MANOR WAY, BOREHAMWOOD, WD6 1GW, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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
- [2.3.2] Importation of Intermediate which undergoes further processing

MHRA-GMDP MHRA