

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 45522

2: Name of authorisation holder MEIRAGTX UK II LIMITED

3: Address(es) of manufacturing site(s) MEIRAGTX UK II LIMITED, 92 BRITANNIA WALK,
LONDON, N1 7NQ, UNITED KINGDOM

4: Legally registered address of authorisation holder MEIRAGTX UK II LIMITED, 92 BRITANNIA WALK,
LONDON, N1 7NQ, 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 12/12/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MEIRAGTX UK II LIMITED, 92 BRITANNIA WALK, LONDON, N1 7NQ, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.4] Small volume liquids [1.1.2] Terminally Sterilised (processing operations for the following dosage forms) [1.1.2.3] Small volume liquids [1.1.3] Batch certification [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological