

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

16/12/2025

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
[1.3] 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

MHRA-GMDP

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