Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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	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	15/07/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

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

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.3.2] Batch certification

MHRA-GMDP MHRA-GMDP MHRA

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

MHRA-GMDP