Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 22352
2: Name of authorisation holder	VERTEX PHARMACEUTICALS (EUROPE) LIMITED
3: Address(es) of manufacturing site(s)	VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, UNITED KINGDOM
4: Legally registered address of authorisation holder	VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, 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	22/12/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, 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

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

MHRA-GMDP MHRA

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.3] Other Importation Activities

[2.3.4] Other

Importation of Autologous drug product into Authorised Treatment Centers in the UK

MHRA-GMDP