

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 22352
<b>2: Name of authorisation holder</b>	VERTEX PHARMACEUTICALS (EUROPE) LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 6BD, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	08/10/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological medicinal products</b> [ 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 <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 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 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

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