

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 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** 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** 08/10/2024

**9: Annexes attached** 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 <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>

**[ 2.2 ] Batch certification of imported medicinal 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 ] 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