# 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

VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2 3: Address(es) of manufacturing site(s)

6BD, UNITED KINGDOM

VERTEX PHARMACEUTICALS (EUROPE) LIMITED, LEVEL 9, 4: Legally registered address of authorisation holder

PADDINGTON CENTRAL, 2 KINGDOM STREET, LONDON, W2

6BD, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 6: Legal Basis of authorisation

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 19/03/2024

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

Issue Date: 19 Mar 2024

# [ 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



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