

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 10555

**2: Name of authorisation holder** EISAI LIMITED

**3: Address(es) of manufacturing site(s)** EISAI LIMITED, EUROPEAN KNOWLEDGE CENTRE,  
MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** EISAI LIMITED, EUROPEAN KNOWLEDGE CENTRE,  
MOSQUITO WAY, HATFIELD, AL10 9SN, 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** 22/03/2024

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**EISAI LIMITED**, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM

Human Investigational 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>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b> [ 1.3.2 ] Batch certification [ 1.3.2.5 ] Biotechnology products

## Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

### [ 2.2 ] Batch certification of imported medicinal products

#### [ 2.2.1 ] Sterile Products

##### [ 2.2.1.1 ] Aseptically prepared

##### [ 2.2.1.2 ] Terminally sterilised

#### [ 2.2.2 ] Non-sterile products

#### [ 2.2.3 ] Biological medicinal products

##### [ 2.2.3.5 ] Biotechnology products

### [ 2.3 ] Other Importation Activities

#### [ 2.3.2 ] Importation of Intermediate which undergoes further processing

#### [ 2.3.4 ] Other

Radiopharmaceuticals/Radionuclide generators and Biological active starting materials / Importation of QP certified IMPs from a country on the approved country for import list