

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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.2] Batch certification [1.3] Biological investigational medicinal products [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