

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |  |
|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 10555  |
| <b>2: Name of authorisation holder</b>  | EISAI LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | EISAI LIMITED, EUROPEAN KNOWLEDGE CENTRE,<br>MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED<br>KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | EISAI LIMITED, EUROPEAN KNOWLEDGE CENTRE,<br>MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED<br>KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials)<br>Regulations 2004 [SI 2004/1031]       |
| <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>  | 22/03/2024   |
| <b>9: Annexes attached</b>  | 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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.2 ] Batch certification<br><b>[ 1.3 ] Biological investigational medicinal products</b><br>[ 1.3.2 ] Batch certification<br>[ 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