

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 3830
<b>2: Name of authorisation holder</b>	UNIVERSITY OF CAMBRIDGE
<b>3: Address(es) of manufacturing site(s)</b>	WOLFSON BRAIN IMAGING CENTRE DEPARTMENT OF CLINICAL NEUROSCIENCES, BOX 65, ADDENBROOKE'S HOSPITAL, HILLS ROAD, CAMBRIDGE, CB2 2QQ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	UNIVERSITY OF CAMBRIDGE, BOX 65, ADDENBROOKE'S HOSPITAL, HILLS ROAD, CAMBRIDGE, CB2 2QQ, UNITED 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) 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>	09/10/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**WOLFSON BRAIN IMAGING CENTRE DEPARTMENT OF CLINICAL NEUROSCIENCES**, BOX 65, ADDENBROOKE'S HOSPITAL, HILLS ROAD, CAMBRIDGE, CB2 2QQ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.4 ] Small volume liquids <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.1 ] Filtration <b>[ 1.5 ] Packaging</b>

- [ 1.5.2 ] Secondary packaging
- [ 1.6 ] **Quality control testing**
  - [ 1.6.2 ] Microbiological: non-sterility
  - [ 1.6.3 ] Chemical/Physical

MHRA-GMDP

MHRA

MHRA-GMDP

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