# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 3830

2: Name of authorisation holder UNIVERSITY OF CAMBRIDGE

WOLFSON BRAIN IMAGING CENTRE DEPARTMENT OF CLINICAL

3: Address(es) of manufacturing site(s)

NEUROSCIENCES, BOX 65, ADDENBROOKE'S HOSPITAL, HILLS

ROAD, CAMBRIDGE, CB2 2QQ, UNITED KINGDOM

4: Legally registered address of authorisation holder

HILLS ROAD, CAMBRIDGE, CB2 2QQ, 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 14/03/2025

9: Annexes attached 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)

### Part 1 - MANUFACTURING OPERATIONS

#### [ 1.1 ] Sterile Investigational Medicinal Products

[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

#### [ 1.4 ] Other investigational medicinal products or manufacturing activitiy

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

Issue Date: 14 Mar 2025

# [ 1.5 ] Packaging

[ 1.5.2 ] Secondary packaging

## [ 1.6 ] Quality control testing

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

