Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 3830
2: Name of authorisation holder	UNIVERSITY OF CAMBRIDGE
3: Address(es) of manufacturing site(s)	WOLFSON BRAIN IMAGING CENTRE DEPARTMENT OF CLINICAL NEUROSCIENCES, BOX 65, ADDENBROOKE'S HOSPITAL, HILLS ROAD, CAMBRIDGE, CB2 2QQ, UNITED KINGDOM
4: Legally registered address of authorisation holder	UNIVERSITY OF CAMBRIDGE, BOX 65, ADDENBROOKE'S HOSPITAL, 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	22/12/2025
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

MHRA-GMDP MHRA-GMDP MHRA

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

MHRA-GMDP