

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 11709

**2: Name of authorisation holder** UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST

**3: Address(es) of manufacturing site(s)** UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST,  
RADIOPHARMACY, NUCLEAR MEDICINE DEPT, TREMONA ROAD,  
SOUTHAMPTON, SO16 6YD, UNITED KINGDOM

**4: Legally registered address of authorisation holder** UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST,  
RADIOPHARMACY, NUCLEAR MEDICINE DEPT, TREMONA ROAD,  
SOUTHAMPTON, SO16 6YD, 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** 13/12/2023

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST, RADIOPHARMACY, NUCLEAR MEDICINE DEPT,  
TREMONA ROAD, SOUTHAMPTON, SO16 6YD, 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) [ 1.1.1.4 ] Small volume liquids [ 1.1.1.6 ] Other aseptically prepared products Radiopharmaceuticals <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

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical