

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 14620
2: Name of authorisation holder	BARTS HEALTH NHS TRUST
3: Address(es) of manufacturing site(s)	BARTS HEALTH NHS TRUST (NUCLEAR MEDICINE RADIOPHARMACY UNIT BASEMENT), NUCLEAR MEDICINE- RADIOPHARMACY, BASEMENT, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON, EC1A 7BE, UNITED KINGDOM
4: Legally registered address of authorisation holder	BARTS HEALTH NHS TRUST, 80 NEWARK STREET, WHITECHAPEL, LONDON, E1 2ES, 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	16/06/2025
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**BARTS HEALTH NHS TRUST (NUCLEAR MEDICINE RADIOPHARMACY UNIT BASEMENT)**, NUCLEAR MEDICINE- RADIOPHARMACY, BASEMENT, KING GEORGE V WING, ST BARTHOLOMEW'S HOSPITAL, WEST SMITHFIELD, LONDON, EC1A 7BE, 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 / Radionuclide Generators/ IMP product dispensing, large and small volumes diagnostic purposes

[ 1.1.3 ] Batch certification

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.10 ] Radionuclide generators

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility