

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 15983
2: Name of authorisation holder	ROYAL MARSDEN NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	RADIOPHARMACY, EAST WING BUILDING (EWB) 912, DOWNS ROAD, SUTTON, SM2 5PT, UNITED KINGDOM
4: Legally registered address of authorisation holder	ROYAL MARSDEN NHS FOUNDATION TRUST, DEPARTMENT OF PHARMACY, DOWNS ROAD, SUTTON, SM2 5PT, 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	08/08/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RADIOPHARMACY, EAST WING BUILDING (EWB) 912, DOWNS ROAD, SUTTON, SM2 5PT, 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)
[1.1.1.4] Small volume liquids
[1.1.1.6] Other aseptically prepared products
Small volume liquids, Radiopharmaceuticals and others.
[1.1.3] Batch certification
[1.2] Non-sterile investigational medicinal products
[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
[1.2.1.6] Liquids for internal use

[1.2.1.10] Radionuclide generators

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Radiopharmaceuticals containing either peptides or monoclonal antibodies.

[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

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical