Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 22443
2: Name of authorisation holder	ALLIANCE MEDICAL RADIOPHARMACY LIMITED
3: Address(es) of manufacturing site(s)	ALLIANCE MEDICAL RADIOPHARMACY LIMITED, NOBEL WAY, DINNINGTON, SHEFFIELD, S25 3QB, UNITED KINGDOM ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL MARSDEN HOSPITAL, DOWNS ROAD, SUTTON, SM2 5PT, UNITED KINGDOM ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL PRESTON HOSPITAL, SHAROE GREEN LANE, FULWOOD, PRESTON, PR2 9HT, UNITED KINGDOM ALLIANCE MEDICAL RADIOPHARMACY LIMITED , KEELE UNIVERSITY SCIENCE PARK, KEELE, NEWCASTLE, ST5 5BX, UNITED KINGDOM ALLIANCE MEDICAL RADIOPHARMACY LIMITED, UNIT 19, QUADRUM PARK, OLD PORTSMOUTH ROAD, PEASMARSH, GUILDFORD, GU3 1LU, UNITED KINGDOM
4: Legally registered address of authorisation holder	ALLIANCE MEDICAL RADIOPHARMACY LIMITED, FIRST FLOOR, THE WOODS, OPUS 40 BUSINESS PARK, HAYWOOD ROAD, WARWICK, CV34 5AH, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	10/11/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLIANCE MEDICAL RADIOPHARMACY LIMITED, NOBEL WAY, DINNINGTON, SHEFFIELD, S25 3QB, UNITED KINGDOM

Human Medicinal Products

MHRA-GMDP MHRA

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile 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

Radiopharmaceuticals (small volume liquids)

[1.1.3] Batch certification

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Radiopharmaceuticals

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL MARSDEN HOSPITAL, DOWNS ROAD, SUTTON, SM2 5PT, UNITED KINGDOM

Human Medicinal Products

MHRA-GMDP MHRA-GMDP MHRA

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

[1.1.2.5] Other terminally sterilised prepared products

Radiopharmaceuticals (Small volume liquids)

[1.1.3] Batch certification

[1.4] Other products or manufacturing activity

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

[1.4.2.3] Moist heat

[1.4.3] Other

Radiopharmaceuticals (moist heat)

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL PRESTON HOSPITAL, SHAROE GREEN LANE, FULWOOD, PRESTON, PR2 9HT, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

[1.1.2.5] Other terminally sterilised prepared products

Radiopharmaceuticals (Small volume liquids)

[1.1.3] Batch certification

[1.4] Other products or manufacturing activity

MHRA-GMDP MHRA

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

[1.4.2.3] Moist heat

[1.4.3] Other

Radiopharmaceuticals (Moist Heat)

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLIANCE MEDICAL RADIOPHARMACY LIMITED , KEELE UNIVERSITY SCIENCE PARK, KEELE, NEWCASTLE, ST5 5BX, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

[1.1.2.5] Other terminally sterilised prepared products

Radiopharmaceuticals(small volume liquids)

[1.1.3] Batch certification

[1.4] Other products or manufacturing activity

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

[1.4.2.3] Moist heat

[1.4.3] Other

Radiopharmaceuticals (moist heat)

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

MHRA-GMDP

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ALLIANCE MEDICAL RADIOPHARMACY LIMITED, UNIT 19, QUADRUM PARK, OLD PORTSMOUTH ROAD, PEASMARSH, GUILDFORD, GU3 1LU, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile 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
Radiopharmaceuticals (Small volume liquids)

[1.1.3] Batch certification

[1.4] Other 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

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.3] Other Importation Activities

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
Radiopharmaceuticals/Radionuclide generators/production of positron emmission tomography isoptopes

MHRA-GMDP MHRA