

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 45366

2: Name of authorisation holder SIEMENS HEALTHCARE LIMITED

3: Address(es) of manufacturing site(s) PETNET SOLUTIONS (SIEMENS HEALTHCARE LIMITED), LESLEY HARRISON BUILDING, MOUNT VERNON HOSPITAL, NORTHWOOD, HA6 2RN, UNITED KINGDOM

4: Legally registered address of authorisation holder PETNET SOLUTIONS (SIEMENS HEALTHCARE LIMITED), NOTTINGHAM CITY HOSPITAL, GATE 1, HUCKNALL ROAD, NOTTINGHAM, NG5 1PB, UNITED KINGDOM

5: Scope of authorisation and dosage forms SIEMENS HEALTHCARE LIMITED, PARK VIEW, WATCHMOOR PARK, RIVERSIDE WAY, CAMBERLEY, GU15 3YL, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date Confidential

9: Annexes attached 19/05/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

PETNET SOLUTIONS (SIEMENS HEALTHCARE LIMITED), LESLEY HARRISON BUILDING, MOUNT VERNON HOSPITAL, NORTHWOOD, HA6 2RN, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
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
Positron Emission Radiopharmaceuticals for injection.

[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

- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

PETNET SOLUTIONS (SIEMENS HEALTHCARE LIMITED), NOTTINGHAM CITY HOSPITAL, GATE 1, HUCKNALL ROAD,
NOTTINGHAM, NG5 1PB, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

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
Positron Emission Radiopharmaceuticals for injection

[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

- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical