

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), NOTTINGHAM CITY HOSPITAL, GATE 1, HUCKNALL ROAD, NOTTINGHAM, NG5 1PB, UNITED KINGDOM

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

4: Legally registered address of authorisation holder SIEMENS HEALTHCARE LIMITED, PARK VIEW, WATCHMOOR PARK, RIVERSIDE WAY, CAMBERLEY, GU15 3YL, 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 04/03/2024

9: Annexes attached Annex 1 and/or Annex 2

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

[1.6] 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), 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