

# Medicines and Healthcare products Regulatory Agency

## REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

### Registrant Details

|   |   |
|---|---|
| 1. Registration Number  | UK API 34938  |
| 2. Name or corporate name of registrant   | ALLIANCE MEDICAL LIMITED  |
| 3. Permanent or legal address of registrant   | ALLIANCE MEDICAL LIMITED, ICENI CENTRE, WARWICK TECHNOLOGY PARK, WARWICK, CD34 6DA, UNITED KINGDOM<br><br>ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL MARSDEN HOSPITAL, DOWNS ROAD, SUTTON, SM2 5PT, UNITED KINGDOM                      |
| 4. Address(es) of site(s) where registered activities take place  | ALLIANCE MEDICAL RADIOPHARMACY LIMITED , ROYAL PRESTON HOSPITAL, SHAROE GREEN LANE, FULWOOD, PRESTON, PR2 9HT, UNITED KINGDOM<br><br>ALLIANCE MEDICAL RADIOPHARMACY LIMITED , KEELE UNIVERSITY SCIENCE PARK, KEELE, ST5 5BX, UNITED KINGDOM |
| 5. National legal basis of registration   | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)   |
| 6. Name of responsible officer of the competent authority of the member state validating the registration | Confidential  |
| 7. Date   | 05/09/2016  |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

### SCOPE OF REGISTRATION

#### Name and address of the site

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

#### 1. MANUFACTURING OPERATIONS

##### Active substance

FLUORODEOXYGLUCOSE (18F)

|   |  |
|---|--|
| A | Manufacture of Active Substance by Chemical Synthesis  |
|   | A.2 Manufacture of Crude Active Substance<br><b>Special Requirements</b><br>Radiopharmaceuticals |
| D | Manufacture of Sterile Active Substance  |
|   | D.2 Terminally sterilised<br><b>Special Requirements</b><br>Radiopharmaceuticals                 |

**Name and address of the site**

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

## 1. MANUFACTURING OPERATIONS

**Active substance**

FLUDEOXYGLUCOSE (18-F)

2000006892

|   |  |
|---|--|
| A | Manufacture of Active Substance by Chemical Synthesis  |
|   | A.2 Manufacture of Crude Active Substance<br><b>Special Requirements</b><br>Radiopharmaceuticals                 |
| D | Manufacture of Sterile Active Substance  |
|   | D.2 Terminally sterilised<br><b>Special Requirements</b><br>Radiopharmaceuticals                                 |
| F | Quality Control Testing  |
|   | F.3 Microbiological testing (including sterility testing)<br><b>Special Requirements</b><br>Radiopharmaceuticals |

**Name and address of the site**

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

## 1. MANUFACTURING OPERATIONS

### Active substance

FLUORODEOXYGLUCOSE (18F)

4000011629

|   |  |
|---|--|
| A | Manufacture of Active Substance by Chemical Synthesis  |
|   | A.2 Manufacture of Crude Active Substance<br><b>Special Requirements</b><br>Radiopharmaceuticals |
| D | Manufacture of Sterile Active Substance  |
|   | D.2 Terminally sterilised<br><b>Special Requirements</b><br>Radiopharmaceuticals                 |