

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 29724

2: Name of authorisation holder ACADEMIC UNIT OF RADIOLOGY UNIVERSITY OF SHEFFIELD

3: Address(es) of manufacturing site(s) UNIVERSITY OF SHEFFIELD, ACADEMIC UNIT OF RADIOLOGY, C FLOOR,
DIVISION OF CLINICAL SCIENCES, ROYAL HALLAMSHIRE HOSPITAL,
GLOSSOP ROAD, SHEFFIELD, S10 2JF, UNITED KINGDOM

4: Legally registered address of authorisation holder NORTHERN GENERAL HOSPITAL, XENON POLARISER
LABORATORY, CLINICAL RESEARCH FACILITY, NORTHERN GENERAL
HOSPITAL, HERRIES ROAD, SHEFFIELD, S5 7AU, UNITED KINGDOM

5: Scope of authorisation and dosage forms ACADEMIC UNIT OF RADIOLOGY UNIVERSITY OF SHEFFIELD, ACADEMIC
UNIT OF RADIOLOGY, C FLOOR, DIVISION OF CLINICAL SCIENCES, ROYAL
HALLAMSHIRE HOSPITAL, GLOSSOP ROAD, SHEFFIELD, S10 2JF, 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 Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

8: Authorisation Date Confidential

9: Annexes attached 25/06/2019

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF SHEFFIELD, ACADEMIC UNIT OF RADIOLOGY, C FLOOR, DIVISION OF CLINICAL SCIENCES, ROYAL HALLAMSHIRE HOSPITAL, GLOSSOP ROAD, SHEFFIELD, S10 2JF, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of: [1.4.1.3] Other Polarisation of inert medicinal gasses. [1.6] Quality control testing [1.6.3] Chemical/Physical
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SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NORTHERN GENERAL HOSPITAL, XENON POLARISER LABORATORY,CLINICAL RESEARCH FACILITY, NORTHERN GENERAL HOSPITAL, HERRIES ROAD, SHEFFIELD, S5 7AU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.1] Primary packaging [1.5.1.7] Medicinal gases [1.6] Quality control testing [1.6.3] Chemical/Physical