

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

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

3: Address(es) of manufacturing site(s) NORTHERN GENERAL HOSPITAL, XENON POLARISER LABORATORY, CLINICAL
RESEARCH FACILITY, NORTHERN GENERAL HOSPITAL, HERRIES ROAD,
SHEFFIELD, S5 7AU, UNITED KINGDOM

4: Legally registered address of authorisation holder 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

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI
2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 25/06/2019

9: Annexes attached 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

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