

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 29724
<b>2: Name of authorisation holder</b>	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
<b>3: Address(es) of manufacturing site(s)</b>	NORTHERN GENERAL HOSPITAL, XENON POLARISER LABORATORY, CLINICAL RESEARCH FACILITY, NORTHERN GENERAL HOSPITAL, HERRIES ROAD, SHEFFIELD, S5 7AU, UNITED KINGDOM  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
<b>4: Legally registered address of authorisation holder</b>	
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	25/06/2019
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> [ 1.4 ] Other investigational medicinal products or manufacturing activity

[ 1.4.1 ] Manufacture of: [ 1.4.1.3 ] Other Polarisation of inert medicinal gasses. <b>[ 1.6 ] Quality control testing</b> [ 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
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging [ 1.5.1.7 ] Medicinal gases <b>[ 1.6 ] Quality control testing</b> [ 1.6.3 ] Chemical/Physical
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