Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 21276

2: Name of authorisation holder

ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS

FOUNDATION TRUST

ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS

FOUNDATION TRUST, THE JOHN CHARNLEY LABORATORY, GOBOWEN,

OSWESTRY, SY10 7AG, UNITED KINGDOM

4: Legally registered address of authorisation

holder FOUNDATION TRUST, ROBERT JONES AND AGNES HUNT ORTHOPAEDIC

HOSPITAL, GOBOWEN, OSWESTRY, SY10 7AG, 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

3: Address(es) of manufacturing site(s)

authority of the member state granting the Confidential

manufacturing authorisation

8: Authorisation Date 26/06/2024

9: Annexes attachedAnnex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST, THE JOHN CHARNLEY LABORATORY, GOBOWEN, OSWESTRY, SY10 7AG, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Issue Date: 26 Jun 2024

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological

