

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
3: Address(es) of manufacturing site(s)	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	ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS 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 authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	12/10/2023
9: Annexes attached	Annex 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

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological