

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 21761
2: Name of authorisation holder	UNIVERSITY OF BIRMINGHAM
3: Address(es) of manufacturing site(s)	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM
4: Legally registered address of authorisation holder	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, 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	21/01/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, 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 [1.1.1.6] Other aseptically prepared products Galacorin Burns Dressings [1.1.3] Batch certification [1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.1] Blood products
 - [1.3.1.3] Cell therapy products
 - [1.3.1.6] Human or animal extracted products
 - [1.3.1.7] Tissue Engineered Products
 - [1.3.1.8] Other biological medicinal products
 - Faecal microbiome
- [1.3.2] Batch certification
 - [1.3.2.1] Blood products
 - [1.3.2.3] Cell therapy products
 - [1.3.2.6] Human or animal extracted products
 - [1.3.2.7] Tissue Engineered Products
 - [1.3.2.8] Other biological medicinal products
 - Faecal microbiome
- [1.4] Other investigational medicinal products or manufacturing activity**
 - [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Extraction of faecal microbiome from human faeces
- [1.5] Packaging**
 - [1.5.2] Secondary packaging
- [1.6] Quality control testing**
 - [1.6.4] Biological