

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, MICROBIOME TREATMENT CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM

5: Scope of authorisation and dosage forms UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

8: Authorisation Date Confidential

9: Annexes attached 30/05/2025

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 [1.5] Packaging [1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF BIRMINGHAM, MICROBIOME TREATMENT CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT,
UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.8] Other biological medicinal products Faecal Microbiome [1.3.2] Batch certification [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 Storage of products in cryobags and cryovials. Extraction of faecal microbiome from human faeces [1.5] Packaging [1.5.1] Primary packaging [1.5.1.6] Liquids for internal use [1.5.1.15] Other non-sterile medicinal products Faecal Microbiome [1.5.2] Secondary packaging