

# 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.5 ] Packaging</b> [ 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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 <b>[ 1.4 ] Other investigational medicinal products or manufacturing activity</b> [ 1.4.1 ] Manufacture of: [ 1.4.1.3 ] Other Storage of products in cryobags and cryovials. Extraction of faecal microbiome from human faeces <b>[ 1.5 ] Packaging</b> [ 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