

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 21761
<b>2: Name of authorisation holder</b>	UNIVERSITY OF BIRMINGHAM
<b>3: Address(es) of manufacturing site(s)</b>	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	26/10/2023
<b>9: Annexes attached</b>	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>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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