

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 16993
<b>2: Name of authorisation holder</b>	LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
<b>3: Address(es) of manufacturing site(s)</b>	ROYAL LIVERPOOL UNIVERSITY HOSPITAL (CSSB), PHARMACY ASEPTIC UNIT, LEVEL 2- CLINICAL SUPPORT SERVICES BUILDING (CSSB), ROYAL LIVERPOOL UNIVERSITY HOSPITAL, MOUNT VERNON STREET, LIVERPOOL, L7 8YE, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST, PHARMACY DEPARTMENT, ROYAL LIVERPOOL UNIVERSITY HOSPITAL, PRESCOT STREET, LIVERPOOL, L7 8XP, 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>	15/02/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**ROYAL LIVERPOOL UNIVERSITY HOSPITAL (CSSB), PHARMACY ASEPTIC UNIT, LEVEL 2- CLINICAL SUPPORT SERVICES BUILDING (CSSB), ROYAL LIVERPOOL UNIVERSITY HOSPITAL, MOUNT VERNON STREET, LIVERPOOL, L7 8YE, 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) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.4 ] Small volume liquids

[ 1.1.1.6 ] Other aseptically prepared products

Cytotoxics

[ 1.1.3 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.4 ] Gene therapy products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.8 ] Other biological medicinal products

Monoclonal antibodies

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.2 ] Secondary packaging