

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 59823

**2: Name of authorisation holder** SEDA CLINICAL MANUFACTURING SERVICES LTD.

**3: Address(es) of manufacturing site(s)** SEDA CLINICAL MANUFACTURING SERVICES LTD., 5000 LAKESIDE, CHEADLE ROYAL BUSINESS PARK, CHEADLE, SK8 3AX, UNITED KINGDOM

**4: Legally registered address of authorisation holder** SEDA CLINICAL MANUFACTURING SERVICES LTD., 5000 LAKESIDE, CHEADLE ROYAL BUSINESS PARK, CHEADLE, SK8 3AX, 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** 10/06/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**SEDA CLINICAL MANUFACTURING SERVICES LTD.**, 5000 LAKESIDE, CHEADLE ROYAL BUSINESS PARK, CHEADLE, SK8 3AX, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.1 ] Capsules, hard shell [ 1.2.1.8 ] Other solid dosage forms <b>Special Requirements</b> Powders [ 1.2.1.13 ] Tablets

[ 1.2.2 ] Batch certification

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical