

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 47685   |
| <b>2: Name of authorisation holder</b>  | CLINICAL SERVICES INTERNATIONAL LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | CLINICAL SERVICES INTERNATIONAL, SUITE 212, 50 SLOANE AVENUE, LONDON, SW3 3DD, UNITED KINGDOM         |
| <b>4: Legally registered address of authorisation holder</b>  | CLINICAL SERVICES INTERNATIONAL LIMITED, SUITE 212, 50 SLOANE AVENUE, LONDON, SW3 3DD, 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>  | 11/06/2024  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**CLINICAL SERVICES INTERNATIONAL, SUITE 212, 50 SLOANE AVENUE, LONDON, SW3 3DD, UNITED KINGDOM**

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|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.1.2 ] Terminally sterilised<br>[ 2.2.2 ] Non-sterile products<br>[ 2.2.3 ] Biological medicinal products<br>[ 2.2.3.2 ] Immunological products<br>[ 2.2.3.5 ] Biotechnology products<br>[ 2.2.3.6 ] Human or animal extracted products |

[ 2.2.3.8 ] Other biological medicinal products

Microbial derived

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

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