Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 47685

2: Name of authorisation holder CLINICAL SERVICES INTERNATIONAL LIMITED

3: Address(es) of manufacturing site(s)

SLOANE AVENUE, LONDON, SW3 3DD, UNITED KINGDOM

CLINICAL SERVICES INTERNATIONAL LIMITED, SUITE 212,

50 SLOANE AVENUE, LONDON, SW3 3DD, UNITED

KINGDOM

Confidential

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

4: Legally registered address of authorisation holder

8: Authorisation Date 11/06/2024

9: Annexes attached 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

Human Investigational Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

Issue Date: 11 Jun 2024

[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

