Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

 1: Authorisation Number
 UK MIA(IMP) 24816

 2: Name of authorisation holder
 IMMUNOCLIN LIMITED

IMMUNOCLIN LIMITED, C/O MEDICAL TECHNOLOGIES INNOVATION

FACILITY (MTIF), CLIFTON CAMPUS, NOTTINGHAM TRENT

UNIVERSITY, CLIFTON LANE, NOTTINGHAM, NG11 8NS, UNITED

KINGDOM

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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

4: Legally registered address of authorisation holder

authority of the member state granting the

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

manufacturing authorisation

Confidential

8: Authorisation Date 14/03/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

IMMUNOCLIN LIMITED, C/O MEDICAL TECHNOLOGIES INNOVATION FACILITY (MTIF), CLIFTON CAMPUS, NOTTINGHAM TRENT UNIVERSITY, CLIFTON LANE, NOTTINGHAM, NG11 8NS, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

Issue Date: 14 Mar 2025

[1.3.1.6] Human or animal extracted products

Special Requirements

Manufacture of biological drug substance and bulk drug product from snake venom

[1.3.2] Batch certification

[1.3.2.6] Human or animal extracted products

Special Requirements

Manufacture of biological drug substance and bulk drug product from snake venom

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.2] Homoeopathic products

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

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