

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 54632

2: Name of authorisation holder ENNOGEN HEALTHCARE INTERNATIONAL LIMITED

3: Address(es) of manufacturing site(s) ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G3,
RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD,
DA1 5BS, UNITED KINGDOM

4: Legally registered address of authorisation holder ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G4,
RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD,
DA1 5BS, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI
2012/1916)

**7: Name of responsible officer of the competent authority
of the member state granting the manufacturing
authorisation** Confidential

8: Authorisation Date 24/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ENNOGEN HEALTHCARE INTERNATIONAL LIMITED, UNIT G3, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY,
DARTFORD, DA1 5BS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification 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

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing