

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

30/01/2026

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