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	25/09/2024
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