Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 40739
2: Name of authorisation holder	ENNOGEN HEALTHCARE LIMITED
3: Address(es) of manufacturing site(s)	ENNOGEN HEALTHCARE LIMITED, UNIT G2,G3 & G4,RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM
4: Legally registered address of authorisation holder	ENNOGEN HEALTHCARE LIMITED, UNIT G2,G3 & 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	15/11/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ENNOGEN HEALTHCARE LIMITED, UNIT G2,G3 & G4,RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.5] Packaging

[1.5.2] Secondary packaging

[2.2] Batch certification of imported medicinal products

MHRA-GMDP MHRA

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

MHRA-GMDP

MHRA-GMDP