

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 G4,RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM

4: Legally registered address of authorisation holder ENNOGEN HEALTHCARE 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 10/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ENNOGEN HEALTHCARE LIMITED, UNIT 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 [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