Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 36390
2: Name of authorisation holder	CIPLA (EU) LIMITED
3: Address(es) of manufacturing site(s)	CIPLA (EU) LIMITED, DIXCART HOUSE, ADDLESTONE ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2LE, UNITED KINGDOM
4: Legally registered address of authorisation holder	CIPLA (EU) LIMITED, DIXCART HOUSE, ADDLESTONE ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2LE, 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	22/01/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CIPLA (EU) LIMITED, DIXCART HOUSE, ADDLESTONE ROAD, BOURNE BUSINESS PARK, ADDLESTONE, KT15 2LE, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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**

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Cold Chain Products