

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 33846

2: Name of authorisation holder CUBIC PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) CUBIC PHARMACEUTICALS LIMITED, UNIT 3, SEXTANT PARK, NEPTUNE CLOSE, MEDWAY CITY ESTATE, ROCHESTER, ME2 4LU, UNITED KINGDOM

4: Legally registered address of authorisation holder CUBIC PHARMACEUTICALS LIMITED, UNIT 3, SEXTANT PARK, NEPTUNE CLOSE, MEDWAY CITY ESTATE, ROCHESTER, ME2 4LU, 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 17/10/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CUBIC PHARMACEUTICALS LIMITED, UNIT 3, SEXTANT PARK, NEPTUNE CLOSE, MEDWAY CITY ESTATE, ROCHESTER, ME2 4LU, 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

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA