

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 46101

2: Name of authorisation holder CALIGOR OPCO UK LIMITED

3: Address(es) of manufacturing site(s) CALIGOR OPCO UK LIMITED, UNIT 8, MASTHEAD, CAPSTAN COURT, CROSSWAYS BUSINESS PARK, DARTFORD, DA2 6QG, UNITED KINGDOM

4: Legally registered address of authorisation holder CALIGOR OPCO UK LIMITED, UNIT 8, MASTHEAD, CAPSTAN COURT, CROSSWAYS BUSINESS PARK, DARTFORD, DA2 6QG, 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 18/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CALIGOR OPCO UK LIMITED, UNIT 8, MASTHEAD, CAPSTAN COURT, CROSSWAYS BUSINESS PARK, DARTFORD, DA2 6QG, 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 [1.5] Packaging [1.5.2] Secondary packaging Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.3] Other Importation Activities [2.3.1] Site of Physical Importation