

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 32606

2: Name of authorisation holder AEM LIMITED

3: Address(es) of manufacturing site(s) AEM LIMITED, DE HAVILLAND HOUSE, AIRPORT EXECUTIVE PARK, PRESIDENT WAY, LUTON, LU2 9NL, UNITED KINGDOM

4: Legally registered address of authorisation holder AEM LIMITED, DE HAVILLAND HOUSE, AIRPORT EXECUTIVE PARK, PRESIDENT WAY, LUTON, LU2 9NL, 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 14/09/2021

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

AEM LIMITED, DE HAVILLAND HOUSE, AIRPORT EXECUTIVE PARK, PRESIDENT WAY, LUTON, LU2 9NL, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.2] Batch certification [1.5] Packaging [1.5.2] Secondary packaging