

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 58738

2: Name of authorisation holder SCIOM LIMITED

3: Address(es) of manufacturing site(s) SCIOM LIMITED, UNIT 4, MARTINFIELD BUSINESS CENTRE, MARTINFIELD, WELWYN GARDEN CITY, AL7 1HG, UNITED KINGDOM

4: Legally registered address of authorisation holder SCIOM LIMITED, UNIT 4, MARTINFIELD BUSINESS CENTRE, MARTINFIELD, WELWYN GARDEN CITY, AL7 1HG, 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 22/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SCIOM LIMITED, UNIT 4, MARTINFIELD BUSINESS CENTRE, MARTINFIELD, WELWYN GARDEN CITY, AL7 1HG, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.1] Microbiological: sterility [2.1.2] Microbiological: non-sterility [2.1.3] Chemical/Physical [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

[2.3.1] Site of Physical Importation