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	19/11/2024
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

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[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

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