Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 43900

2: Name of authorisation holder VIATRIS UK HEALTHCARE LIMITED

VIATRIS UK HEALTHCARE LIMITED, BUILDING 20, STATION CLOSE, POTTERS BAR, EN6 1TL, UNITED

KINGDOM

3: Address(es) of manufacturing site(s)

VIATRIS UK HEALTHCARE LIMITED, UNIT 4, TRIDENT

PLACE, MOSQUITO WAY, HATFIELD, AL10 9UL, UNITED

KINGDOM

4: Legally registered address of authorisation holder

POTTERS BAR, EN6 1TL, 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 Confidential

member state granting the manufacturing authorisation

8: Authorisation Date 24/10/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

VIATRIS UK HEALTHCARE LIMITED, BUILDING 20, STATION CLOSE, POTTERS BAR, EN6 1TL, 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

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

Issue Date: 24 Oct 2025

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

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Manufacturer's Authorisation: UK MIA 43900 Page 2 of 2 Issue Date: 24 Oct 2025