Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 43900
2: Name of authorisation holder	VIATRIS UK HEALTHCARE LIMITED
3: Address(es) of manufacturing site(s)	VIATRIS UK HEALTHCARE LIMITED, BUILDING 4, TRIDENT PLACE, MOSQUITO WAY, HATFIELD, AL10 9UL, UNITED KINGDOM VIATRIS UK HEALTHCARE LIMITED, BUILDING 20, STATION CLOSE, POTTERS BAR, EN6 1TL, UNITED KINGDOM
4: Legally registered address of authorisation holder	VIATRIS UK HEALTHCARE LIMITED, 20 STATION CLOSE, 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 member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	11/03/2024
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 4, TRIDENT PLACE, MOSQUITO WAY, HATFIELD, AL10 9UL, 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 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

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

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