

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 43900
<b>2: Name of authorisation holder</b>	VIATRIS UK HEALTHCARE LIMITED VIATRIS UK HEALTHCARE LIMITED, BUILDING 4, TRIDENT PLACE, MOSQUITO WAY, HATFIELD, AL10 9UL, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	VIATRIS UK HEALTHCARE LIMITED, BUILDING 20, STATION CLOSE, POTTERS BAR, EN6 1TL, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	VIATRIS UK HEALTHCARE LIMITED, 20 STATION CLOSE, POTTERS BAR, EN6 1TL, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	11/03/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> [ 1.1 ] <b>Sterile Products</b> [ 1.1.3 ] Batch certification [ 1.2 ] <b>Non-sterile products</b> [ 1.2.2 ] Batch certification <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> [ 2.2 ] <b>Batch certification of imported medicinal products</b>

<ul style="list-style-type: none"> <li>[ 2.2.1 ] Sterile Products <ul style="list-style-type: none"> <li>[ 2.2.1.1 ] Aseptically prepared</li> <li>[ 2.2.1.2 ] Terminally sterilised</li> </ul> </li> <li>[ 2.2.2 ] Non-sterile products</li> </ul>
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**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
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Authorised Operations
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<p>MANUFACTURING OPERATIONS (according to part 1)  IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)</p>
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<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.3 ] Batch certification</li> </ul> <p><b>[ 1.2 ] Non-sterile products</b></p> <ul style="list-style-type: none"> <li>[ 1.2.2 ] Batch certification</li> </ul> <p>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</p> <p><b>[ 2.2 ] Batch certification of imported medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 2.2.1 ] Sterile Products <ul style="list-style-type: none"> <li>[ 2.2.1.1 ] Aseptically prepared</li> <li>[ 2.2.1.2 ] Terminally sterilised</li> </ul> </li> <li>[ 2.2.2 ] Non-sterile products</li> </ul>
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