

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 62112
<b>2: Name of authorisation holder</b>	SMIRO QUALITAS MANUFACTURING LTD SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	SMIRO QUALITAS MANUFACTURING LTD, UNIT 14, 19, 26 AND 27 HOLLANDS ROAD BUSINESS CENTRE, 21-27 HOLLANDS ROAD, HAVERHILL, CB9 8PU, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, 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>	30/06/2026
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM**

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [ 2.2 ] <b>Batch certification of imported medicinal products</b> [ 2.2.1 ] Sterile Products [ 2.2.1.1 ] Aseptically prepared [ 2.2.1.2 ] Terminally sterilised [ 2.2.3 ] Biological medicinal products [ 2.2.3.1 ] Blood products

- [ 2.2.3.2 ] Immunological products
- [ 2.2.3.3 ] Cell therapy products
- [ 2.2.3.4 ] Gene therapy products
- [ 2.2.3.5 ] Biotechnology products
- [ 2.2.3.6 ] Human or animal extracted products

**[ 2.3 ] Other Importation Activities**

- [ 2.3.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)  
GMP Importation and batch release of recombinant proteins,vaccines and adjuvants

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**SMIRO QUALITAS MANUFACTURING LTD**, UNIT 14, 19, 26 AND 27 HOLLANDS ROAD BUSINESS CENTRE, 21-27 HOLLANDS ROAD, HAVERHILL, CB9 8PU, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.5 ] Packaging</b></p> <ul style="list-style-type: none"> <li>[ 1.5.2 ] Secondary packaging</li> </ul> <p><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b></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> <li>[ 2.2.3 ] Biological medicinal products <ul style="list-style-type: none"> <li>[ 2.2.3.1 ] Blood products</li> <li>[ 2.2.3.2 ] Immunological products</li> <li>[ 2.2.3.3 ] Cell therapy products</li> <li>[ 2.2.3.4 ] Gene therapy products</li> <li>[ 2.2.3.5 ] Biotechnology products</li> <li>[ 2.2.3.6 ] Human or animal extracted products</li> </ul> </li> </ul> <p><b>[ 2.3 ] Other Importation Activities</b></p> <ul style="list-style-type: none"> <li>[ 2.3.1 ] Site of Physical Importation</li> <li>[ 2.3.2 ] Importation of Intermediate which undergoes further processing</li> <li>[ 2.3.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc) GMP Importation and batch release of recombinant proteins,vaccines and adjuvants.</li> </ul>