

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 62112
2: Name of authorisation holder	SMIRO QUALITAS MANUFACTURING LTD SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	SMIRO QUALITAS MANUFACTURING LTD, UNIT 14, 19, 26 AND 27 HOLLANDS ROAD BUSINESS CENTRE, 21-27 HOLLANDS ROAD, HAVERHILL, CB9 8PU, UNITED KINGDOM
4: Legally registered address of authorisation holder	SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, 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	30/06/2026
9: Annexes attached	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] Batch certification of imported medicinal products [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.3] 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>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.5] Packaging</p> <ul style="list-style-type: none"> [1.5.2] Secondary packaging <p>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</p> <p>[2.2] Batch certification of imported medicinal products</p> <ul style="list-style-type: none"> [2.2.1] Sterile Products <ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.2.3] Biological medicinal products <ul style="list-style-type: none"> [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 <p>[2.3] Other Importation Activities</p> <ul style="list-style-type: none"> [2.3.1] Site of Physical Importation [2.3.2] Importation of Intermediate which undergoes further processing [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.