Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 62112
2: Name of authorisation holder	SMIRO QUALITAS MANUFACTURING LTD
3: Address(es) of manufacturing site(s)	SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM 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	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	27/08/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational 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 [2.2.2] Non-sterile products

MHRA-GMDP

[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

[2.2.3.8] Other biological medicinal products

Monoclonal antibodies, Vaccines, oral vaccines, recombinants proteins, MVSS, adjuvants and modified vaccina ankara(MVA)

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP certified IMP from a country on the"approved country for import list. Importation of radiopharmaceuticals. beta-lactams and sensitising antibiotics

SCOPE OF AUTHORISATION

Annex 2

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 Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

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

[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

MHRA-GMDP MHRA

[2.2.3.8] Other biological medicinal products

Monoclonal antibodies, Vaccines, oral vaccines, recombinants proteins, MVSS, adjuvants and modified vaccina ankara(MVA)

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMP from a country on the"approved country for Import" list. Importation of radiopharmaceuticals. beta-lactams and sensitising antibiotics

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA