

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 44646
2: Name of authorisation holder	SMIRO QUALITAS LIMITED
3: Address(es) of manufacturing site(s)	SMIRO QUALITAS LIMITED, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM
4: Legally registered address of authorisation holder	SMIRO QUALITAS LIMITED, 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	18/03/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SMIRO QUALITAS LIMITED, 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 [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, RECOMBINANT PROTEINSS, MVSs AND ADJUVANTS,
MODIFIED VACCINIA ANKARA(MVA)

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP certified IMPs from a country on the 'approved country for import list'. Importation from third countries of radiopharmaceuticals, B lactam and highly sensitising antibiotics