

# 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