Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)
- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

SCOPE OF AUTHORISATION

UK MIA(IMP) 44646 SMIRO QUALITAS LIMITED

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

SMIRO QUALITAS LIMITED, 4 FLATFORD ROAD, HAVERHILL, CB9 7WW, UNITED KINGDOM ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

Confidential

26/01/2024 Annex 1 and/or Annex 2

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	4
[2.2] Batch certification of imported medicinal products	
[2.2.1] Sterile Products	
[2.2.1.1] Aseptically prepared	0
[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

[2.3] Other Importation Activities

[2.3.4] Other

Monoclonal antibodies, Vaccines, Oral vaccines, Recombinant proteins, Modified Vaccinia Ankara (MVA) and Adjuvants/Importation of QP certified IMPs from a country on the 'approved country for import list'