Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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	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	16/12/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SMIRO QUALITAS LIMITED, 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
- [2.2.2] Non-sterile products
- [2.2.3] Biological medicinal products
  - [2.2.3.2] Immunological products

[2.3] Other Importation Activities

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

GMP Certification and Batch release of imported biological imported Product- Monoclonal antibodies, Vaccines, oral vaccines, recombinant proteins, MVAs and adjuvants