

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 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

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| 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