

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 62112   |
| <b>2: Name of authorisation holder</b>  | SMIRO QUALITAS MANUFACTURING LTD<br>SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD,<br>HAVERHILL, CB9 7WW, UNITED KINGDOM                          |
| <b>3: Address(es) of manufacturing site(s)</b>  | SMIRO QUALITAS MANUFACTURING LTD, UNIT 14, 19, 26 AND 27<br>HOLLANDS ROAD BUSINESS CENTRE, 21-27 HOLLANDS ROAD,<br>HAVERHILL, CB9 8PU, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | SMIRO QUALITAS MANUFACTURING LTD, 4 FLATFORD ROAD,<br>HAVERHILL, CB9 7WW, UNITED KINGDOM  |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004<br>[SI 2004/1031]  |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential  |
| <b>8: Authorisation Date</b>  | 08/06/2026  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**SMIRO QUALITAS MANUFACTURING LTD, 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<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.1.2 ] Terminally sterilised<br>[ 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, recombinants proteins, MVSS, adjuvants and modified vaccina ankara(MVA)

**[ 2.3 ] Other Importation Activities**

- [ 2.3.4 ] Other
  - Importation of QP certified IMP from a country on the "approved country for import list. Importation of radiopharmaceuticals. beta-lactams and sensitising antibiotics

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**SMIRO QUALITAS MANUFACTURING LTD**, UNIT 14, 19, 26 AND 27 HOLLANDS ROAD BUSINESS CENTRE, 21-27 HOLLANDS ROAD, HAVERHILL, CB9 8PU, UNITED KINGDOM

|   |
|---|
| Human Investigational Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.5 ] Packaging**

- [ 1.5.2 ] Secondary packaging

**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

**[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMP from a country on the "approved country for Import" list. Importation of radiopharmaceuticals, beta-lactams and sensitising antibiotics

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