

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 8801
2: Name of authorisation holder	BIO PRODUCTS LABORATORY LIMITED
3: Address(es) of manufacturing site(s)	BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, WD6 3BX, UNITED KINGDOM
4: Legally registered address of authorisation holder	BIO PRODUCTS LABORATORY LIMITED, DAGGER LANE, ELSTREE, BOREHAMWOOD, WD6 3BX, 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	22/07/2024
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**BIO PRODUCTS LABORATORY LIMITED**, DAGGER LANE, ELSTREE, BOREHAMWOOD, WD6 3BX, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.2 ] Lyophilisates [ 1.1.1.4 ] Small volume liquids [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms) [ 1.1.2.3 ] Small volume liquids [ 1.1.3 ] Batch certification <b>[ 1.3 ] Biological investigational medicinal products</b>

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.1 ] Blood products
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.1 ] Blood products
- [ 1.4 ] Other investigational medicinal products or manufacturing activity**
  - [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
    - [ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.1 ] Microbiological: sterility
- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.1 ] Microbiological: sterility
- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical
- [ 2.1.4 ] Biological

**[ 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

**[ 2.3 ] Other Importation Activities**

- [ 2.3.2 ] Importation of Intermediate which undergoes further processing