

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 14988

**2: Name of authorisation holder** MELBOURN SCIENTIFIC LIMITED

**3: Address(es) of manufacturing site(s)** MELBOURN SCIENTIFIC LIMITED, SAXON WAY,  
MELBOURN, ROYSTON, SG8 6DN, UNITED KINGDOM

**4: Legally registered address of authorisation holder** MELBOURN SCIENTIFIC LIMITED, SAXON WAY,  
MELBOURN, ROYSTON, SG8 6DN, 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** 20/11/2024

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**MELBOURN SCIENTIFIC LIMITED, SAXON WAY, MELBOURN, ROYSTON, SG8 6DN, 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> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.1 ] Capsules, hard shell <b>Special Requirements</b> Epinephrine bitartrate capsules for inhalation [ 1.2.1.5 ] Liquids for external use [ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.15 ] Other non-sterile medicinal products

Suspension nasal spray, Powder for Reconstitution, Pancreatin Powder Blend, Pre-metered cartridge for vaporisation (Inhalation), Nasal spray emulsion, Soft mist for inhalation

[ 1.2.2 ] Batch certification

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.1 ] Herbal products

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.15 ] Other non-sterile medicinal products

Manual filling into sachets

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

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

[ 2.1.3 ] 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

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation