

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 14988
<b>2: Name of authorisation holder</b>	MELBOURN SCIENTIFIC LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	MELBOURN SCIENTIFIC LIMITED, SAXON WAY, MELBOURN, ROYSTON, SG8 6DN, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	MELBOURN SCIENTIFIC LIMITED, SAXON WAY, MELBOURN, ROYSTON, SG8 6DN, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<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>	20/11/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**MELBOURN SCIENTIFIC LIMITED, SAXON WAY, MELBOURN, ROYSTON, SG8 6DN, UNITED KINGDOM**

Human 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 Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.17 ] Other non-sterile medicinal products Nasal spray emulsion, Soft mist for inhalation [ 1.2.2 ] Batch certification <b>[ 1.6 ] Quality control testing</b> [ 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

[ 2.2.3.6 ] Human or animal extracted products

[ 2.2.3.8 ] Other biological medicinal products

This variation in support of an MA application for Enoxoparin which is derived from porcine sources.