

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 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 08/01/2025

9: Annexes attached 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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [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

[2.2.3.6] 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.