

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 15872

2: Name of authorisation holder FDC INTERNATIONAL LIMITED

3: Address(es) of manufacturing site(s) FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15 7FE, UNITED KINGDOM

4: Legally registered address of authorisation holder FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15 7FE, 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 31/03/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15 7FE, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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 [2.2.2] Non-sterile products