

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 15872   |
| <b>2: Name of authorisation holder</b>  | FDC INTERNATIONAL LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15 7FE, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15 7FE, 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>  | 31/03/2025   |
| <b>9: Annexes attached</b>  | 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<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.2 ] Non-sterile products |