## Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 15872

2: Name of authorisation holder FDC INTERNATIONAL LIMITED

FDC INTERNATIONAL LIMITED, UNIT 6 FULCRUM 1, SOLENT

BUSINESS PARK, SOLENT WAY, WHITELEY, FAREHAM, PO15

7FE, UNITED KINGDOM

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

4: Legally registered address of authorisation holder

the member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 23/09/2025

9: Annexes attached Annex 1 and/or Annex 2

## SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

## 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

Issue Date: 23 Sep 2025