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	13/12/2023
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