Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 52811

KINDEVA DRUG DELIVERY LIMITED

KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM

KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012

(SI 2012/1916)

Confidential

01/07/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.9] Pressurised preparations

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Micronisation of active pharmaceutical ingredient for use in the manufacture of finished products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.9] Pressurised preparations

Issue Date: 01 Jul 2025

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

