Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 52811
2: Name of authorisation holder	KINDEVA DRUG DELIVERY LIMITED
3: Address(es) of manufacturing site(s)	KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM
4: Legally registered address of authorisation holder	KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	09/07/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.9] Pressurised preparations

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.9] Pressurised preparations

Special Requirements

Dry Powder Inhalers

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation