

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

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|---|---|
| 1. Registration Number | UK API 52811 |
| 2. Name or corporate name of registrant | KINDEVA DRUG DELIVERY LIMITED |
| 3. Permanent or legal address of registrant | KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | KINDEVA DRUG DELIVERY LIMITED, DERBY ROAD, LOUGHBOROUGH, LE11 5SF, UNITED KINGDOM |
| 5. National legal basis of registration | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 6. Name of responsible officer of the competent authority of the member state validating the registration | Confidential |
| 7. Date | 18/10/2024 |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

FORMOTEROL FUMARATE
(4000006640)

3rd Country Manufacturer

INDUSTRIAL CHEMICA, VIA E H GRIEG 13, SARONNO VA, I-21047,
ITALY

3rd Country Distributor

SALMETEROL XINAFOATE
(2000008392) **HOVIONE PHARMASCIENCE LIMITED**, ESTRADA CORONEL NICOLAU
DE MESQUITA, TAIPA, ILHAS, MACAO, Data Not Available, MACAO SAR
CHINA

HOVIONE, SETE CASAS, LOURES, PT-2674-506, PORTUGAL

CICLESONIDE (1000001273) **DYNAMIT**, EXPLOSIVSTOFF UND SYSTEMTECHNIK, STANDORT
SCHLEBUSH, KALKSTRASSE 218, LEVERKUSEN, D-51377, GERMANY

BECLOMETHASONE
DIPROPIONATE (2000008376) **SICOR**, VIA TERRAZZANO 77, RHO MI, I-20017, ITALY

FLUTICASONE PROPIONATE
(2000008220) **HOVIONE**, SETE CASAS, LOURES, PT-2674-506, PORTUGAL

SALBUTAMOL SULPHATE
(2000007742) **SICOR**, VIA ENRICO FERMI 520, CARONNO PERTUSELLA (VA), I-21042,
ITALY

MOMETASONE FUROATE
(2000008125) **DHL PHARMA LOGISTICS NV**, LEUVENSESTEENWEG 242,
BOORTMEERBEEK, B-3190, BELGIUM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

BECLOMETHASONE DIPROPIONATE (2000008376)

SALBUTAMOL SULPHATE (2000007742)