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

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	14/09/2026

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

1. MANUFACTURING OPERATIONS

Active substance
SALBUTAMOL SULPHATE
2000007742

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation of salbutamol sulphate
	E.2 Primary Packaging

MHRA-GMDP MHRA-GMDP MHRA MHRA

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	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	
BECLOMETHASONE DIPROPIONATE (2000008376)	**SICOR**, VIA TERRAZZANO 77, RHO MI, I-20017, ITALY	
SALBUTAMOL SULPHATE (2000007742)	**SICOR SOCIET ITALIANA CORTICOSTEROIDI S.R.L**, VIA ENRICO FERMI 520, CARONNO PERTUSELLA (VA), I-21042, ITALY **GLAXO WELLCOME PRODUCTION**, ZONE INDUSTRIELLE NO 2, 23 RUE LAVOISIER, EVREUX CEDEX 9, F-27091, FRANCE	
FORMOTEROL FUMARATE (4000006640)	**INDUSTRIALE CHIMICA S.R.L**, VIA E H GRIEG 13, SARONNO VA, I-21047, ITALY	
MOMETASONE FUROATE (2000008125)	**MSD INTERNATIONAL GMBH (SINGAPORE BRANCH)**, 50 TUAS WEST DRIVE, SINGAPORE, SG-638408, SINGAPORE	
FLUTICASONE PROPIONATE (2000008220)	**HOVIONE**, SETE CASAS, LOURES, PT-2674-506, PORTUGAL	
CICLESONIDE (1000001273)	**DYNAMIT**, EXPLOSIVSTOFF UND SYSTENTECHNIK,STANDORT SCHLEBUSH, KALKSTRASSE 218, LEVERKUSEN, D-51377, GERMANY	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

BECLOMETHASONE DIPROPIONATE (2000008376)

SALBUTAMOL SULPHATE (2000007742)

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