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 54857

2. Name or corporate name of registrant OQEMA LONDON LIMITED

3. Permanent or legal address of registrant

LONDON, N12 8NU, UNITED KINGDOM

OQEMA LONDON LIMITED, DENABY LANE INDUSTRIAL ESTATE,

DENABY LANE, OLD DENABY, DONCASTER, DN12 4LQ, UNITED

4. Address(es) of site(s) where registered activities KINGDOM

take place

OQEMA LONDON LIMITED, NEPTUNE HOUSE, 2A ALEXANDRA GROVE,

LONDON, N12 8NU, UNITED KINGDOM

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 29/06/2022

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

OQEMA LONDON LIMITED, DENABY LANE INDUSTRIAL ESTATE, DENABY LANE, OLD DENABY, DONCASTER, DN12 4LQ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

TRISODIUM CITRATE DIHYDRATE (4000006894)

CITRIC ACID (1000004323)

Name and address of the site

OQEMA LONDON LIMITED, NEPTUNE HOUSE, 2A ALEXANDRA GROVE, LONDON, N12 8NU, UNITED KINGDOM

API Registration Number: UK API 54857

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Issue Date: 29 Jun 2022

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

| Active Substance | 3rd Country Manufacturer | 3rd Country Distributor |
|---|---|----------------------------|
| CITRIC ACID (1000004323) | CITRIQUE BELGE NV SA, PASTORIJSTRAAT 249, TIENEN B-3300, BELGIUM | l, |
| TRISODIUM CITRATE DIHYDRATE (4000006894) | CITRIQUE BELGE NV SA, PASTORIJSTRAAT 249, TIENEN B-3300, BELGIUM | l, |