Therapeutic Goods Administration
Australia
This is a true and correct copy of the original on file
Department of Health
Office of Manufacturing Quality
29.01.2019
Date

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2017-LI-14360-1

Issued to:

iX Syrinx Pty Ltd
ABN: 20 149 728 825

Manufacturing Site Address:

110 Merrindale Drive
CROYDON SOUTH VIC 3136
Australia

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer holds a Licence with number **MI-2012-LI-05038-3** to manufacture therapeutic goods under section 38 of the *Therapeutic Goods Act 1989* and is included in the national inspection program following section 40(4)(b) of the *Therapeutic Goods Act 1989*.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 22 to 24 August 2018, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 January 2017.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status after the expiry date. This certificate should also not be relied upon where the status of the Licence to manufacture therapeutic goods is not current. Where required, the Therapeutic Goods Administration as the issuing authority should be consulted.

EXPIRY DATE: 24 August 2021

ISSUE DATE: 30 January 2019

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

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MANUFACTURING OPERATIONS

The manufacturer above is authorised under section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Tablet, orally disintegrating	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Liquids	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Tablet, orally disintegrating	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Cream	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Wafer	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Wafer	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Paste	Registered Therapeutic Good	Full Product Manufacture - excluding Testing
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Full Product Manufacture - excluding Testing

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In addition to the statutory conditions that apply to all Licences granted under section 38 of the *Therapeutic Goods Act 1989*, the following specific conditions have been imposed on the Licence under sections 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The licence does not authorise the manufacture of preparations containing penicillins, cephalosporins, hormones, steroids and antineoplastic drugs.

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