Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-05038-3

Granted to:

iX Syrinx Pty Ltd
ABN: 20 149 728 825

Manufacturing Site Address:

110 Merrindale Drive
CROYDON SOUTH VIC 3136

The manufacturer above is hereby 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 Microbiological Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Liquids	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Cream	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Wafer	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Wafer	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Paste	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

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Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2012-LI-05038-3

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Wafer	Not Applicable	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Oil	Not Applicable	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Oil	Therapeutic Goods for Clinical Trials	Full Product Manufacture - excluding Microbiological Testing

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **5 July 2013** Date Revised: **16 September 2020**

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TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-2012-LI-05038-3

Granted to:

iX Syrinx Pty Ltd
ABN: 20 149 728 825

Manufacturing Site Address:

110 Merrindale Drive
CROYDON SOUTH VIC 3136

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

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

The manufacture of dosage forms in the Product Category 'Not Applicable' is restricted to therapeutic goods that are intended for export or exempt from registration and listing on the ARTG under the provisions of Section 18(1) or Section 19(1)(a) of the Therapeutics Goods Act 1989.

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production: Alan Thompson

Quality Control: Colin Liu

Originally Imposed: **5 July 2013** Date Revised: **16 September 2020**

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