



**Australian Government**

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**Department of Health**  
Therapeutic Goods Administration

Mr Alan Doughty  
Managing Director  
Chemika Pty Ltd  
119 Magowar Road  
GIRRAWEEEN NSW 2145

TGA Reference: E21-294819

**Subject: Reissue of licence to manufacture therapeutic goods MI-2012-LI-00095-3**

Dear Alan Doughty,

Please find enclosed the reissued Licence Part 1 (Authorisations) and Part 2 (Schedule of Conditions) for your manufacturing premises as requested.

Please do not hesitate to contact the Manufacturing Quality Branch if you require any further information.

Yours sincerely,

Signed and authorised by

David Rowbury  
Delegate of the Secretary  
Manufacturing Quality Branch

18 May 2021

Contact: [GMP@health.gov.au](mailto:GMP@health.gov.au), Phone: 1800 020 653



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## Licence to Manufacture Therapeutic Goods – Part 1

**Licence Number:**

MI-2012-LI-00095-3

**Granted to:**

Chemika Pty Ltd  
ABN: 44 093 373 534

**Manufacturing Site Address:**

119 Magowar Road  
GIRRAWEE NSW 2145

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
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Not Applicable	Testing chemical and physical

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, 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: **14 June 2012**

Date Revised: **18 May 2021**

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/>



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## **Licence to Manufacture Therapeutic Goods – Part 2: Schedule of Conditions**

**Licence Number:**

MI-2012-LI-00095-3

**Granted to:**

Chemika Pty Ltd  
ABN: 44 093 373 534

**Manufacturing Site Address:**

119 Magowar Road  
GIRRAWEE NSW 2145

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*:

No further conditions are applicable.

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

Production: Alan Doughty

Quality Control: Catherine Micallef

Originally Imposed: **14 June 2012**

Date Revised: **18 May 2021**

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