Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2010-LI-05076-3

Previously granted under Licence number: 80

Granted to:

Steritech Pty Ltd
ABN: 30 451 935 502

Primary Manufacturing Site Address:

5 Widemere Road
WETHERILL PARK DC NSW 2164

Secondary Manufacturing Site Addresses:

7 Widemere Road
WETHERILL PARK DC NSW 2164

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 addresses specified above.

Primary site:

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	All Dosage Forms	Registered Therapeutic Good	Sterilisation
Medical Device	Sterile	Not Applicable	Not Applicable	Sterilisation

Secondary site:

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Sterile	All Dosage Forms	Registered Therapeutic Good	Storage

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations. For the secondary manufacturing site/s, refer to Section 38A of the *Therapeutic Goods Act 1989.*

Signed: Dmilic .....

Dr Dragana Milic, Delegate of the Secretary

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This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
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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 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2010-LI-05076-3

Previously granted under Licence number: 80

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*.

No additional specific conditions have been imposed on this licence under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989* and consequently this licence does not have a Part 2.

Originally Granted: **23 October 1991** Date Revised: **25 February 2015**

Signed: Dmilic .....

Dr Dragana Milic, Delegate of the Secretary

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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-2010-LI-05076-3

Previously issued under Licence number: 80

Issued to:

Steritech Pty Ltd
ABN: 30 451 935 502

Manufacturing Site Address:

5 Widemere Road
WETHERILL PARK DC NSW 2164

Secondary Manufacturing Site Addresses:

7 Widemere Road
WETHERILL PARK DC NSW 2164

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: John Irwin

Quality Control: Colin Staed

Originally imposed: **23 October 1991** Date Revised: **25 February 2015**

Signed: D Milic .....

Dr Dragana Milic , Delegate of the Secretary

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