STERITECH
Protecting what matters

Steritech Pty Ltd
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TO WHOM IT MAY CONCERN

This letter is to confirm that Steritech Pty Ltd holds the following TGA Licences to Manufacture Therapeutic Goods:

Licence No MI-27012005-LI-000402-1
This licence authorises Steritech to sterilise therapeutic goods by either gamma irradiation or ethylene oxide gas at its 160 South Gippsland Highway, Dandenong South, Victoria, 3175 facility.

Licence No MI-2010-LI-05075-3
This licence authorises Steritech to sterilise therapeutic goods by gamma irradiation at its 180-186 Potassium Street, Narangba, Queensland, 4504 facility.

Licence No MI-2010-LI-05076-3
This licence authorises Steritech to sterilise therapeutic goods by either gamma irradiation or ethylene oxide gas at its 5 Widemere Road, Wetherill Park, NSW, 2164 facility.

As a licenced manufacturer, Steritech is regularly audited by officers of the TGA against the requirements ISO13485. During these audits the TGA auditors ensure that Steritech has adequate controls of both irradiation and ethylene oxide routine sterilization processes.

The TGA requirements for routine control of gamma irradiation sterilization processes for medical devices are equivalent to those described in ISO11137 and the requirements for routine control of ethylene oxide sterilization processes for medical devices are equivalent to those described in ISO11135. However, it must be noted that the TGA audits do not include the requirements for occupational health and safety of Steritech's employees as well as the clauses dealing with the requirements for environmental protection measures.

The TGA has verified that Steritech have included in their quality system all applicable requirements of ISO13485 and all requirements of ISO11137 and ISO11135 relevant to the control of routine sterilisation processes, in accordance with their responsibilities under their agreements/contracts with their customers.
Steritech was last audited across its three sites in November and December 2017. The next audit is due in early 2019.

Barry Cox
Group Quality Manager
Steritech
1 March 2019

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

This Licence is valid only if the security provisions (blue and grey curved dotted lines across the bottom half of each page) are visible.
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: 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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