Australian Government

Department of Health
Therapeutic Goods Administration

To Whom It May Concern

SUBJECT: Steritech Pty Ltd ISO 13485 Quality Management System (QMS) Certificate

This letter is to confirm that, at the time of writing, Steritech Pty Ltd holds the following manufacturing licences:

- 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 DC, NSW 2164 facility; and

Steritech has previously been audited by the Therapeutic Goods Administration (TGA) against ISO 13485:2003 and has previously held a TGA issued ISO 13485:2003 QMS certificate, which expired on 1 March 2019. The expiry of a TGA issued ISO 13485:2003 QMS Certificate does not affect a manufacturer's inclusions on the Australian Register of Therapeutic Goods (ARTG).

Due to the end of the ISO 13485:2016 transition period, the TGA is not able to issue or extend any ISO 13485:2003 QMS Certificates beyond 1 March 2019. Also, the TGA can only issue ISO 13485:2016 QMS Certificates to manufacturers who have been audited against the new revision of the standard.

In November 2019, the TGA audited Steritech to the requirements in ISO 13485:2016. The new certificate will be re-issued when the audit is closed out after a process that can take several months, but is expected to occur before January 2021, therefore **this letter should not be used as an assurance of compliance with QMS requirements beyond 1 January 2021.**

Any questions in relation to this matter can be referred to Kathleen McCormick on 03 9665 8174; katheleen.mccormick@health.gov.au.

Hon. Prof. Jorge Garcia

[electronically signed]

Director, Device Quality Audits and Assessment Section
Medical Devices Surveillance Branch

25 August 2020

TGA Reference: 2014/016753 D20-3232863

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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