Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2020-LI-03302-1

Granted to:

Steritech Pty Ltd
ABN: 30 451 935 502

Manufacturing Site Address:

21 Titan Drive
MICKLEHAM VIC 3064

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
Active Pharmaceutical Ingredient Manufacture	Non Sterile	Not Applicable	Raw Material	Decontamination – Specifically relating to cannabis decontamination using irradiation only
Medical Device	Sterile & Non Sterile	Not Applicable	Not Applicable	Sterilisation
Human Tissue	Sterile & Non Sterile	Not Applicable	Not Applicable	Sterilisation

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: **29 April 2020** Date Revised: **N/A**

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

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Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-2020-LI-03302-1

Granted to:

Steritech Pty Ltd
ABN: 30 451 935 502

Manufacturing Site Address:

21 Titan Drive
MICKLEHAM VIC 3064

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 is granted to ensure the emergency supply of therapeutic goods during the COVID-19 pandemic. The licence is conditional on the following specific circumstances applying in relation to the manufacture of therapeutic goods:

- The sterilisation of medical devices is restricted to the sterilisation of personal protective equipment needed to combat the COVID-19 pandemic emergency needs.
- This licence requires that additional performance qualification studies are performed for each customer product, if operational qualification data is not available to support the validation.
- The conditions on this licence remain in force until a subsequent on-site audit has been performed.
- The decontamination is limited to irradiation of medicinal cannabis material of herbal origin.

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

Licence Number:

MI-2020-LI-03302-1

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

Production: Simon Scott

Quality Control: Macdarragh O'Neill

Originally Imposed: **29 April 2020** Date Revised: **N/A**

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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