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	Not Applicable	Decontamination - Specifically relating to cannabis decontamination using irradiation only
Medicine Manufacture	Non Sterile	All Dosage Forms	Not Applicable	Decontamination - Specifically relating to cannabis decontamination using irradiation only
Medicine Manufacture	Non Sterile	All Dosage Forms	Therapeutic Goods for Clinical Trials	Decontamination - Specifically relating to cannabis decontamination using irradiation only
Medicine Manufacture	Sterile	All Dosage Forms	Registered Therapeutic Goods	Sterilisation
Medicine Manufacture	Sterile	All Dosage Forms	Not Applicable	Sterilisation
Medical Device	Sterile	Not Applicable	Not Applicable	Sterilisation
Human Tissue	Sterile	Not Applicable	Not Applicable	Sterilisation
Human Tissue	Non Sterile	Not Applicable	Not Applicable	Irradiation

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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

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Licence Number:

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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: 29 April 2020 **Date Revised: 13 May 2022**

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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*:

- Sterilisation and irradiation is limited to e Beam technology

- For the manufacture of Therapeutic Goods:
  - The authorisation for the decontamination of medicinal cannabis products with the product category 'Not Applicable' is restricted to therapeutic goods that are either registered in the ARTG, intended for export, or exempt from registration and listing on the ARTG under the provisions of Section 18(1) or Section 19(1)(a) of the *Therapeutic Goods Act 1989.*

- For the manufacture of Medicines and Human Tissues:
  - This licence requires that the licence holder maintain records of the validation of each process and, if relevant, the requirements of the Product Marketing Authorisation. Steritech is required to maintain records that links them as an approved service provider for the treatment step of a product manufacturing process. An evidentiary record that details suitability of the irradiation process or equivalent, must be obtained from the product sponsor and filed, prior to undertaking the treatment of goods.

- For the manufacture of Medical Devices:
  - 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.

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

Licence Number:

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

Production:	Simon Scott
Quality Control:	Macdarragh O'Neill

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