Australian Government

Australian Pesticides and Veterinary Medicines Authority

LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: **Steritech Pty. Ltd.** **Licence No:** **6103**

ACN 007 308 027

The APVMA hereby issues a licence under section 123 of the Agricultural and Veterinary Chemicals Codes (Agvet Codes) to the above named person (the Licence Holder) to carry out the following step(s) of manufacture of veterinary chemical products:

Category 6 ***(Single step)*** **– Sterilisation (radiation) and microbiological reduction treatment (radiation)**

—at the following premises:

180-186 Potassium Street
NARANGBA QLD 4504

This licence is subject to the conditions set out in subsection 126(4) of the Agvet Codes, regulations 60–62 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations) and the **additional conditions in the attached Schedule(s).**

For the purposes of paragraph 126 (4)(b) of the Agvet Codes and in accordance with regulation 60 of the Agvet Code Regulations, the following persons are nominated as the persons having control of production and quality respectively:

Production: **Michael Scott**

Quality: **Seth Hamilton**

This licence comes into force on the date of issue and replaces the previous licence issued on 22 September 2009 This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 16th **day of June 2012**

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Kathryn Winterton
Senior Reviewer, Manufacturing Quality and Licensing
Delegate of the Australian Pesticides and Veterinary Medicines Authority

This licence remains the property of the APVMA and must be returned on request

SCHEDULE 1 OF ADDITIONAL LICENCE CONDITIONS

The following additional conditions apply to and form part of Licence No. **6103** issued to the Licence Holder:

Steritech Pty. Ltd.

ACN 007 308 027

S1.1 This Licence authorises only those steps of manufacture, product type(s) and premises listed.

S1.2 The Licence Holder must manufacture the veterinary chemical products that are the subject of this Licence, in accordance with the APVMA's Manufacturing Principles and associated Codes of Good Manufacturing Practice, and any standards that apply to the products.

S1.3 At the direction of the APVMA, the Licence Holder must undergo an audit by an APVMA-authorised person of the manufacturing facilities, equipment, systems, processes, procedures and personnel used in the manufacture of veterinary chemical products and must demonstrate to the satisfaction of the APVMA that their operation and conduct is in compliance with the Agvet Codes, the APVMA's Manufacturing Principles, associated Codes of Good Manufacturing Practice and any standards that apply to the products.

S1.4 The Licence Holder must provide to the APVMA within 25 working days of the completion date of every audit conducted by an APVMA-authorised person, the original signed copy of each audit report and associated audit checklists, together with details of all corrective actions that they propose to take with respect to the non-conformances identified therein and timeframes for their implementation. Where an audit conducted by an APVMA-authorised person identifies critical non-conformances, the Licence Holder must notify the APVMA of the critical non-conformances in writing within three (3) working days of the completion date of that audit.

S1.5 The Licence Holder must implement all the corrective actions arising from audits within the timeframes agreed to or specified by the APVMA, and provide the APVMA with sufficient objective evidence to confirm that all the corrective actions have been implemented to the APVMA's satisfaction.

S1.6 The Licence Holder must allow, for the purposes of an audit, an APVMA-authorised person ready access to all relevant facilities, equipment, systems, processes, procedures, personnel and information and must not knowingly conceal or withhold relevant information.

S1.7 The licence holder may sub-contract work out only to Australian manufacturers or laboratories that are licensed by the APVMA or to overseas manufacturers or laboratories whose evidence of GMP compliance is recognised by the APVMA to carry out the contracted steps in the manufacture of veterinary chemical products.

Dated this 16th **day of June 2012**

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Senior Reviewer, Manufacturing Quality and Licensing
Delegate of the Australian Pesticides and Veterinary Medicines Authority

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SCHEDULE 2 OF ADDITIONAL LICENCE CONDITIONS

The following additional conditions apply to and form part of Licence No. **6103** issued to the Licence Holder:

Steritech Pty. Ltd.

ACN 007 308 027

S2.1 The Licence Holder must perform all aspects of veterinary chemical manufacture, including analysis and testing, in accordance with Good Manufacturing Practice using the same:

a) premises,
b) plant and equipment,
c) processes and procedures,
d) documentation, and
e) personnel (including those persons responsible for Production and Quality)

that are used in the manufacture of human therapeutics, as licensed by the Therapeutic Goods Administration (TGA Licence No. **M-2010-LI-05075-3**):

S2.2 Prior to each TGA audit, the Licence Holder must arrange for the TGA auditor to verify during the audit that all aspects of veterinary chemical manufacture are carried out within the scope of that TGA licence.

S2.3 The Licence Holder must maintain their TGA licence and advise the APVMA in writing within 10 working days, of any changes in the scope of that licence. The Licence Holder must also provide the APVMA with copies of all TGA audit reports and correspondence related to the conduct and closure of such audits, within 10 working days of receipt of those reports or correspondence.

Dated this 16th **day of June 2012**

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