



**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 Act 1989*, and its Regulations. For the secondary manufacturing site/s, refer to Section 38A of the *Therapeutic Goods Act 1989*.

Signed:

*Dragana Milic*  
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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.  
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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:

Dr Dragana Milic, Delegate of the Secretary

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## **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:

Dr Dragana Milic, Delegate of the Secretary

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