



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Quality Management System Certificate
ISO 13485:2003

Issued to:

Steritech Pty Ltd

This is to certify that the Quality Management System for the manufacture of the devices described below conforms to the relevant provisions of ISO13485:2003.

TGA File Number: 2014/016771, 2014/016788 and 2014/016754

Manufacturer Name: Steritech Pty Ltd

Manufacturer Address: 160 South Gippsland Highway
Dandenong South VIC 3175

Facility Address: 160 South Gippsland Highway, Dandenong South VIC 3175

Scope of Certification: Provision of contract ethylene oxide and gamma irradiation services, in accordance with the relevant clauses of ISO11135:2007 and ISO11137:2006

Facility Address: 5 Widemere Road, Wetherill Park DC NSW 2164

Scope of Certification: Provision of contract ethylene oxide and gamma irradiation services, in accordance with the relevant clauses of ISO11135:2007 and ISO11137:2006

Facility Address: 180-186 Potassium Street, Narangba QLD 4504

Scope of Certification: Provision of contract gamma irradiation services, in accordance with the relevant clauses of ISO11137:2006

Effective Date: 7 September 2018

Expiry Date: 1 March 2019

This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.

Keith M Smith
Quality Audits and Assessments Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden, ACT, 2606, Australia
Phone: +61 (0)2 6221 6856

7 September 2018
Date

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