



Australian Government
Department of Health
Therapeutic Goods Administration

Quality Management System Certificate

ISO 13485: 2016

Certificate Number:

MI-2018-LI-12200-1

Issued to:

Steritech Pty Ltd

This is to certify that the Quality Management System for providing sterilization services in relation to medical devices described below conforms to the relevant provisions of ISO13485:2016, excluding clauses 4.2.3, 7.3, 7.5.2, 7.5.3, 7.5.4, 7.5.9.2, 8.2.3.

TGA File Number: 2011/001850, 2014/016771, 2014/016754, E20-57160

Manufacturer Name: Steritech Pty Ltd

Manufacturer Address: 160 South Gippsland Highway

Dandenong South VIC 3175, Australia
Facility Address:
Site 1:
160 South Gippsland Highway, Dandenong South VIC 3175, Australia
Site 2:
5 and 7 Widemere Road, Wetherill Park, NSW 2164, Australia
Site 3:
180-186 Potassium Street, Narangba, QLD 4504, Australia
Site 4:
21 Titan Drive Mickleham VIC 3064, Australia

Scope of Certification: Provision of contract ethylene oxide gas (Sites 1-2) and irradiation services (all 4 sites) in accordance with relevant clauses of the current ISO 11135 and ISO 11137 standards

Effective Date: 26 March 2021

Expiry Date: 24 October 2022

Name and signature of an authorised person of the Regulatory Authority of Australia:

Signed:

Jorge Garcia, Director

Medical Devices Surveillance Branch

This certificate is only valid for the period indicated, subject to periodic and satisfactory surveillance audits.
This Certificate remains the property of the Therapeutic Goods Administration and must be return upon demand.
The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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TGA Health Safety
Regulation