



Certificate Number
MRA Q00053

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

EC Certificate

Production Quality Assurance Procedures

Annex V of Directive 93/42/EEC on Medical Devices

This is to certify that the quality management system described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure that each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

Manufacturer Name: The Pipette Company Pty Ltd

Manufacturer Address: Unit 13, 22 Ware Street
Thebarton SA 5031
Australia

Commencement Date: 27 May 2013

Certificate Expiry Date: 27 May 2018

Associated CA Certificate AU Q00154

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked. Its validity is dependent on the currency of the associated CA Certificate listed above.

This certificate is issued by:

Mr Gary Burgess

Signed electronically

Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

**Notified Body
Identification Number**

0805



Australian Government

Department of Health and Ageing
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Scope of Certificate

Manufacturer Facilities

Name and Address		Scope
1.	Unit 15, 22 Ware Street Thebarton SA 5031 Australia	Temporary storage of excess packaging and shipping materials.

Device Categories

Description	Limitations (if applicable)
1. Micropipettes	Supplied sterile

Critical Suppliers

Name and Address	Scope
1. Steritech Pty Ltd 160 South Gippsland Highway Dandenong VIC 3175 Australia	Radiation sterilisation



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Certificate History

Version	Details	Issue Date	File Reference
1	Initial certification	28 May 2013	2007/010391
2	Recertification & reformatting of certificate. Addition of new temporary storage facility.	27 May 2013	2013/003046
Certificate Location (Manufacturer Root File Number):			2010/010764