Notified Body
Identification number

0805

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate Number
MRA Q00053

EC Certificate

Production Quality Assurance Procedures

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

Issued to

Manufacturer Name: The Pipette Company Pty Ltd

Manufacturer Address: Unit 13/ 22 Ware Street
THEBARTON SA 5031
Australia

For the Manufacture and Final inspection of device categories specified on page two of this certificate.

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.

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.

Commencement Date: 15 June 2018

Certificate Expiry Date: 25 May 2023

Associated CA Certificate: AU Q00154

This certificate is issued by:

Fiona McCormack
Signed electronically
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

Notified Body Identification number

0805

Australian Government

Department of Health

Therapeutic Goods Administration

Certificate Number
MRA Q00053

Scope of Certificate

Manufacturer Facilities

	Name and Address	Scope
1	The Pipette Company Unit 15, 22 Ware Street Thebarton SA 5031 Australia	Labeling, Distribution, Warehousing
2	The Pipette Company Unit 13, 22 Ware Street Thebarton South Australia 5031 Australia	Production, Packaging, Labeling, Quality control, Distribution, Warehousing, Release for supply

Manufacture and Final Inspection of 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	Gamma sterilisation

Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	28 May 2013	2007/010391
2.1	Recertification & reformatting of certificate Addition of new temporary storage facility	27 May 2013	2013/003046
2.2	Update the scope of manufacturer facilities Update the certificate version numbers - internal modification	25 August 2017	E17-23827
3.1	Recertification	15 June 2018	E18-209790
Certificate Location (Manufacturer Root File Number):			2010/010764