The Pipette Company Pty. Ltd.
Unit 13, 22 Ware Street, Thebarton, South Australia 5031
Telephone: +61-8-8152 0266; Facsimile: +61-8-8152 0277
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MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY MANAGEMENT SYSTEM

This is a declaration made in accordance with the requirements of clause 4.7 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the stated devices:

Manufacturer's Name: The Pipette Company Pty. Ltd.

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

Classification: Class I Sterile

GMDN Code and Term: 45410 - Micropipette, user-induced

Scope of Application: All micromanipulation pipettes - holding, injection, biopsy, drilling, cutting - manufactured from 2008 onwards.

For each kind of medical device to which the Production Quality Assurance procedures have been applied the Type Examination procedures have also been applied. The kind of device has been shown to conform to an approved Type and to the applicable provisions of the essential principles and the classification rules before being supplied. This declaration is being made on the basis of the following certificates:

Type Examination and Production Quality Management System Certificate:

Conformity Assessment Certificate AU Q00154

Conformity Assessment Standards Applied:

ISO 13485:2003. *Medical devices - Quality management systems - Requirements for regulatory purposes*.

ISO 14971:2007. *Medical devices - Application of risk management to medical devices*.

ISO 11137:2006. *Sterilization of health care products - Radiation.*

Authorised Signatory:

Sean P. Flaherty, Ph.D.
Quality Manager

Date: 19 February 2016