The Pipette Company Pty. Ltd.
Unit 13, 22 Ware Street, Thebarton, South Australia 5031
Telephone: +61-8-8152 0266; Facsimile: +61-8-8152 0277
www.pipetteco.com

BATCH QUALITY CERTIFICATE

Batch: S0211P

Expiry Date: 1 November 2016

PRODUCT LOT NUMBERS

This certificate covers TPC micromanipulation pipettes with lot numbers S0211P (6505) to S0211P (6612).

PRODUCTION QUALITY CONTROL

Each pipette was checked and measured repeatedly during manufacture and inspected by an experienced technician before packaging to ensure that it was intact, clean and complied with specifications.

Strict rejection criteria were used during all stages of manufacturing. Pipettes which did not strictly conform to specifications and standards of cleanliness were rejected without compromise.

STERILISATION

This batch was sterilised on 6 December 2012 using Gamma Irradiation at a measured dose of 20.1 kGy.

This process has been validated to a Sterilization Assurance Level (SAL) of 10^{-6} per ISO 11137.

MOUSE EMBRYO ASSAY

Sterilised samples were independently tested for embryo cytotoxicity using a validated mouse embryo assay (MEA).

To maximise sensitivity: (i) one-cell zygotes were cultured to fully expanded blastocysts (FEB); (ii) a simple culture medium was used to slightly “stress” the embryos; (iii) protein-free culture medium was used so that toxicity would not be masked by protein; (iv) embryos were directly exposed to pipette tips for the entire 96 hour culture period.

Products pass this MEA if > 80% of the embryos develop to FEB after 96 hours in culture.

All the samples tested from batch S0211P passed the MEA. The results were as follows:

	% FEB	RESULT	INTERPRETATION
Batch samples:	84-100*	PASS	No evidence of cytotoxicity
Non-toxic control:	97	PASS	Acceptable control result
Toxic control:	60	FAIL	Acceptable control result

** Results were not significantly different from the non-toxic control.*

PRE-RELEASE QUALITY CONTROL

Sterilised samples were tested by an experienced embryologist using an inverted microscope and micromanipulators to ensure that the pipettes were clean, non-sticky and functioned efficiently and smoothly under routine conditions of use.

ROUTINE QUALITY ASSURANCE PROCEDURES

Our quality management system is certified to ISO 13485.

The production cleanroom is certified to ISO 14644 (class 7) and undergoes regular microbiological screening.

Ultrapure water systems are tested regularly for bacteria (< 1 cfu per 500 ml) and endotoxins (< 0.03 EU per ml), and are certified annually by the manufacturer.

Packaging materials are thoroughly inspected and tested to ensure cleanliness and sterility.

AUTHORISATION

This batch was authorised for release on 21 December 2012 by:

Dianna Payne
Production Manager

Sean P. Flaherty
Quality Manager

CE 0805