



**The Pipette Company Pty. Ltd.**

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**BATCH QUALITY CERTIFICATE**

**Batch: S1311W**

**Expiry Date: 12 November 2023**

**PRODUCT LOT NUMBERS**

This certificate covers TPC micromanipulation pipettes with lot numbers S1311W (15238) to S1311W (15350).

**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 7 December 2019 using Gamma Irradiation at a measured dose of 24.5 kGy.

This process has been validated to a Sterilization Assurance Level (SAL) of 10<sup>-6</sup> 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 S1311W passed the MEA. The results were as follows:

|                    | <b>% FEB</b> | <b>RESULT</b> | <b>INTERPRETATION</b>       |
|--------------------|--------------|---------------|-----------------------------|
| Batch samples:     | 90-95*       | PASS          | No evidence of cytotoxicity |
| Non-toxic control: | 100          | PASS          | Acceptable control result   |
| Toxic control:     | NA           | 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 17 December 2019 by:

Dijana Jerkovic  
Quality Manager

