



The Pipette Company Pty. Ltd.

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EC DECLARATION OF CONFORMITY

The Pipette Company Pty. Ltd. declares that the products listed below conform to the essential requirements of Medical Devices Directive MDD 93/42/ECC:

Description: Injection Pipette
Holding Pipette
Biopsy Pipette
Drilling Pipette
Cutting Pipette

Classification: Class I Sterile

GMDN Code: 45410 - Micropipette, user-induced

Conformity Assessment: Production Quality Assurance
Annex V of Medical Devices Directive MDD 93/42/ECC

Referenced Standards: ISO 14971:2007 *Medical devices - Application of risk management to medical devices.*
ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purposes.*
ISO 11137:2006. *Sterilization of health care products - Radiation.*

CE Certificate: MRA Q00053

Notified Body: Therapeutic Goods Administration (0805)
PO Box 100
Woden, ACT 2606, Australia

Authorised Representative: Advena Ltd.
Pure Offices, Plato Close
Warwick CV34 6WE, United Kingdom

Authorised Signatory:

Sean P. Flaherty, Ph.D.
Quality Manager

Date: 19 February 2016