



Certificate Number: AU Q00152/01

CONFORMITY ASSESSMENT CERTIFICATE
PRODUCTION QUALITY ASSURANCE PROCEDURES

Schedule 3 – Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australia)

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3 – Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Production Quality Management System for production and final inspection to ensure that each medical device to which the system is applied conforms to the type described in the scope of the respective Type Examination certificate (Schedule 3 – Part 2) or is in accordance with the technical documentation prepared by the manufacturer under Schedule 3 - clause 6.4.

TGA File Number: 2007/004245

Manufacturer Name: Logikal Health Products Pty Ltd.

Address: 3/18 & 3/20 Accolade Avenue
Morisset NSW 2264
Australia

Facility: As above

Suppliers: as per attached Schedule of Suppliers

Scope of the certification: Tubing set, heart-lung bypass [GMDN 35441]
Dialysis start/stop set [GMDN 32142]
Drainage kit, wound [GMDN 35824]
Pessary [GMDN 35237]
Suction unit, thoracic [36787]

Automatic Conditions: apply under section 41EJ of the *Therapeutic Goods Act 1989*

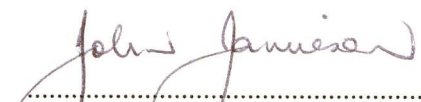
Additional Conditions: In this certificate, devices covered under the term Pessary [GMDN 35237] are not intended for contraception or prevention of sexually transmissible diseases.

Commencement Date: 15 May 2008

Re-issue date:

Expiry date: 15 May 2013

This certificate is valid from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.


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John Jamieson
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