



*Certificate Number: AU Q00079/01*

**CONFORMITY ASSESSMENT CERTIFICATE**  
**FULL QUALITY ASSURANCE PROCEDURES**

Schedule 3 – Part 1 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 1, excluding clause 1.6, of the Therapeutic Goods (Medical Devices) Regulations 2002. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

**TGA File Number:** 2006/036561

**Manufacturer Name:** Whiteley Corporation Pty Ltd (t/a Whiteley Medical)

**Address:** 19-23 Laverick Avenue  
Tomago NSW 2322

**Facility:** As above

**Suppliers:** AMS Laboratories Pty Ltd  
118 Hattersley Street  
Rockdale NSW 2216  
*Microbiological verification and validation*

**Scope of the certification:** GMDN 40579 Sterilant, glutaraldehyde  
GMDN 45057 Disinfectant, medical device, glutaraldehyde  
GMDN 46405 Disinfectant, medical device, benzylkonium chloride

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

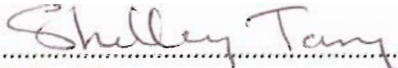
**Additional Conditions:** Nil

**Commencement Date:** 30 January 2007

**Re-issue date:**

**Expiry date:** 30 January 2012

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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.

  
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**Shelley Tang**  
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Office of Devices, Blood and Tissues  
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