



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

*Certificate Number: MRA Q00069/01*

**CE CERTIFICATE**  
**PRODUCTION QUALITY ASSURANCE SYSTEM**  
(Annex V of the Directive 93/42/EEC on Medical Devices)

This is to certify that the Production Quality Assurance System described below conforms to the relevant provisions of Annex V of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for production and final inspection to ensure each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

**TGA File Number:** 2007/004245, 2009/000100

**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:** as per attached Schedule of Categories

**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:** 26 June 2009

**Re-issue date:**

**Expiry date:** 26 June 2014

*This Certificate is valid for the period indicated subject to periodic and satisfactory surveillance.*



*Notified to EC. In compliance with Article 17, CE marking shall be accompanied by our identification number: 0805.*

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**Dr. Larry Kelly**  
Head  
Office of Devices, Blood and Tissues  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606 AUSTRALIA

*This Certificate is the property of the Therapeutic Goods Administration and must be returned upon demand*  
C-MRA-5