



Certificate Number: AU Q00082/01

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: 2005/082801

Manufacturer Name: Biokosmes s.r.l

Address: Via Dei Livelli No 1
23842 Bosisio Parini, Lecco
Italy

Facility: As above

Suppliers: Pentapharm Ltd
Engelgasse 109
CH-4002 Basel
Switzerland

Scope of the certification: Dressing, hydrogel [GMDN 34082]

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

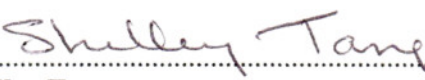
Additional Conditions: NIL

Commencement Date: 06 March 2007

Re-issue date:

Expiry date: 06 March 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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.


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