



Certificate Number: AU Q00164/01

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: 2007/008669

Manufacturer Name: Bio Nova International Pty Ltd

Address: 36 Munster Terrace
North Melbourne VIC 3051
Australia

Facility: As per attached Schedule of Suppliers

Suppliers: As per attached Schedule of Suppliers

Scope of the certification: Graft, vascular, synthetic [GMDN 35281]
(including ovine origin material)

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

Additional Conditions: NIL

Commencement Date: 11 July 2008

Re-issue date:

Expiry date: 11 July 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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.

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Rodolfo Ferrari
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