



*Certificate Number: AU DE00166/01*

**CONFORMITY ASSESSMENT CERTIFICATE**  
**DESIGN EXAMINATION**

Schedule 3 – Part 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Australia)

This is to certify that the design of the device(s) below complies with the relevant provisions of Schedule 3 – Part 1.6 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on examination of the evidence of conformity to the Essential Principles.

**TGA File Number:** 2007/008669

**Manufacturer Name:** Bio Nova International Pty Ltd

**Address:** 36 Munster Terrace  
North Melbourne VIC 3051  
Australia

**Scope of the certification:** Omniflow II Vascular Prosthesis  
  
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from the commencement date, subject to ongoing compliance, and unless it has been restricted, suspended, revoked or is no longer in effect.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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