

**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60036431 0001

**Report No.:** 21160964 001

**Manufacturer:** BIO NOVA International PTY LTD  
36 Munster Terrace  
North Melbourne VIC 3051  
Australia

**Scope:** Design, Production and Distribution  
of STERILE, VASCULAR PROSTHESES

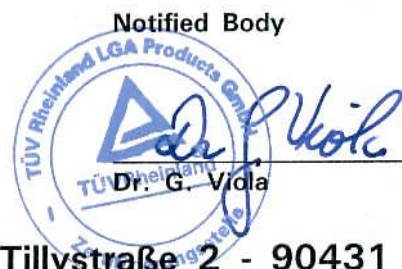
Product: OMNIFLOW II

Replaces Approval, Registration No.: HD 60013518 0001

**Date of Expiry:** 03.02.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 14.02.2011



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

**CE** The CE marking may be used if all relevant and effective EC Directives are complied with. **CE**