

EC Design Examination Certificate
EC Directive 93/42/EEC Annex II, Article 4
Medical Devices

Registration No.: ID 60017380 0001

Report No.: 21127023 003

Manufacturer:

Bio Nova International Pty Ltd.
36 Munster Terrace
North Melbourne 3051
Victoria, Australia

Manufacturer Facility:

Bio Nova International Pty Ltd.
36 Munster Terrace
North Melbourne 3051
Victoria, Australia

Product:

Medical Device
Vascular Prosthesis

Identification:

OMNIFLOW II Vascular Prosthesis
OMNIFLOW II Vascular Prosthesis Curved Vascular Access

Products: see attachment

Replaces Certificate, Registration No.: ID 60015945 0001

The EC design examination certificate refers to the above mentioned product. It certifies that the design documentation of the product complies with Annex II, Article 4 of Directive 93/42/EEC. Furthermore the compliance with the specifications laid down in the Annex of Directive 2003/32/EC as well as the compliance with the essential requirements of Directive 93/42/EEC is attested.


The manufacturer is subject to EC surveillance in accordance with Annex II, Article 5 of the directive. The manufacturer is entitled to use this certificate with the manufacturer's declaration of conformity.

Date of Expiry: 19.02.2012

Cologne, 20.02.2007



Notified Body


Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

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

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: ID 60017380 0001
Report No.: 21127023 003

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

Scope: Omniflow II Vascular Prosthesis Curved Vascular Access

Configuration: Curved, Length 30 to 45 cm,
Internal Diameter (ID) 5 to 8 mm

Catalogue No.'s: 5 to 8 mm ID (*=5 to 8 mm)

741-*45

741-*40

741-*35

741-*30

751-*45

Cologne, 20.02.2007




Dr. H. Lüdemann

TÜV Rheinland
Product Safety GmbH

Doc. 2/2, Rev. 0

Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: ID 60017380 0001
Report No.: 21127023 003

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

Scope: Omniflow II Vascular Prosthesis

Configuration: Straight, Length 10 to 65 cm,
Internal Diameter (ID) 3 to 8 mm

Catalogue No.'s: 5 to 8 mm ID (*=5 to 8 mm)

751-*65	751-*40	721-*35
751-*60	751-*35	721-*20
751-*55	751-*20	
751-*50	751-*10	
751-*45		

3 to 4 mm ID (*=3 to 4 mm)

751-*20
751-*15

Cologne, 20.02.2007




Dr. H. Lüdemann