

Certificate



TUV Rheinland of North America, Inc., a CMDCAS
recognized registrar, certifies that

Neovasc Inc.
13700 Mayfield Place, Unit 2135
Richmond BC V6V 2E4
Canada

has established and maintained a
Quality Management System
according to
ISO 13485:2003

Audit Report No.: 30892711 001
Certificate Registration No.: 74 500 3580
Expiry Date: July 10, 2009

Design and Development, Manufacture
and Distribution of
(1) Intravascular Catheters and Diagnostic Systems and
(2) Xenograft Tissue Patches and Sleeves Derived from
Equine & Bovine Pericardial Tissue




Certification Officer: B. Ludovico

TUV Rheinland of North America, Inc.
Newtown, Connecticut

Effective Date: December 11, 2008

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

Neovasc Inc.
13700 Mayfield Place, Unit 2135
Richmond BC V6V 2E4
Canada

has established and applies a quality management system for medical devices
for the following scope:

See Attachment for Details

Proof has been furnished that the requirements specified in

EN ISO 13485:2003 + AC:2007

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60023370 0001

An audit was performed. Report No.: 30892711 001

This Certificate is valid until: 27.04.2009

Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Cologne, 11.12.2008



B. Ludovico
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