



# EC - CERTIFICATE

## **DQS GmbH**

**Deutsche Gesellschaft zur Zertifizierung von Managementsystemen**

hereby certifies that the company

### **MicroVention, Inc.**

75 Columbia, Ste.A  
Aliso Viejo, CA 92656  
United States of America

has implemented and maintains a

### **Quality Management System.**

An audit, documented in a report, performed by DQS  
has verified that this quality management system  
fulfills the requirements of

### **Annex II of Directive 93/42/EEC**

with respect to the following medical devices:

as listed in the annex

As set out in section 5, Annex II, of the said directive,  
the manufacturer of these devices is subject to surveillance. The CE-mark with the number  
of the notified body may be used on the devices listed in the certificate.

**CE 0297**

This certificate is valid until 2011-10-29

Certificate Registration No. 411133 MR2

Frankfurt am Main 2008-07-22

Ass. iur. M. Drechsel

MANAGING DIRECTORS

Dipl.-Ing. S. Heinloth

D-60433 Frankfurt am Main, August-Schanz-Straße 21

EC code number of DQS as notified body: 0297



**Annex to Certificate Registration No.: 411133 MR2  
(Edition 2008-07-22)**

**MicroVent, Inc.**

75 Columbia, Ste.A  
Aliso Viejo, CA 92656  
United States of America

**Products:**

| <b>Product Groups:</b>       | <b>Product Family</b>   | <b>Products:</b>   | <b>Risk Class</b> |
|------------------------------|---|--|-------------------|
| Embolization<br>Prostheses   | Detachable Embolization Coils with HydroLink® Detachment System | MicroPlex® Platinum Detachable Embolization Coils<br>- Helical – Helical-Reg. and Soft 10 & 18<br>- HyperSoft™ 10<br>- Complex 1D 10 & 18<br><br>HydroCoil® Platinum/Hydrogel Detachable Embolization Coils<br>- Helical 10 & 14 & 18  | III               |
|                              | V-Trak® Detachable Embolization Coils System                    | MicroPlex® Platinum Detachable Embolization Coils<br>- Helical - Standard Helical-Reg. and Soft 10 & 18,<br>- HyperSoft™ 10<br>- Complex - Complex 10 & 18, Compass 10 & 18,<br>- COSMOS 10<br><br>HydroCoil® Platinum/Hydrogel Detachable Embolization Coils<br>- HydroCoil® 10 & 14 & 18, HydroSoft™ 10,<br>HydroSoft™ Plus 10 | III               |
|                              | AZUR™ Peripheral HydroCoil® Embolization Coil System            | AZUR™ HydroCoil Detachable Embolization Coils 18<br>AZUR™ HydroCoil Pushable Embolization Coils 18 & 35  | IIb               |
|                              | Detachment Controller Units                                     | V-Grip™ Detachment Controller<br>V-Grip™ PLUS Detachment Controller<br><br>AZUR™ Detachment Controller   | IIa<br><br>IIa    |
| Intravascular Access Devices |   | Traxcess™ Guidewires   | III               |
| Catheters                    |   | Chaperon Guiding Catheter System   | III               |