



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## MicroVention, Inc.

1311 Valencia Ave.  
Tustin, CA, 92780  
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

## Annex II excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Embolization Prostheses, Detachment Controller Units, Syringe Kits, Stents, Clot and Foreign Body Retrieval Devices, Intravascular Access Devices (Occlusion Balloon Catheters, Micro Catheters, Guidewires), Liquid Embolic System, EPS Embolic Protection System, Microspheres and Aneurysm Embolization Device as listed in Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 411133 MR2

Certificate unique ID 170711729

Effective date 2018-06-11

Expiry date 2022-11-02

Frankfurt am Main 2018-06-11

## DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

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Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

Prepared for Romania



**Annex to certificate**  
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### **Production Sites:**

1.  
MicroVention, Inc.  
1311 Valencia Ave.  
Tustin, CA 92780  
United States of America
2.  
MicroVention, Inc.  
35 Enterprise,  
Aliso Viejo, CA 92656  
United States of America
3.  
MicroVention Costa Rica, S.R.L.  
Zona Franca Coyol  
Alajuela, Costa Rica



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| <b>Device Groups:</b>       | <b>Device Family:</b>                        | <b>Devices:</b>                                                                                                                                                                                                                                                                              | <b>Risk Class</b> | <b>Production Site</b> |
|-----------------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|------------------------|
| Embolization Prothese       | V-Trak® Detachable Embolization Coils System | MicroPlex® Platinum Detachable Embolization Coils<br>- Helical IStandard Helical-Reg. and Soft 10 & 18,<br>- HyperSoft® 10 & 3D<br>- Complex 10 & 18<br>- Compass 10 & 18,<br>- COSMOS® 10 & 18<br>- VFC™                                                                                    | III               | 1,2,3                  |
|                             |                                              | HydroCoil® Platinum/Hydrogel Detachable Embolization Coils<br>- HydroCoil® 10 & 14 & 18,<br>- HydroSoft® 10<br>- HydroFill®<br>- HydroFrame® 10 & 18<br>- HydroSoft 3D                                                                                                                       | III               | 1,2,3                  |
|                             | AZUR® Peripheral Coil System                 | AZUR® HydroCoil Detachable Embolization Coils 18 & 35<br>AZUR® HydroCoil Pushable Embolization Coils 18 & 35<br>AZUR® Framing Detachable Coils 18 & 35<br>AZUR® Injectable Coil System 18 & 35<br>AZUR Detachable 18<br>AZUR PURE Pushable Coil System 18 & 35<br>AZUR CX Detachable 18 & 35 | IIb               | 1,2,3                  |
| Detachment Controller Units |                                              | V-Grip® Detachment Controller                                                                                                                                                                                                                                                                | IIa               | 1                      |
|                             |                                              | V-Grip® PLUS Detachment Controller                                                                                                                                                                                                                                                           | IIa               | 1                      |
|                             |                                              | WEB Detachment Controller                                                                                                                                                                                                                                                                    | IIa               | 1                      |
|                             |                                              | AZUR® Detachment Controller                                                                                                                                                                                                                                                                  | IIa               | 1                      |





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|------------------------------|-----------------------|-----------------------------------------|-------------------|------------------------|
| Intravascular Access Devices |                       | Traxcess® 14 Guidewire                  | III               | 1                      |
|                              |                       | Traxcess® 14 EX Guidewire               |                   |                        |
|                              |                       | Traxcess® 14 SELECT Guidewire           |                   |                        |
|                              |                       | Traxcess® 7 Mini Guidewire              |                   |                        |
|                              |                       | Traxcess® 7 Mini XSoft Guidewire        |                   |                        |
|                              |                       | Traxcess® Docking Wire                  | Ila               | 1                      |
| Catheters                    |                       | Chaperon® Guiding Catheter System       | III               | 1                      |
|                              |                       | Headway® 17 Advanced Soft Microcatheter |                   | 1,3                    |
|                              |                       | Headway® 17 Advanced Microcatheter      |                   | 1,3                    |
|                              |                       | Headway® 21 Microcatheter               |                   | 1,3                    |
|                              |                       | Headway® 27 Microcatheter               |                   | 1,3                    |
|                              |                       | Headway Duo Microcatheter               |                   | 1,3                    |
|                              |                       | Scepter C™ Occlusion Balloon Catheter   |                   | 1,3                    |
|                              |                       | Scepter XC™ Occlusion Balloon Catheter  |                   | 1,3                    |
|                              |                       | SOFIA Distal Access Catheter            |                   | 1,2,3                  |
|                              |                       | SOFIA Select Catheter                   |                   | 1,2,3                  |
|                              |                       | SOFIA PLUS Catheter                     |                   | 1,2,3                  |
|                              |                       | SOFIA Flow PLUS Catheter                |                   | 1,2,3                  |
|                              |                       | SOFIA Guiding Catheter                  |                   | 1,2,3                  |
|                              |                       | SOFIA Flow Catheter                     |                   | 1,2,3                  |
|                              |                       | KANSHAS Drug Coated Balloon             |                   | 1                      |
|                              |                       | VIA 117 Microcatheter                   |                   | 1                      |
|                              |                       | VIA 121 Microcatheter                   |                   |                        |
|                              |                       | VIA 127 Microcatheter                   |                   |                        |
|                              |                       | VIA 133 Microcatheter                   |                   |                        |
|                              |                       | Wedge Microcatheter                     |                   | 1                      |



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|----------------------------------|-----------------------|------------------------------------------------|-------------------|------------------------|
| Stents                           |                       | LVIS™ Intraluminal Support Device              | III               | 1,2,3                  |
|                                  |                       | LVIS Jr.™ Intraluminal Support Device          |                   |                        |
|                                  |                       | FRED® Flow Re-Direction Endoluminal Device     | III               | 1,3                    |
|                                  |                       | FRED Jr.® Flow Re-Direction Endoluminal Device |                   | 1,3                    |
|                                  |                       | CASPER IRX Carotid Artery Stent System         |                   | 1,3                    |
|                                  |                       | Roadsaver Carotid Artery Stent System          |                   | 1,3                    |
|                                  |                       |                                                |                   |                        |
|                                  |                       |                                                |                   |                        |
| Peripheral vascular stent system |                       | CASPER Peripheral Vascular Stent System        | IIb               | 1,3                    |
|                                  |                       | RENZAN Peripheral Vascular Stent System        | IIb               | 1,3                    |
| Clot Retriever                   |                       | ERIC™ Retrieval Device                         | III               | 1,2                    |
| Liquid Embolic System            |                       | PHIL™ Liquid Embolic System                    | III               | 1                      |
| Microspheres                     |                       | HydroPearl Microspheres                        | IIb               | 1                      |
|                                  |                       | LifePearl Microspheres                         | III               | 1,2                    |
| Embolic Protection Device (EPS)  |                       | Empro Embolic Protection System                | III               | 1,2,3                  |
|                                  |                       | Nanoparasol Embolic Protection System          |                   |                        |
| Aneurysm Embolization Device     |                       | WEB I Aneurysm Embolization System             | III               | 1                      |