



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 and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires) and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units 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 | 170752398 |
| Effective date | 2019-10-07 |
| Expiry date | 2022-11-02 |
| Frankfurt am Main | 2019-10-07 |

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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



Annex to certificate
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Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America

2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela,
Costa Rica



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| Device Groups: | Device Family: | Devices: | Risk Class | Production Site |
|------------------------------|--|--|------------|-----------------|
| Embolization Prothese | V-Trak® Detachable Embolization Coils System | MicroPlex® Platinum Detachable Embolization Coils - Helical – Standard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 & 3D - Complex 10 & 18 - Compass 10 & 18, - COSMOS® 10 & 18 - VFC™ | III | 1,2,3 |
| | | HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, - HydroSoft® 10 - HydroFill® - HydroFrame® 10 & 18 - HydroSoft 3D | III | 1,2,3 |
| | AZUR® Peripheral Coil System | AZUR® HydroCoil Detachable Embolization Coils 18 & 35 AZUR® HydroCoil Pushable Embolization Coils 18 & 35 AZUR® Framing Detachable Coils 18 & 35 AZUR® Injectable Coil System 18 & 35 AZUR Detachable 18 AZUR PURE Pushable Coil System 18 & 35 AZUR CX Detachable 18 & 35 | IIb | 1,2,3 |
| Detachment Controller Units | | V-Grip® Detachment Controller | IIa | 1,2 |
| | | V-Grip® PLUS Detachment Controller | IIa | 1,2 |
| | | WEB Detachment Controller | IIa | 1,2 |
| | | AZUR® Detachment Controller | IIa | 1,2 |
| Intravascular Access Devices | | Traxcess® 14 Guidewire | III | 2 |
| | | Traxcess® 14 EX Guidewire | | |
| | | Traxcess® 14 SELECT Guidewire | | |
| | | Traxcess® 7 Mini Guidewire | | |
| | | Traxcess® 7 Mini XSoft Guidewire | | |
| | | Traxcess® Docking Wire | IIa | 2 |

This annex is only valid in connection with the above-mentioned certificate.





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|--|----------------|--|------------|-----------------|
| Catheters | | Chaperon® Guiding Catheter System | III | 2 |
| | | Headway® 17 Advanced Soft Microcatheter | | 2,3 |
| | | Headway® 17 Advanced Microcatheter | | 2,3 |
| | | Headway® 21 Microcatheter | | 2,3 |
| | | Headway® 27 Microcatheter | | 2,3 |
| | | Headway Duo Microcatheter | | 2,3 |
| | | Scepter C™ Occlusion Balloon Catheter | | 1,2,3 |
| | | Scepter XC™ Occlusion Balloon Catheter | | 1,2,3 |
| | | Scepter Mini™ Occlusion Balloon Catheter | | 1,2 |
| | | 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 |
| | | SOFIA® EX Catheter | | 1,2,3 |
| | | KANSHAS Drug Coated Balloon | | 1 |
| | | VIA™ 17 Microcatheter | | 2 |
| | | VIA™ 21 Microcatheter | | 2 |
| | | VIA™ 27 Microcatheter | | 2 |
| | | VIA™ 33 Microcatheter | | 2 |
| | | Wedge Microcatheter | | 2,3 |
| | | Stents | | |
| LVIS Jr.™ Intraluminal Support Device | | | | |
| LVIS™ EVO Intraluminal Support Device | | | | |
| FRED® Flow Re-Direction Endoluminal Device | III | | 1,2,3 | |
| FRED Jr.® Flow Re-Direction Endoluminal Device | | | | |
| CASPER™ RX Carotid Artery Stent System | 1,2,3 | | | |
| Roadsaver Carotid Artery Stent System | | | | |



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| Peripheral Vascular Stent System | | CASPER™ Peripheral Vascular Stent System | IIb | 1,2,3 |
| | | RENZAN™ Peripheral Vascular Stent System | IIb | 1,2,3 |
| Clot Retriever | | ERIC™ Retrieval Device | III | 1,2,3 |
| Liquid Embolic System | | PHIL™ Liquid Embolic System | III | 1,2 |
| Microspheres | | HydroPearl Microspheres | IIb | 1,2 |
| | | LifePearl Microspheres | III | 1,2 |
| | | BioPearl® Microspheres | III | 1,2 |
| Embolic Protection Device (EPS) | | Empro Embolic Protection System | III | 1,2,3 |
| | | Nanoparasol Embolic Protection System | | |
| Aneurysm Embolization Device | | WEB™ Aneurysm Embolization System | III | 1,2 |
| Aspiration Tubing Kit | | Aspiration Tubing Kit | Is | 2 |
| Aspiration Syringe Kit | | Aspiration Syringe Kit | Is | 2 |
| AZUR Vascular Plug | | AZUR Vascular Plug | IIb | 1,2 |
| PG Pro Microcatheter | | PG Pro Microcatheter | IIa | 1,2 |

