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	170728800
Effective date	2018-12-01
Expiry date	2022-11-02
Frankfurt am Main	2018-12-01

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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.

411.20 Version 1.0

Annex to certificate
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MicroVention, Inc.

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United States of America

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
		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	1,2
		Traxcess® 14 EX Guidewire		
		Traxcess® 14 SELECT Guidewire		
		Traxcess® 7 Mini Guidewire		
		Traxcess® 7 Mini XSoft Guidewire		
		Traxcess® Docking Wire	IIa	1,2
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		2,3
		Scepter XC™ Occlusion Balloon Catheter		2,3
		SOFIA™ Distal Access Catheter		1,3
		SOFIA™ Select Catheter		1,3
		SOFIA™ PLUS Catheter		1,3
		SOFIA™ Flow PLUS Catheter		1,3
		SOFIA™ Guiding Catheter		1,3
		SOFIA™ Flow Catheter		1,3
		KANSHAS Drug Coated Balloon		1
		VIA™ 17 Microcatheter		2
		VIA™ 21 Microcatheter		2
		VIA™ 27 Microcatheter		2
		VIA™ 33 Microcatheter		2
		Wedge Microcatheter		1

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,3
		LVIS Jr.™ Intraluminal Support Device	III	1,3
		FRED® Flow Re-Direction Endoluminal Device		1,3
		FRED Jr.® Flow Re-Direction Endoluminal Device		1,3
		CASPER™ RX Carotid Artery Stent System		1,3
		Roadsaver Carotid Artery Stent System		1,3
Peripheral vascular stent system		RENZAN™ Peripheral Vascular Stent System	IIb	1,3
Clot Retriever		ERIC™ Retrieval Device	III	1
Liquid Embolic System Microspheres		PHIL™ Liquid Embolic System	III	1
		HydroPearl Microspheres	IIb	1
		LifePearl Microspheres	III	1
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1
		Nanoparasol Embolic Protection System		
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	2
Aspiration Syringe Kit		Aspiration Syringe Kit	Is	1