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

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.

Prepared for Romania

411.20 Version 1.0

Digitally signed by Grabazei Alexandru
Date: 2021.12.30 20:22:39 EET
Reason: MoldSign Signature
Location: Moldova

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170711729
Effective date: 2018-06-11

MicroVention, Inc.

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United States of America

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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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical IStandard 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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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
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	IIa	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 I17 Microcatheter		1
		VIA I21 Microcatheter		
		VIA I27 Microcatheter		
		VIA I33 Microcatheter		
		Wedge Microcatheter		1

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
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 IAneurysm Embolization System	III	1