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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Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
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 V-Grip® PLUS Detachment Controller WEB Detachment Controller AZUR® Detachment Controller	IIa IIa IIa IIa	1,2 1,2 1,2 1,2
Intravascular Access Devices		Traxcess® 14 Guidewire Traxcess® 14 EX Guidewire Traxcess® 14 SELECT Guidewire Traxcess® 7 Mini Guidewire Traxcess® 7 Mini XSoft Guidewire Traxcess® Docking Wire	III IIa	2 2

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
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™ Intraluminal Support Device	III	1,2,3
		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		1,2,3
		CASPER™ RX Carotid Artery Stent System		1,2,3
		Roadsaver Carotid Artery Stent System		1,2,3

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
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 Microspheres		PHIL™ Liquid Embolic System	III	1,2
		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

CERTIFICATE

This is to certify that the company

MicroVention, Inc.

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

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	411133 MP2016
Certificate unique ID	170758666
Effective date	2019-11-17
Expiry date	2022-11-16
Frankfurt am Main	2019-11-17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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

Annex to certificate
Certificate registration No.: 411133 MP2016
Certificate unique ID: 170758666
Effective date: 2019-11-17

MicroVention, Inc.

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

Location	Scope
MicroVention, Inc. **Production Site** 35 Enterprise Aliso Viejo, CA, 92656 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention, Inc. **Production Site** 1311 Valencia Ave. Tustin, CA, 92780 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
MicroVention Costa Rica, S.R.L. **Production Site** Zona Franca Coyol Alajuela Costa Rica	Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.

PHIL™
Precipitating Hydrophobic Injectable Liquid

Liquid Embolic System

PHIL™ - Precipitating Hydrophobic Injectable Liquid

PHIL™
Non-adhesive Liquid Embolic System

Product Code	Concentration	Viscosity	Content Per Syringe
1 pre-filled syringe of PHIL™ liquid embolic, 1 pre-filled syringe of DMSO and microcatheter hub adaptors*			
LEN10250	25%	Low	1mL
LEN10300	30%	Medium	1mL
LEN10350	35%	High	1mL

**Available for Headway® DUO Microcatheter, Headway®17 Microcatheter, Scepter C® and Scepter XC® Balloon Occlusion Catheters and BALT® SONIC Microcatheter*

Features	Benefits
3 Concentrations Available	For different flow rate scenarios and distal or proximal penetration
Pre-loaded Syringes	No preparation required, ready to use
Iodine Bonded Radiopacifier	Homogeneous radiopacity No shaking needed No added metal for minimal artifact
High Volume of Embolic Precipitate	More embolic capacity with less DMSO agent

Microcatheter Compatibility

PHIL™ device must be used with DMSO compatible catheters such as Headway® DUO Microcatheter, Headway®17 Microcatheter or Scepter Occlusion Balloon.

Product Name	Product Codes	Description	Working Length (cm)	Dead Space (mL)	Dead Space with PHIL™ Adaptor (mL)	OD Prox./Dist. (French)	Tip Markers
Scepter C®	BC0410C BC0415C BC0420C	Compliant Occlusion Balloon	150	0.44	0.23	2.8/2.1	3
Scepter XC®	BC0411XC	X-tra Compliant Occlusion Balloon	150	0.44	0.23	2.8/2.1	3
Headway® 17	MC172150S MC172150SX	Headway® 17 Microcatheter	150	0.41	0.26	2.4/1.7	2
Headway® Duo 156cm	MC162156S	Headway® Duo Microcatheter	156	0.34	0.24	2.1/1.6	2
Headway® Duo 167cm	MC162167S	Headway® Duo Microcatheter	167	0.35	0.25	2.1/1.3	1

Dead space of BALT® SONIC 1.2F (165cm) Microcatheter with MicroVention adaptor is approximately 0.17mL

MicroVention TERUMO

INDICATIONS FOR USE:
The PHIL™ Device is intended for use in the embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

CE 0297

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