EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention Europe

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

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 and Accessories, Stents, Clot, and Foreign Body Retrieval Devices, Liquid Embolic System, Catheter and Microspheres and Embolic Protection Devices 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.	487703 MR2
Certificate unique ID	170711726
Effective date	2018-06-11
Expiry date	2021-12-26
Frankfurt am Main	2018-06-11

DQS Medizinprodukte GmbH

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Managing Director

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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.

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

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

Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS Intraluminal Support Device LVIS Jr. Intraluminal Support Device	III	1,2,3
	FRED® Flow Re-Direction Endoluminal Devices FRED Jr.® Flow Re-Direction Endoluminal Devices	III	1,3
	CASPER JRX Carotid Artery Stent System	III	1,3
	Roadsaver Carotid Artery Stent System	III	1,3
	CASPER Peripheral Vascular Stent System	IIb	1,3
	RENZAN Peripheral Vascular Stent System	IIb	1,3
Clot Retriever	ERIC JRetrieval Device	III	1,2

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Device Groups:	Devices:	Risk Class	Production Site
Liquid Embolic System	PHIL Liquid Embolic System	III	1
Catheter	SOFIA Distal Access Catheter	III	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		
	KANSHAS Drug Coated Balloon	III	1,2
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 Aneurysm Embolization System	III	1