EC DECLARATION OF CONFORMITY

FD08-001, Rev. R

We, MicroVention, Inc., located in Tustin, California, USA declare according to Directive 93/42/EEC Annex II (incl. section 4.) under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Directives 93/42/EEC Council Directive Concerning Medical Devices
Conformity Assessment Route
EC Design Examination: 411133 MRA (Section 4)
Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Traxcess 14 Guidewire*	GW1420040	III – Annex IX, Rule 7, Subclause 1	2018-05-27	35094
Traxcess 14EX Guidewire*	GW1420040X			
Traxcess 14 SELECT Guidewire	GW1420040S			
Traxcess 7 Mini	GW0721006M			
Traxcess 7 Mini XSoft	GW0721006S			
Traxcess Docking Wire*	GW14100EX	IIa- Annex IX, Rule 7		61281

Manufacturer/ Production Site:
MicroVention Inc,
1311 Valencia Avenue
Tustin, CA 92780 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main, Germany
Notified Body Number: 0297

EU Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Ashitaka Factory of Terumo Corp. *
150 Maimaigi-Cho
Fujinomiya, Sizuoka Japan

Intended Use: The Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Sal Palomares
Regulatory Affairs Director
MicroVention, Inc.

Tustin, CA 92780, USA — Place of Issue

28 June 2018 — Date of Issue

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:36:48 EET
Reason: MoldSign Signature
Location: Moldova

Expiry Date: 2023-05-26
Prepared for Romania

DCMicroVention Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

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

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
Certificate registration No.: 487703 MR2
Certificate unique ID: 170711726
Effective date: 2018-06-11

MicroVention Europe

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

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

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170711726
Effective date: 2018-06-11

MicroVention Europe

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

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

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

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

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
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

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

MicroVention, Inc.

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

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 V-Grip® PLUS Detachment Controller WEB Detachment Controller AZUR® Detachment Controller	IIa IIa IIa IIa	1 1 1 1

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

MicroVention, Inc.

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

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

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

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		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 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

CERTIFICATE

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 **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device and Microspheres.

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.	487703 MP2016
Certificate unique ID	170726669
Effective date	2018-10-31
Expiry date	2019-12-26
Frankfurt am Main	2018-10-31

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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