EC DECLARATION OF CONFORMITY

FD15-0038, Rev. E

We, MicroVention Europe, located in France, declare according to Directive 93/42/EEC Annex II (excl. 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:

Full Quality Assurance: 487703 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN Code
HydroPearl™ Microspheres	8HP2S75 8HP2S200 8HP2S400 8HP2S600 8HP2S800 8HP2S1100	IIb– Annex 9, rule 8	2016-12-27	60938

Manufacturer	Notified Body	Production Site
MicroVention Europe 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	**DQS Medizinprodukte GmbH** Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	**MicroVention, Inc.** 1311 Valencia Avenue Tustin, CA 92780 USA

Intended Use: The HydroPearl™ microspheres are intended to occlude blood vessels for therapeutic or adjunctive purposes in hypervascularized tumors, hepatocellular carcinoma, uterine fibroids, benign prostatic hyperplasia, peripheral arteriovenous malformations, tumors of the neck, torso and skeletal system, bleeding and trauma and pre-operative reduction of bleeding.

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.

Cynthia Valenzuela
Regulatory Affairs Manager
MicroVention Europe

Saint-Germain-en-Laye
Place of Issue

28SEP2017
Date of Issue

Expiry Date: 2021-12-26

MICROVENTION EUROPE
30 bis rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
Tel: 01 39 21 77 46 - Fax: 01 39 21 16 01
R.C.S. 440 775 674

MicroVention Europe S.A.R.L. au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) : 20 Quatar rue Schnapper – 78100 Saint-Germain-en-Laye
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 – E-mail : contact-europe@microvention.com

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:13:34 EET
Reason: MoldSign Signature
Location: Moldova

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, Microspheres, Embolic Protection Devices 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.	487703 MR2
Certificate unique ID	170690242
Effective date	2017-08-14
Expiry date	2021-12-26
Frankfurt am Main	2017-08-14

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170690242
Effective date: 2017-08-14

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

Distribution Site:

MicroVention, Inc.
1800 E. Wilshire Ave.
Santa Ana, CA 92705
United States of America

Device Groups:	Devices:	Risk Class	Production Site
Stents	LVIS Intraluminal Support Device LVIS Jr. Intraluminal Support Device	III	1, 2
	FRED® Flow Re-Direction Endoluminal Devices FRED Jr.® Flow Re-Direction Endoluminal Devices	III	1,2
	CASPER™ RX Carotid Artery Stent System	III	1,2
	Roadsaver™ Carotid Artery Stent System	III	1,2
	CASPER™ Peripheral Vascular Stent System	IIb	1
Clot Retriever	ERIC ™ Retrieval Device	III	1
Liquid Embolic System	PHIL™ Liquid Embolic System	III	1
Catheter	SOFIA™ Distal Access Catheter SOFIA™ PLUS Catheter SOFIA™ Guiding Catheter	III	1,2

Annex to certificate
Certificate registration No.: 487703 MR2
Certificate unique ID: 170690242
Effective date: 2017-08-14

MicroVention Europe

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

Device Groups:	Devices:	Risk Class	Production Site
Microspheres	HydroPearl Microspheres LifePearl Microspheres	IIb	1
EPS – Embolic Protection Device	Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1,2
Aneurysm Embolization Device	WEB™ Aneurysm 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 and Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices and Liquid Embolic System and Embolic Protection Device.

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:

EN ISO 13485 : 2012 + AC : 2012

Certificate registration no.	487703 MP2012
Certificate unique ID	170659980
Effective date	2016-12-27
Expiry date	2019-12-26
Frankfurt am Main	2016-11-21

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany

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 and Microspheres 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	170670034
Effective date	2016-12-10
Expiry date	2019-10-31
Frankfurt am Main	2016-12-10

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170670034
Effective date: 2016-12-10

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

3 MicroVention, Inc.
Production Site
75 Columbia,
Aliso Viejo, CA 92656
United States of America

Distribution Site:

MicroVention, Inc.
1800 E. Wilshire Ave.
Santa Ana, CA 92705
United States of America

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170670034
Effective date: 2016-12-10

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 – Standard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 and 3D - Complex – Complex 10 & 18, Compass 10 & 18, - COSMOS® 10 & 18 - VFC™	III	1, 2
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, HydroSoft® 10 - HydroFill® - HydroFrame® 10 & 18	III	1
	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 AZUR PURE Peripheral Coil System, Pushable 18 & 35 (AZUR PURE)	IIb	1,2
Detachment Controller Units		V-Grip® Detachment Controller V-Grip® PLUS Detachment Controller	IIa IIa	1 1
		AZUR® Detachment Controller	IIa	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170670034
Effective date: 2016-12-10

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 Traxcess® 14 EX Guidewire Traxcess® 14 SELECT Guidewire	III	1
		Traxcess® Docking Wire	IIa	1
Catheters		Chaperon® Guiding Catheter System	III	1
		Headway® 17 Advanced Soft Microcatheter		1,2
		Headway® 17 Advanced Microcatheter		1,2
		Headway® 21 Microcatheter		1,2
		Headway® 27 Microcatheter		1,2
		Headway Duo Microcatheter		1,2
		Scepter C™ Occlusion Balloon Catheter		1,2
		Scepter XC™ Occlusion Balloon Catheter		1,2
		SOFIA™ Distal Access Catheter		1,2
		SOFIA™ PLUS Catheter		1,2
		SOFIA™ Guiding Catheter		1,2
Stents		LVIS™ Intraluminal Support Device LVIS Jr.™ Intraluminal Support Device FRED® Flow Re-Direction Endoluminal Devices FRED Jr.® Flow Re-Direction Endoluminal Devices CASPER™ RX Carotid Artery Stent System Roadsaver Carotid Artery Stent System	III	1,2
		CASPER™ Peripheral Vascular Stent System	IIb	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170670034
Effective date: 2016-12-10

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Clot Retriever		ERIC™ Retrieval Device	III	1
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1
Microspheres		HydroPearl Microspheres LifePearl Microspheres	IIb	1
EPS – Embolic Protection Device		Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1,3

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	170694175
Effective date	2017-11-03
Expiry date	2022-11-02
Frankfurt am Main	2017-11-03

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170694175
Effective date: 2017-11-03

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: 170694175
Effective date: 2017-11-03

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 – Standard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 and 3D - Complex – 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 AZUR PURE Peripheral Coil System, Pushable 18 & 35 (AZUR PURE)	IIb	1,2,3
Detachment Controller Units		V-Grip® Detachment Controller	IIa	1
		V-Grip® PLUS Detachment Controller	IIa	1
		WEB Detachment Controller	IIa	
		AZUR® Detachment Controller	IIa	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170694175
Effective date: 2017-11-03

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 Traxcess® 14 EX Guidewire Traxcess® 14 SELECT Guidewire Traxcess® 7 Mini Traxcess® 7 Mini XSoft	III	1
		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		1,3
		SOFIA™ PLUS Catheter		1,3
		SOFIA™ Guiding Catheter		1,3
		VIA™ 33 Microcatheter		1,3
		VIA™ 27 Microcatheter		
		VIA™ 21 Microcatheter		
		VIA™ 17 Microcatheter		
		Wedge Microcatheter		1
Stents		LVIS™ Intraluminal Support Device	III	1,3
		LVIS Jr.™ Intraluminal Support Device		
		FRED® Flow Re-Direction Endoluminal Devices		
		FRED Jr.® Flow Re-Direction Endoluminal Devices		
		CASPER™ RX Carotid Artery Stent System		
		Roadsaver Carotid Artery Stent System		

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170694175
Effective date: 2017-11-03

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Peripheral vascular stent system		CASPER™ Peripheral Vascular Stent System	IIb	1
Clot Retriever		ERIC™ Retrieval Device	III	2
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1
Microspheres		HydroPearl Microspheres LifePearl Microspheres	IIb	1
EPS – Embolic Protection Device		Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1