EC DECLARATION OF CONFORMITY

FD08-014 / AF

We, MicroVention, Inc., located in Tustin, California, USA 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:
411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
AZUR Peripheral Coil System	See attached list	IIb – Annex 9, rule 8	2018-06-11	60941

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

Notified Body:
DQS 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(s) :
MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656, USA

MicroVention Costa Rica SRL
Zona Franca Coyol
Alajuela, Costa Rica

Intended Use: The Azur Peripheral Embolization Coil System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

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, Inc.

Tustin, CA 92780, USA
Place of Issue

11 JUL 2018
Date of Issue

Expiry Date: 2022-11-02

Digitally signed by Grabazei Alexandru
Date: 2019.03.28 20:39:55 EET
Reason: MoldSign Signature
Location: Moldova

MASTER

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

AZUR Peripheral Coil System

I - AZUR Detachable (18 and 35) Coil

AZUR Detachable (18) Coil (Helical)		
45-480202	45-480510	45-481015
45-480204	45-480515	45-481020
45-480302	45-480520	45-481215
45-480305	45-480610	45-481220
45-480310	45-480615	45-481515
45-480405	45-480620	45-481520
45-480410	45-480810	45-481530
45-480415	45-480815	45-482020
45-480420	45-480820	45-482030
45-480505	45-481010	
AZUR Detachable (35) Coil (Helical)		
45-450305	45-450610	45-451215
45-450405	45-450615	45-451220
45-450410	45-450620	45-451230
45-450415	45-450815	45-451520
45-450505	45-450820	45-451530
45-450510	45-451015	45-452020
45-450515	45-451020	45-452030

II - AZUR Pushable (18 and 35) Coil

AZUR Pushable (18) Coil System		
45-280202	45-280506	45-280810
45-280302	45-280510	45-280814
45-280304	45-280514	45-280820
45-280402	45-280606	45-281014
45-280404	45-280610	45-281020
45-280406	45-280614	
45-280504	45-280620	
AZUR Pushable (35) Coil System		
45-250404	45-250614	45-251020
45-250406	45-250806	45-251514
45-250504	45-250810	45-251520
45-250506	45-250814	45-251614
45-250510	45-250820	45-251620
45-250606	45-251010	45-250304
45-250610	45-251014	

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III- AZUR Detachable (18 and 35) Framing Coils

AZUR Detachable Framing (18) Coil System		
45-680410	45-680923	45-681434
45-680512	45-681026	45-681639
45-680615	45-681128	45-681844
45-680717	45-681231	45-682050
45-680820	45-681332	
AZUR Detachable Framing (35) Coil System		
45-650820	45-651434	45-652050
45-651026	45-651639	
45-651231	45-651844	

IV- AZUR Injectable (18 and 35) Coils

AZUR Injectable (18) Coil System		
55-180202	55-180501	55-180810
55-180302	55-180504	55-180815
55-180304	55-180506	55-180820
55-180402	55-180510	55-181010
55-180404	55-180605	55-181015
55-180406	55-180610	
55-180410	55-180615	
AZUR Injectable (35) Coil System		
55-350405	55-350620	55-351020
55-350410	55-350810	55-351030
55-350505	55-350815	55-351010
55-350510	55-350820	55-351020
55-350610	55-351010	55-351030

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V- AZUR PURE Pushable Coil System

AZUR PURE (18) System		
45-080302	45-080506	45-080614
45-080402	45-080606	45-080814
45-080304	45-080410	45-081014
45-080404	45-080510	45-080620
45-080504	45-080610	45-080820
45-080306	45-080810	45-081020
45-080406	45-080514	
AZUR PURE (35) System		
45-050404	45-050806	45-051010
45-050504	45-050510	45-050714
45-050406	45-050610	45-050814
45-050506	45-050710	45-051014
45-050606	45-050806	45-051514
45-050706	45-050810	

VI- AZUR CX Detachable Coil System

AZUR CX Detachable (18) Coil System		
45-780413	45-780828	45-781434
45-780516	45-780928	45-781639
45-780620	45-781032	45-781836
45-780724	45-781238	45-782040
45-780202	45-780204	45-780304
45-780308		

AZUR CX Detachable (35) Coil System		
45-750407	45-750812	45-751632
45-750511	45-750824	45-752039
45-750609	45-751019	
45-750617	45-751324	

MicroVention 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, 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
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Effective date: 2017-11-03

MicroVention, Inc.

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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.
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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

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

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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	170728800
Effective date	2018-12-01
Expiry date	2022-11-02
Frankfurt am Main	2018-12-01

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: 170728800
Effective date: 2018-12-02

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

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170728800
Effective date: 2018-12-02

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 & 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: 170728800
Effective date: 2018-12-02

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	1,2
		Traxcess® 14 EX Guidewire		
		Traxcess® 14 SELECT Guidewire		
		Traxcess® 7 Mini Guidewire		
		Traxcess® 7 Mini XSoft Guidewire		
		Traxcess® Docking Wire	IIa	1,2
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		2,3
		Scepter XC™ Occlusion Balloon Catheter		2,3
		SOFIA™ Distal Access Catheter		1,3
		SOFIA™ Select Catheter		1,3
		SOFIA™ PLUS Catheter		1,3
		SOFIA™ Flow PLUS Catheter		1,3
		SOFIA™ Guiding Catheter		1,3
		SOFIA™ Flow Catheter		1,3
		KANSHAS Drug Coated Balloon		1
		VIA™ 17 Microcatheter		2
		VIA™ 21 Microcatheter		2
		VIA™ 27 Microcatheter		2
		VIA™ 33 Microcatheter		2
		Wedge Microcatheter		1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170728800
Effective date: 2018-12-02

MicroVention, Inc.

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Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,3
		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™ RX Carotid Artery Stent System		1,3
		Roadsaver Carotid Artery Stent System		1,3
Peripheral vascular stent system		RENZAN™ Peripheral Vascular Stent System	IIb	1,3
Clot Retriever		ERIC™ Retrieval Device	III	1
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1
Microspheres		HydroPearl Microspheres	IIb	1
		LifePearl Microspheres	III	1
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1
		Nanoparasol Embolic Protection System		
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	2
Aspiration Syringe Kit		Aspiration Syringe Kit	Is	1