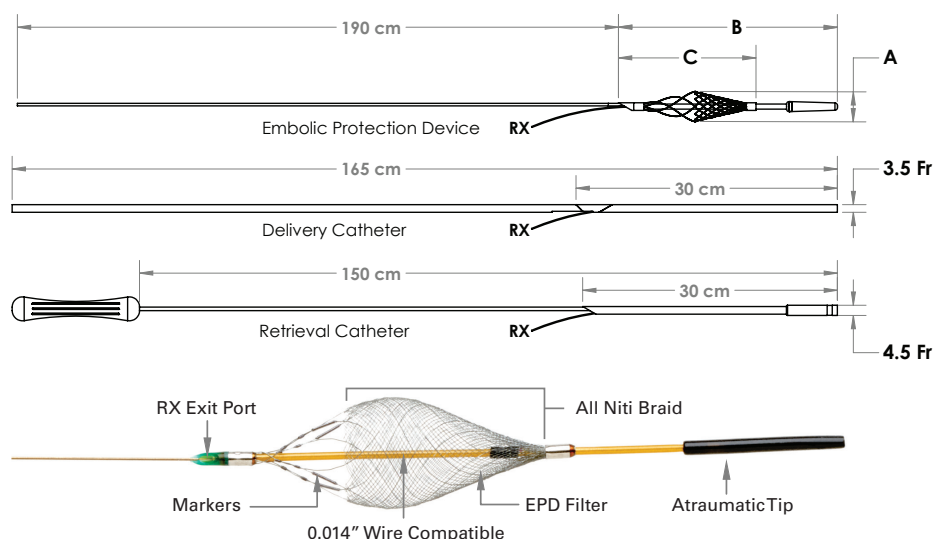


Micromesh technology for acute embolic protection.

EmPro® Embolic Protection System

1 per box / Includes delivery catheter and retrieval catheter

Catalog Number	Device Size	Ref. Vessel Size (mm)	Dimension A (mm)	Dimension B (mm)	Dimension C (mm)
EP4514C-190	Small	3.0 – 4.5mm	5.2mm	36.3mm	19.6mm
EP6514C-190	Large	4.5 – 6.5mm	7.2mm	42.7mm	23.1mm



Design Benefits

- Concentric filter design
- Micromesh technology for embolic protection
- Complete peel away

Features¹

- Good wall apposition
- Highly flexible
- Great trackability
- Designed to provide rapid deployment

Technical Specifications

- **Material:** All Nitinol w/Tantalum Markers
- **Construction:** Braided hybrid mesh
- **Compatibility:** Compatible with 0.014\" guidewire

INDICATIONS FOR USE:

The EmPro® Embolic Protection System is indicated for use as a guidewire to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0 and 6.5 mm.

For Healthcare Professional Use Only.

This product is not approved by FDA for marketing and distribution in US.

¹Data on file MicroVention (TR14-192, TR16-142, TR16-179).



CERTIFICATE



This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvour
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 Devices 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 170736547

Effective date 2019-11-14

Expiry date 2022-11-13

Frankfurt am Main 2019-11-14



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

EC DECLARATION OF CONFORMITY

RF 19-0053 Rev. C

DC Number: 20-06556

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, declare according to Directive 93/42/EEC Annex II 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.

Council Directive 93/42/EEC


Conformity Assessment Procedure Performed:

EC Design Examination Certificate <input checked="" type="checkbox"/> (Annex II.4) <u>524858 MRA</u> Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> (Annex II.3) <u>487703 MR2</u> Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
Empro™ Embolic Protection System	EP4514C-190 EP6514C-190	III – Annex 9, rule 7	58112

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvour 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA MicroVention, Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.

DocuSigned by:

Signer Name: Irina Kulinets
Signing Reason: I approve this document
Signing Time: 10/15/2020 | 5:36:47 PM PDT
F47F956B62B5424CBF023EA37BA8F01F

Irina Kulinets
Sr. Vice President, Regulatory
Affairs, Quality, Clinical Research
MicroVention Europe SARL

Saint-Germain-en-Laye,
France
Place of Issue

10/15/2020
Date of Issue

Certificate Expiry Date: 2024-05-26



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.



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



Annex to certificate
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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
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Effective date: 2018-12-02

MicroVention, Inc.

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United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,3
		LVIS Jr.™ Intraluminal Support Device		
		FRED® Flow Re-Direction Endoluminal Device	III	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



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
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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.



Annex to certificate
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Effective date: 2018-12-02

MicroVention, Inc.

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Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
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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	IIa	1
		V-Grip® PLUS Detachment Controller	IIa	1
		WEB Detachment Controller	IIa	1
		AZUR® Detachment Controller	IIa	1



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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
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United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,3
		LVIS Jr.™ Intraluminal Support Device		
		FRED® Flow Re-Direction Endoluminal Device	III	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