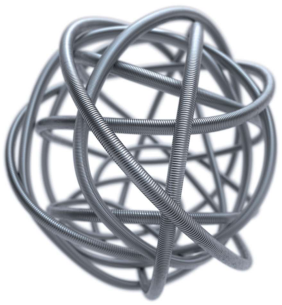
AZUR® FRAMING COIL

Embolization coils

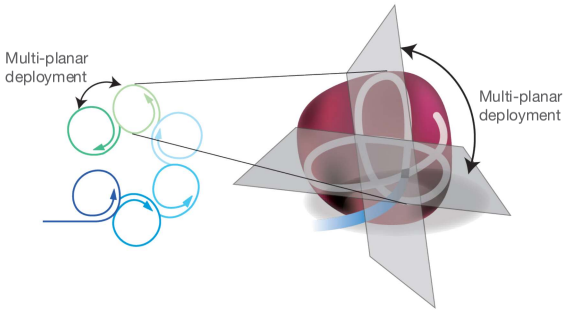


AZUR® Framing coil is a platinum coil that offers a three-dimensional shape to cover the aneurysm wall or the inner lumen of an artery.

This coil is intended to give greater stability and safety in challenging situations such as wide neck aneurysm or high flow territories.

Product Characteristics

- *Reduces compartmentalization and provides greater coverage with a three-dimensional approach to embolization*
- *Provides even distribution of coil loops at the lesion*
- *No time restriction for repositioning*
- *Longer coils for added stability (up to 50 cm)*
- *Conforms to diverse morphologies*
- *Facilitates placement of multiple consecutive framing coils*
- *Each successive loop gently rotates course, changing direction as it is deployed*



General Specifications

Core material	Platinum
Delivery type	Electromechanical detachment
Coating	None
Coil diameter	0.018" (0.46 mm)
Delivery wire length	175 cm
Catheter compatibility	Microcather – 0.021" inner lumen

Item Specifications

Loop diameter (mm)	Length (cm)	Item reference
8	20	45-680820
10	26	45-681026
14	34	45-681434
20	50	45-682050

Please quote above item reference codes when placing an order

IS616/39GB0616ITI

AZUR® PERIPHERAL HYDROCOIL®

Embolization coils

AZUR® peripheral HydroCoil® embolization system combines a platinum coil and an expandable hydrogel polymer. The hydrogel coating expands in the direction of less resistance to fill space when introduced into the bloodstream.

Product Characteristics

Expanding Hydrogel technology that delivers:
- *Permanent mechanical occlusion with less reliance on thrombus formation*
- *Improved volume filling, packing density, and occlusion efficacy*
- *Mechanical stability*
- *Increased delivery control and long-term durability*

AZUR® detachable system:
- *First detachable system dedicated to peripheral use*
- *Can be retracted and repositioned, reducing the risk of migration*
- *Detached in less than one second at the push of a button*

AZUR® pushable system has been designed to be pushed by a wire without the need of a dedicated coil pusher.

Detachable system

General Specifications

Coil type	Catheter / Microcatheter	Max length
AZUR® Detachable 18	0.021" (0.53 mm)	150 cm
AZUR® Detachable 35	0.038" (0.97 mm)	150 cm

Item Specifications

System	Loop (mm)	Length (cm)						
		2	4	5	10	15	20	30
0.018" AZUR® Detachable 18	2	45-480202	45-480204	—	—	—	—	—
	3	45-480302	—	45-480305	45-480310	—	—	—
	4	—	—	45-480405	45-480410	45-480415	45-480420	—
	6	—	—	—	45-480610	45-480615	45-480620	—
	8	—	—	—	45-480810	45-480815	45-480820	—
	10	—	—	—	45-481010	45-481015	45-481020	—
	12	—	—	—	—	45-481215	45-481220	—
	15	—	—	—	—	45-481515	45-481520	45-481530
	20	—	—	—	—	—	45-482020	45-482030
0.035" AZUR® Detachable 35	3	—	—	45-450305	—	—	—	—
	4	—	—	45-450405	45-450410	45-450415	—	—
	5	—	—	45-450505	45-450510	45-450515	—	—
	6	—	—	—	45-450610	45-450615	45-450620	—
	8	—	—	—	—	45-450815	45-450820	—
	10	—	—	—	—	45-451015	45-451020	—
	12	—	—	—	—	45-451215	45-451220	45-451230
	15	—	—	—	—	—	45-451520	45-451530
	20	—	—	—	—	—	45-452020	45-452030

Product description	Item reference
AZUR® Detachment Controller for use with Detachable System - Pack of 5 units	45-4001

Please quote above item reference codes when placing an order

Pushable system

General Specifications

Coil type	Catheter / Microcatheter	Max length
AZUR® Pushable 18	0.021" – 0.022" (0.53 – 0.56 mm)	N/A
AZUR® Pushable 35	0.041" – 0.047" (1.04 – 1.19 mm)	N/A

Item Specifications

System	Loop (mm)	Length (cm)					
		2	4	6	10	14	20
0.018" AZUR® Pushable 18	2	45-280202	—	—	—	—	—
	3	45-280302	45-280304	—	—	—	—
	4	45-280402	45-280404	45-280406	—	—	—
	5	—	45-280504	45-280506	45-280510	45-280514	—
	6	—	—	45-280606	45-280610	45-280614	45-280620
	8	—	—	—	45-280810	45-280814	45-280820
	10	—	—	—	—	45-281014	45-281020
0.035" AZUR® Pushable 35	4	—	45-250404	45-250406	—	—	—
	5	—	—	45-250506	45-250510	—	—
	6	—	—	—	45-250610	45-250614	—
	8	—	—	—	45-250810	45-250814	45-250820
	10	—	—	—	—	45-251014	45-251020
	15	—	—	—	—	45-251514	45-251520
	16	—	—	—	—	—	45-251620

Please quote above item reference codes when placing an order

IS616/40GB0616IT1

AZUR® CX

Embolization coils

Introducing a unique concept.
The first and only peripheral HydroCoil® with cross-sectional coverage and the benefits of patented hydrogel technology, allowing more control in high-flow areas.

Product Characteristics

Cross-sectional coverage
- *Complex shape with variable diameter loops for optimal coverage in high-flow areas*
- *Smaller[1] first loop to ease coil placement in tortuous anatomy*

Soft, flexible design
- *Second generation Hydrogel technology on coil interior to enhance softness profile*
- *Solid coil core to increase volume fill*

Ease of deployment
- *AZUR Detachment System to deliver precise positioning and placement*
- *Progreat Double Marker Microcatheter System to enhance visibility during detachment*

1 Compared to Azur Hydrocoil

Detachment controller for use with detachable systems / pack of 5	
Product code	**Product description**
45-4001	AZUR detachment controller

Microcatheter ID requirements			
Coil type	**Microcatheter ID**		**Repositioning time**
	Inches	**Millimeters**	
AZUR CX 18	0.021 - 0.027	0.53 - 0.69	30 minutes

Please quote above item reference codes when placing an order

Item Specifications

Detachable 0.018'' system / pack of 1		
Product code	**Loop diameter**	**Length****
45-780413	4 mm	13 cm
45-780516	5 mm	16 cm
45-780620	6 mm	20 cm
45-780724	7 mm	24 cm
45-780828	8 mm	28 cm
45-780928	9 mm	28 cm
45-781032	10 mm	32 cm
45-781238	12 mm	38 cm
45-781434	14 mm	34 cm
45-781639	16 mm	39 cm
45-781836	18 mm	36 cm
45-782040	20 mm	40 cm

0.018" = 0.46mm

** Length is calculated from the tip of the coil to the point of connection with the pusher wire when the coil is straight.

Detachment controller for use with detachable systems / pack of 5	
Product code	**Product description**
45-4001	AZUR detachment controller

Catether compatibility CX35			
Coil type	**Catheter ID**		**Reposition time**
	Inches	**Millimeters**	
AZUR DETACHABLE 35	0.041 - 0.047	1.04 - 1.19	20 minutes

Please quote above item reference codes when placing an order

Item Specifications

Detachable 0.035" system / pack of 1		
Product code	**Loop diameter**	**Length****
45-750407	4 mm	7 cm
45-750511	5 mm	11 cm
45-750609	6 mm	9 cm
45-750617	6 mm	17 cm
45-750812	8 mm	12 cm
45-750824	8 mm	24 cm
45-751019	10 mm	19 cm
45-751324	13 mm	24 cm
45-751632	16 mm	32 cm
45-752039	20 mm	39 cm

** Length is calculated from the tip of the coil to the point of connection with the pusher wire when the coil is straight.

IS616/41GB0616IT1

EC DECLARATION OF CONFORMITY

RF20-0022 Rev. B
ECN Number: 22-03348

We, MicroVention, Inc., located in Aliso Viejo, California, USA, 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 ☐ (Annex II.4) Not applicable **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 411133 MR2 (Excluding Section 4) **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
AZUR™ Peripheral Coil System	Refer to Table 1 below	Class IIb, Annex 9, Rule 8	60941

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

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:
Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:24:57 PM PDT
6A007ED64EB548AE8E3F9AB77A2F27F6

Amy Smith VP, Global Regulatory Affairs MicroVention, Inc.	Aliso Viejo, CA, USA Place of Issue	8/24/2022 Date of Issue

Certificate Expiry Date: 2024-05-26

MicroVention Inc., 35 Enterprise, Aliso Viejo, California, 92656, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

EC DECLARATION OF CONFORMITY

Table 1. Azur Model Numbers

Azur™ 18 Detachable Peripheral Coil System Helical HydroCoil™ Embolization System		
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™ 35 Detachable Peripheral Coil System Helical HydroCoil™ Embolization System		
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
Azur™ 18 Detachable Peripheral Coil System Framing Coil		
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™ 35 Detachable Peripheral Coil System Framing Coil		
45-650820	45-651434	45-652050
45-651026	45-651639	
45-651231	45-651844	
Azur™ CX18 Detachable Peripheral Coil System CX Coil		
45-780202	45-780620	45-781238
45-780204	45-780724	45-781434
45-780304	45-780828	45-781639
45-780308	45-780928	45-781836
45-780413	45-781032	45-782040
45-780516		
Azur™ CX35 Detachable Peripheral Coil System CX Coil		
45-750407	45-750812	45-751632
45-750511	45-750824	45-752039
45-750609	45-751019	
45-750617	45-751324	
AZUR™ 18 Pushable Peripheral 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™ 35 Pushable Peripheral Coil System		
45-250304	45-250610	45-251014
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	

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

MicroVention, Inc
35 Enterprise
Aliso Viejo
92656 USA

Our ref.: CAB, Phone: 069 95427-8211, Fax: -388
E-Mail: carrie-ann.brown@dqs-med.de

Frankfurt a. M.
2022-07-21

Certification confirmation letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.
We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.
DQS Medizinprodukte GmbH is registered as NB 0297.

Furthermore, DQS Medizinprodukte GmbH is an accredited certification body for management systems under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems according to DIN EN ISO 13485:2016.

DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 411133MR2 with the unique certification ID 170776096 valid from 2021-04-29 until 2024-05-26) and the **corresponding EC Design Examination certificates for class III medical devices** have been issued to the following auditee:

MicroVention, Inc
35 Enterprise
Aliso Viejo
92656 USA

in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.

DQS Medizinprodukte as the Notified Body hereby acknowledges that the Address of MicroVention, Inc, 1311 Valencia Ave.Tustin, CA, 92780 United States of America has been changed to 35 Enterprise, Aliso Viejo, 92656 United States of America as of 22.06.2022. The existing **Annex II and EC Design Examination certificates** remain valid per this confirmation letter.

Yours faithfully,
DQS Medizinprodukte GmbH

i.A. Francine Emakam
Regulatory Affairs Manager

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, Aspiration Devices, 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	170776096
Effective date	2021-04-29
Expiry date	2024-05-26
Frankfurt am Main	2021-04-29

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: 170776096
Effective date: 2021-04-29

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: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	MicroPlex Coil System (MCS) & HydroCoil Embolic System (HES) with V-Trak Delivery System	MicroPlex 10 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos10 - HyperSoft 3D - HyperSoft Helical - Helical 10 - VFC - Compass 10 - Complex 10	III	1,2,3
		MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos 18 - Helical 18 - Compass 18 - Complex 18	III	1,2,3
		HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 10 - HydroSoft Helical - HydroSoft 3D - HydroFill	III	1,2,3
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 18	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® HydroCoil Pushable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® Framing Detachable Coils 18 & 35	IIb	1,2,3
		AZUR® Injectable Coil System 18 & 35	IIb	1,2,3
		AZUR Detachable 18	IIb	1,2,3
		AZUR PURE Pushable Coil System 18 & 35	IIb	1,2,3
		AZUR CX Detachable 18 & 35	IIb	1,2,3
		AZUR Vascular Plug	IIb	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Detachment Controller Units		V-Grip® Detachment Controller	IIa	1,2
		V-Grip® PLUS Detachment Controller	IIa	1,2
		WEB Detachment Controller	IIa	1,2
		AZUR® Detachment Controller	IIa	1,2
Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires)		Traxcess® 14 Guidewire	III	1,2
		Traxcess® 14 EX Guidewire	III	1,2
		Traxcess® 14 SELECT Guidewire	III	1,2
		Traxcess® 7 Mini Guidewire	III	1,2
		Traxcess® 7 Mini XSoft Guidewire	III	1,2
		Traxcess® Docking Wire	IIa	1,2
		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter	III	1,2,3
		Headway® 17 Advanced Microcatheter	III	1,2,3
		Headway® 21 Microcatheter	III	1,2,3
		Headway® 27 Microcatheter	III	1,2,3
		Headway Duo Microcatheter	III	1,2,3
		Scepter C™ Occlusion Balloon Catheter	III	1,2,3
		Scepter XC™ Occlusion Balloon Catheter	III	1,2,3
		Scepter Mini™ Occlusion Balloon Catheter	III	1,2,3
		SOFIA™ Distal Access Catheter	III	1,2,3
		SOFIA™ Select Catheter	III	1,2,3
		SOFIA™ PLUS Catheter	III	1,2,3
		SOFIA™ Flow PLUS Catheter	III	1,2,3
		SOFIA™ Guiding Catheter	III	1,2,3
		SOFIA™ Flow Catheter	III	1,2,3
		SOFIA® EX Catheter	III	1,2,3
		KANSHAS Drug Coated Balloon	III	1
		VIA™ 17 Microcatheter	III	1,2
		VIA™ 21 Microcatheter	III	1,2
		VIA™ 27 Microcatheter	III	1,2
		VIA™ 33 Microcatheter	III	1,2
		Wedge Microcatheter	III	1,2,3
		PG Pro Microcatheter	IIa	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

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	1,2,3
		LVIS™ EVO™ Intraluminal Support Device	III	1,2,3
		LVIS™ X™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. X™ Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ X™ Intraluminal Support Device	III	1,2,3
		FRED™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED X™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		FRED OMEGA™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		CASPER™ RX Carotid Artery Stent System	III	1,2,3
		Roadsaver Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1,2
Microspheres		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,3
		Nanoparasol Embolic Protection System	III	1,3
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Kit		Aspiration Tubing Kit	Is	1,2
		Aspiration Syringe Kit	Is	1,2
BOBBY™ Balloon Guide Catheter		BOBBY™ Balloon Guide Catheter	III	1,2

CERTIFICATE

This is to certify that the company

MicroVention, Inc.

35 Enterprise
Aliso Viejo, CA, 92656
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.

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.	411133 MP2016
Certificate unique ID	170780788
Effective date	2022-07-07
Expiry date	2024-09-26
Frankfurt am Main	2022-07-07

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

DQS IS A MEMBER OF
IQNET

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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Effective date: 2022-07-07

MicroVention, Inc.

35 Enterprise
Aliso Viejo, CA, 92656
United States of America

Location	Scope
497135 **MicroVention, Inc.** 35 Enterprise Aliso Viejo, CA, 92656 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
499088 **MicroVention Costa Rica, S.R.L.** **Production Site** Zona Franca Coyol Alajuela Costa Rica	Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.