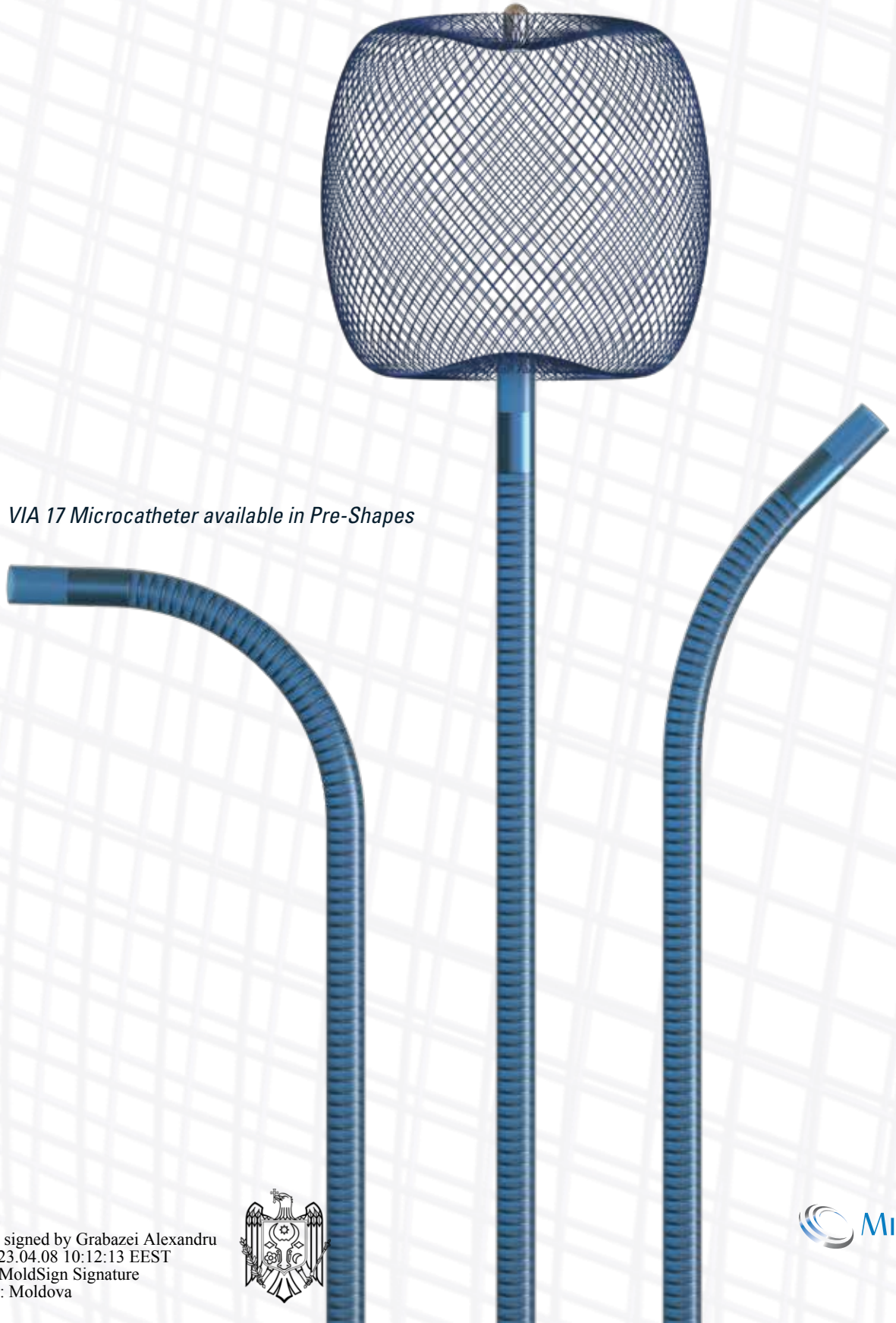
VIA™

Microcatheter

OUS

Control VIA Stability



VIA 17 Microcatheter available in Pre-Shapes

MicroVention™ TERUMO

VIA Microcatheter

Product Name	Tip Shape	Product Code	Inner Diameter			Distal Outer Length			Proximal Outer Length			Usable Length
			(F)	(in)	(mm)	(F)	(in)	(mm)	(F)	(in)	(mm)	(cm)
VIA 17	Straight	VIA-17-154-01	1.3	0.0175	0.44	2.2	0.029	0.74	2.5	0.032	0.81	154
VIA 17	45° Pre-Shape	VIA-17-154-45	1.3	0.0175	0.44	2.2	0.029	0.74	2.5	0.032	0.81	154
VIA 17	90° Pre-Shape	VIA-17-154-90	1.3	0.0175	0.44	2.2	0.029	0.74	2.5	0.032	0.81	154
VIA 21	Straight	VIA-21-154-01	1.6	0.021	0.53	2.5	0.033	0.84	2.8	0.036	0.91	154
VIA 27	Straight	VIA-27-154-01	2.1	0.027	0.69	3.0	0.039	0.99	3.2	0.042	1.07	154
VIA 33	Straight	VIA-33-133-01	2.5	0.033	0.84	3.4	0.045	1.14	3.8	0.050	1.27	133

Packed 1 per box; includes shaping mandrel

INDICATIONS FOR USE
VIA 21, 27, 33 - The VIA Microcatheter is intended for the introduction of non-liquid interventional devices (such as aneurysm embolization devices (e.g. WEB device / stents / flow diverters) and infusion of diagnostic (such as contrast media) or non-liquid therapeutic agents into the neuro, peripheral, and coronary vasculature.

VIA 17, 17 Preshaped 45°, 17 Preshaped 90° - The VIA Microcatheter is intended for the introduction of non-liquid interventional devices (such as aneurysm embolization devices (e.g WEB device / coils / stents) and infusion of diagnostic (such as contrast media) or non-liquid therapeutic agents into the neuro, peripheral, and coronary vasculature.

CONTRAINDICATIONS
The VIA Microcatheter is contraindicated for use with liquid embolic materials, such as n-butyl 2-cyanoacrylate or ethylene vinyl alcohol & DMSO (dimethyl sulfoxide).

Intended for Healthcare professional use only

MicroVention Worldwide
Innovation Center PH +1.714.247.8000
35 Enterprise
Aliso Viejo, CA 92656 USA
MicroVention UK Limited PH +44 (0) 191 258 6777
MicroVention Europe, S.A.R.L. PH +33 (1) 39 21 77 46
MicroVention Deutschland GmbH PH +49 211 210 798-0
Web **microvention.com**

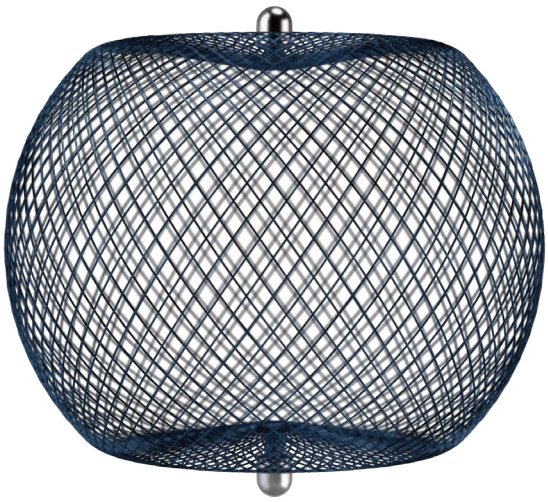
MicroVention™ TERUMO

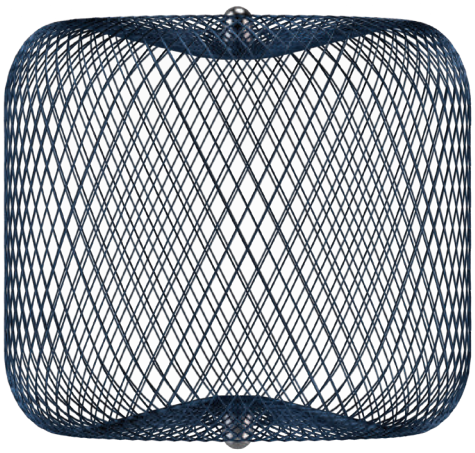
WEB™
Aneurysm
Embolization
System

INTRODUCING WEB™ 17 LOW PROFILE

Innovative Therapy for Aneurysm Treatment

EMEA





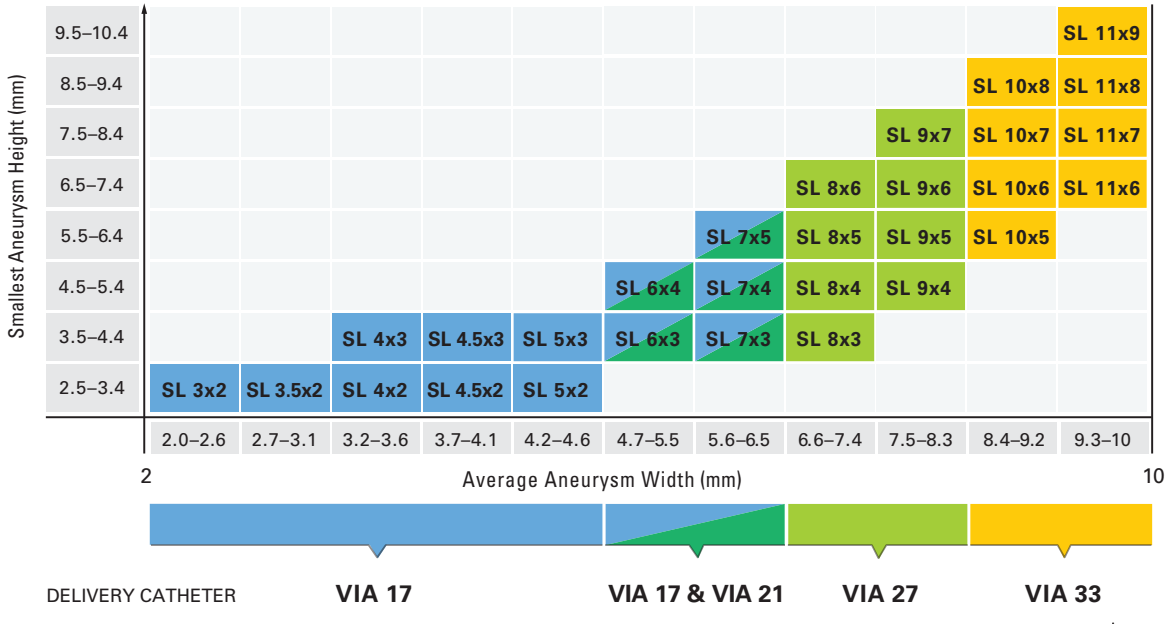
Aneurysm Therapy Solutions

MicroVention® TERUMO

Device Selection Tables

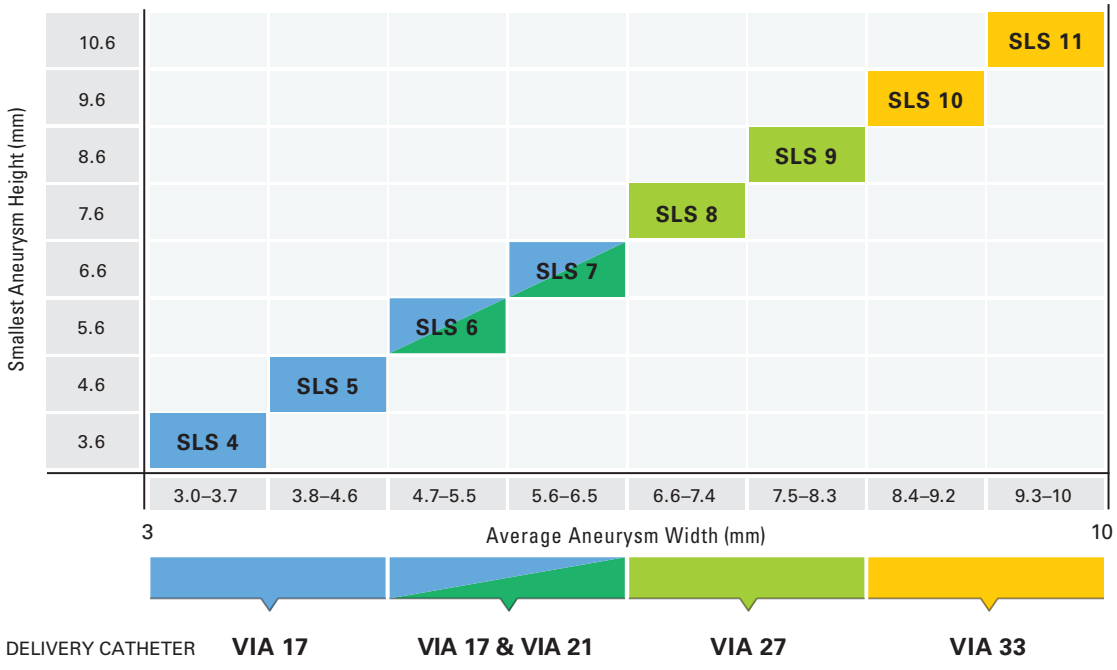
WEB™ SL Device Selection Table

Treat Aneurysms Between 2mm and 10mm



WEB™ SLS Device Selection Table

Treat Aneurysms Between 3mm and 10mm



WEB™ Device Part Numbers

WEB™ SL 

Name	Ref No.	Diameter (mm)	Height (mm)	Recommended Catheter
WEB SL 3×2	W5-3-2	3	2	VIA 17
WEB SL 3.5×2	W5-3.5-2	3.5	2	
WEB SL 4×2	W5-4-2	4	2	
WEB SL 4×3	W5-4-3	4	3	
WEB SL 4.5×2	W5-4.5-2	4.5	2	
WEB SL 4.5×3	W5-4.5-3	4.5	3	
WEB SL 5×2	W5-5-2	5	2	
WEB SL 5×3	W5-5-3	5	3	
WEB SL 6×3	W5-6-3	6	3	
WEB SL 6×4	W5-6-4	6	4	
WEB SL 7×3	W5-7-3	7	3	
WEB SL 7×4	W5-7-4	7	4	
WEB SL 7×5	W5-7-5	7	5	
WEB SL 6×3	W4-6-3	6	3	VIA 21
WEB SL 6×4	W4-6-4	6	4	
WEB SL 7×3	W4-7-3	7	3	
WEB SL 7×4	W4-7-4	7	4	
WEB SL 7×5	W4-7-5	7	5	
WEB SL 8×3	W2-8-3	8	3	VIA 27
WEB SL 8×4	W2-8-4	8	4	
WEB SL 8×5	W2-8-5	8	5	
WEB SL 8×6	W2-8-6	8	6	
WEB SL 9×4	W2-9-4	9	4	
WEB SL 9×5	W2-9-5	9	5	
WEB SL 9×6	W2-9-6	9	6	
WEB SL 9×7	W2-9-7	9	7	
WEB SL 10×5	W2-10-5	10	5	VIA 33
WEB SL 10×6	W2-10-6	10	6	
WEB SL 10×7	W2-10-7	10	7	
WEB SL 10×8	W2-10-8	10	8	
WEB SL 11×6	W2-11-6	11	6	
WEB SL 11×7	W2-11-7	11	7	
WEB SL 11×8	W2-11-8	11	8	
WEB SL 11×9	W2-11-9	11	9	

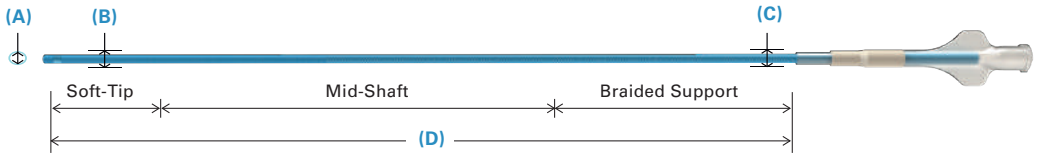
WEB™ SLS 

Name	Ref No.	Diameter (mm)	Height (mm)	Recommended Catheter
WEB SLS 4	W5-4-S	4	2.6	VIA 17
WEB SLS 5	W5-5-S	5	3.6	
WEB SLS 6	W5-6-S	6	4.6	
WEB SLS 7	W5-7-S	7	5.6	
WEB SLS 6	W4-6-S	6	4.6	VIA 21
WEB SLS 7	W4-7-S	7	5.6	
WEB SLS 8	W2-8-S	8	6.6	VIA 27
WEB SLS 9	W2-9-S	9	7.6	
WEB SLS 10	W2-10-S	10	8.6	VIA 33
WEB SLS 11	W2-11-S	11	9.6	

WEB™ Accessories Part Numbers

VIA™ Microcatheter

Name	Ref No.	(A) ID (inch)	(B) Distal OD (French)	(C) Proximal OD (French)	(D) Working Length (cm)	Tip Markers
VIA 17	VIA-17-154-01	0.0175″	2.2F	2.5F	154 cm	2
VIA 21	VIA-21-154-01	0.021″	2.5F	2.8F	154 cm	1
VIA 27	VIA-27-154-01	0.027″	3.0F	3.2F	154 cm	1
VIA 33	VIA-33-133-01	0.033″	3.4F	3.8F	133 cm	1

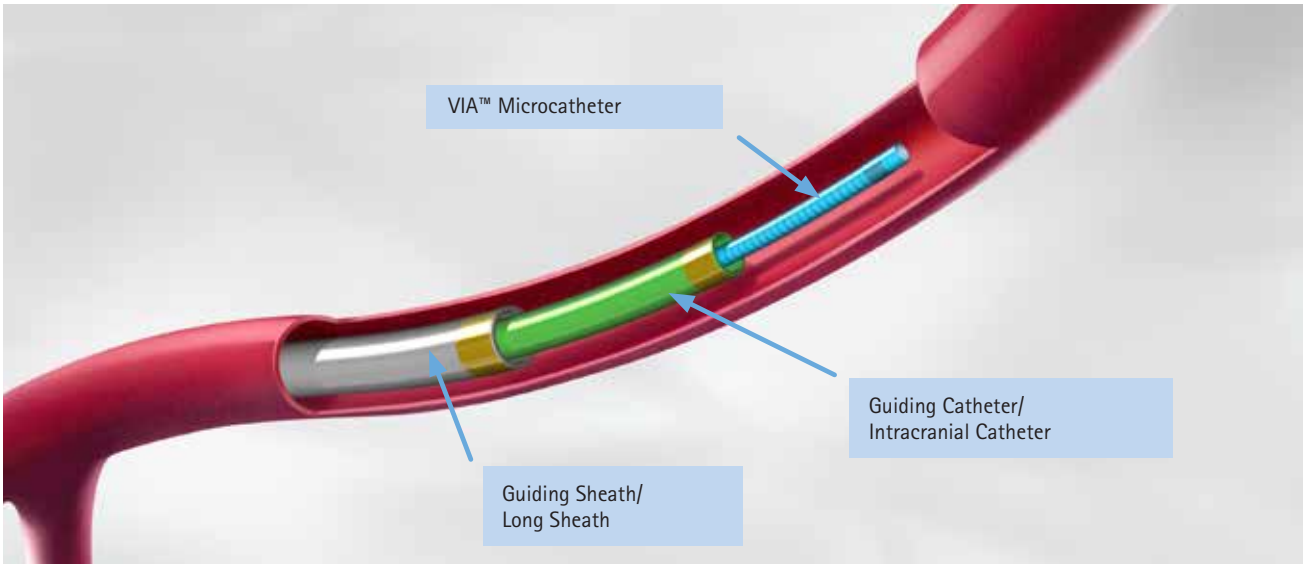


WEB™ Detachment Controller

Name	Ref No.
WDC: WEB™ Detachment Controller	WDC-1

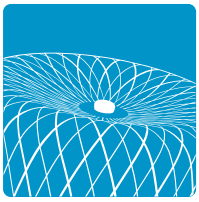
Access Technique & Compatibility

Triaxial Technique for Stable Distal Access



Access Devices Compatibility

WEB™ SL / SLS Device Width (mm)	VIA™ Microcatheter (Delivery Catheter)	Guiding Catheter / Intracranial Catheter	Guiding Sheath / Long Sheath
3 – 7	**VIA 17** ID: 0.0175" / 1.3F / 0.44 mm Distal OD: 2.2F / 0.029" / 0.74 mm Proximal OD: 2.5F / 0.032" / 0.81 mm Length: 154 cm	5F, 0.056" ID or larger, 90 – 125 cm long	6F: 80 / 90 cm long
6 – 7	**VIA 21** ID: 0.021" / 1.6F / 0.53 mm Distal OD: 2.5F / 0.033" / 0.84 mm Proximal OD: 2.8F / 0.036" / 0.91 mm Length: 154 cm	5F, 0.056" ID or larger, 90 – 125 cm long	6F: 80 / 90 cm long
8 – 9	**VIA 27** ID: 0.027" / 2.1F / 0.69 mm Distal OD: 3.0F / 0.039" / 0.99 mm Proximal OD: 3.2 F / 0.042" / 1.07 mm Length: 154 cm	6F, 0.070" ID or larger, 90 – 125 cm long	6F: 80 / 90 cm long
10 – 11	**VIA 33** ID: 0.033" / 2.5F / 0.84 mm Distal OD: 3.4F / 0.045" / 1.14 mm Proximal OD: 3.8F / 0.050" / 1.27 mm Length: 133 cm	6F, 0.070" ID or larger, 90 – 115 cm long	6F: 80 / 90 cm long



WEB™
Aneurysm
Embolization
System

The WEB™ Aneurysm Embolization System and VIA™ Microcatheter have both received the CE mark. The WEB™ Aneurysm Embolization System is not approved or available for sale or use in the United States.

INDICATIONS FOR USE:
The WEB™ Aneurysm Embolization System is a class III device intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms. For complete indications, potential complications, warnings and instructions, see instructions for use (IFU provided in the device). The WEB™ device is not currently listed in the LPPR (List des Produits et Prestations Remboursables).

The VIA™ Catheter is intended for the introduction of non-liquid interventional devices (such as coils/stents/flow diverters) and infusion of diagnostic (such as contrast media) or non-liquid therapeutic agents into the neuro, peripheral, and coronary vasculature.

Global Headquarters / Manufacturer
Sequent Medical, Inc.,
11 Columbia, Aliso Viejo, CA 92656 | USA
Office: +1-949 830 9600

Authorized European Representative
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11 rue Emile Zola – PB 2332, 38033 Grenoble Cedex 2 | France
Office +33-4 7686-4322

www.sequentmedical.com

CE 0297

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

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

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 411133 MP2016
Certificate unique ID: 170780788
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.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Sequent Medical Inc.

11A Columbia
Aliso Viejo, CA 92656
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:

Medical devices for the treatment of intravascular diseases according to 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.	456350 MR2
Certificate unique ID	170705029
Effective date	2018-03-01
Expiry date	2023-02-28
Frankfurt am Main	2018-02-02

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.: 456350 MR2
Certificate unique ID: 170705029
Effective date: 2018-03-01

Sequent Medical Inc.

11A Columbia
Aliso Viejo, CA, 92656
United States of America

Device family	Device	Class
Aneurysm Embolization Device	WEB™ Aneurysmen Embolization System	III
	Detachment Control Device	IIa
Microcatheter	VIA™ Microcatheter	III

EC DECLARATION OF CONFORMITY

RF18-0147, Rev. B

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:	535858 MRA (Section 4)
Full Quality Assurance:	411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity Date	GMDN Code
WEB Detachment Controller	WDC-1, WDC-2	IIa – Annex IX, Rule 9	2019-04-04	43978

Legal Manufacturer:
MicroVention, Inc.
1311 Valencia Avenue
Tustin, California 92780

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

European Representative:
MicroVention Europe, S.A.R.L.
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Sequent Medical, Inc.
11A Columbia
Aliso Viejo, California 92656

MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656

Intended Use: The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and un-ruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).
The WEB Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.

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.

J. Kulinets

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Place of Issue

4/30/2019

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