MicroVention®
TERUMO

Sofia® PLUS

Soft torqueable catheter Optimized For Intracranial Access

Sofia® Distal Access Catheter

Soft torqueable catheter Optimized For Intracranial Access

EXTREMELY TRACKABLE INTRACRANIAL

LARGE LUMEN SUPPORT CATHETERS

CE

Large inner diameter and enhanced softness for superior distal navigation and procedural versatility

SOFIA® PLUS
Soft torqueable catheter Optimized For Intracranial Access

SOFIA® Distal Access Catheter
Soft torqueable catheter Optimized For Intracranial Access

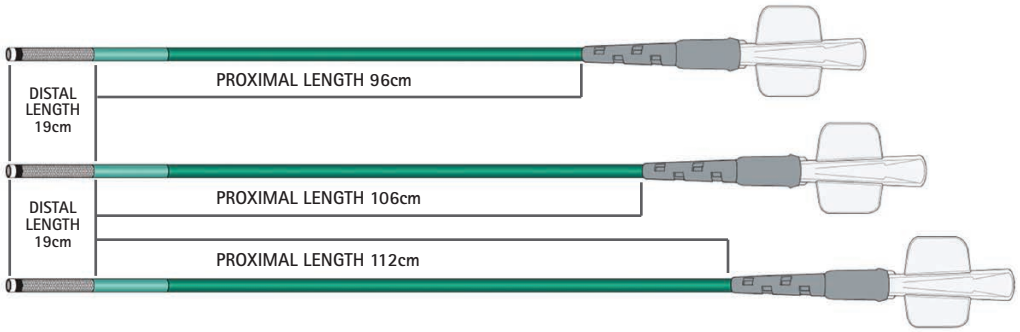
One unit per box, includes shaping mandrel and introducer sheath

PRODUCT CODE	CATHETER SIZE	PROXIMAL OD	DISTAL OD	ID	WORKING LENGTH	DISTAL LENGTH	PROXIMAL LENGTH	DISTAL TIP SHAPE
DA6115ST	6F	0.0825" / 2.1mm	0.0815" / 2.1mm	0.070"	115cm	19cm	96cm	Straight
DA6125ST	6F	0.0825" / 2.1mm	0.0815" / 2.1mm	0.070"	125cm	19cm	106cm	Straight
DA6131ST	6F	0.0825" / 2.1mm	0.0815" / 2.1mm	0.070"	131cm	19cm	112cm	Straight

SOFIA® 6F 115cm

SOFIA® 6F 125cm

SOFIA® 6F 131cm



Design Features

FEATURES	BENEFITS
0.070" Lumen	Wide Inner Lumen for Capture of Larger Clots*
Exceptionally Soft Distal Tip	Allows Smooth Bypass of the Ophthalmic Artery
Hybrid Braid and Coil Design	Provides Superior 1:1 Push Response
Steam Shapeable Tip and Torqueable Shaft	Ability to Steer Distal Tip Past Difficult Bifurcations
Enhanced Kink Resistance	Maintains Distal and Proximal Lumen Integrity

INDICATIONS FOR USE: The SOFIA® Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA® Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA® Catheter is not intended for use in coronary arteries.

*with FDA cleared Stentrievers

MicroVention, Inc., Worldwide Headquarters, 1311 Valencia Avenue, Tustin, CA 92780 USA
Phone: 714.247.8000 Customer Service: 800.990.8368

MicroVention® TERUMO

microvention.com

Sofia™ Distal Access Catheter

Soft torqueable catheter Optimized For Intracranial Access

Image courtesy of **Michael Marks,** MD
Stanford Hospital
Stanford, CA USA

SHAPABILITY

Steam shapability allows the Sofia™ catheter to overcome challenging anatomies

NAVIGATE

Exceptionally soft distal segment allows the Sofia™ catheter to navigate further distal

STABILITY

Hybrid braid & coil design enhances stability supporting distal navigation of interventional devices

KINK RESISTANCE

Inner layer coil reinforcement provides excellent kink resistance even in tortuous vessels

TORQUE

Braid overlay provides vital torque control for easier vessel selection in tortuous bends

SUPPORT

Designed for distal delivery and precise placement of the LVIS® and LVIS® Jr. Devices and Scepter Occlusion Balloon Catheters

LVIS® Intraluminal Support Device
LVIS® Jr. Intraluminal Support Device
Scepter® Occlusion Balloon Catheter

MicroVention® TERUMO

Sofia™ Distal Access Catheter

Soft torqueable catheter Optimized For Intracranial Access

Distal Access Catheter

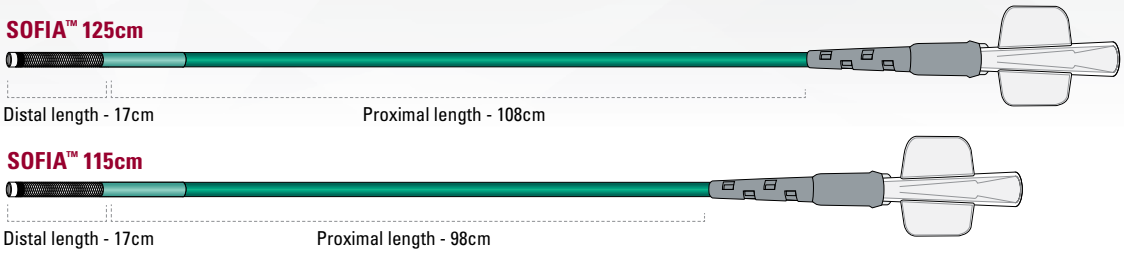
Enhanced control and stability for superior microcatheter performance and reliable device delivery

SOFIA™
Distal Access Catheter

Soft Torqueable Catheter **O**ptimized **F**or **I**ntracranial **A**ccess

1 per box and includes shaping mandrel and introducer sheath

Product Code	Catheter Size (French)	Proximal OD (inch/mm)	Distal OD (inch/mm)	ID (inch)	Working Length (cm)	Distal Length (cm)	Proximal Length (cm)	Distal Tip Shape
DA5115ST	5F	0.068 / 1.7	0.068 / 1.7	0.055	115	17	98	STRAIGHT
DA5125ST	5F	0.068 / 1.7	0.068 / 1.7	0.055	125	17	108	STRAIGHT



Features

Benefits

Features	Benefits
Exceptionally Soft Distal Shaft	Easier navigation in tortuous vessels
Low Profile	Compatible with 6F .070 inch ID guide catheter systems
Steam Shapeable Tip and Torqueable Shaft	Steerable around bifurcations
Enhanced Kink Resistance	Easy to handle with 1:1 push/pull control

MicroVention® TERUMO

microvention.com

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EC DECLARATION OF CONFORMITY

FD14-0142 / F

We, MicroVention Europe, located in France, 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: 487703 MRA (Section 4)
Full Quality Assurance: 487703 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
SOFIA™ Distal Access/Guiding Catheter	DA6095ST DA6105ST DA5115ST DA6115ST DA5125ST	III – Annex 9, rule 7	2018-04-27	58173
SOFIA™ PLUS	DA6125ST DA6131ST DA6135ST			

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 **MicroVention, Inc.** 35 Enterprise Aliso Viejo, CA 92656, USA **MicroVention Costa Rica, S.R.L.** Zona Franca Coyol Alajuela, Costa Rica

Intended Use: The SOFIA™ Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA™ Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA™ Catheter is not intended for use in coronary arteries. Moreover, the SOFIA™ Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures.

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.

Salvadore Palomares
Director, Regulatory Affairs
MicroVention Europe

Saint-Germain-en-Laye
Place of Issue

11-Jul-2018
Date of Issue

Expiry Date: 2023-04-26

Prepared for Romania

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 Quater 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

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 Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe

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

that the design of the following device(s)

SOFIA dDistal Access Catheter
SOFIA Select Catheter
SOFIA PLUS Catheter
SOFIA dFlow PLUS Catheter
SOFIA dGuiding Catheter
SOFIA dFlow Catheter

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: SOFIA Dossier Summary 06JAN2018 Final dated 2018-01-06

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_SOFIA_V1.docx dated 2018-04-21

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	487703 MRA
Certificate unique ID	170713987
Effective date	2018-04-27
Expiry date	2023-04-26
Frankfurt am Main	2018-04-27

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.

Prepared for Romania

Sofia™ Distal Access Catheter

Soft torqueable catheter Optimized For Intracranial Access

Distal Access Catheter

Enhanced control and stability for superior microcatheter performance and reliable device delivery

SOFIA™
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Features

Benefits

Features	Benefits
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MicroVention® TERUMO

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Worldwide Headquarters 1.714.247.8000
1311 Valencia Avenue
Tustin, CA 92780 USA
Customer Service 1.800.990.8368
Web **microvention.com**

CE 0297

• Scientific and clinical data related to this document are on file at MicroVention, Inc. Refer to Instructions for Use for additional information. Federal (USA) law restricts this device for sale by or on the order of a physician.