

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

6F

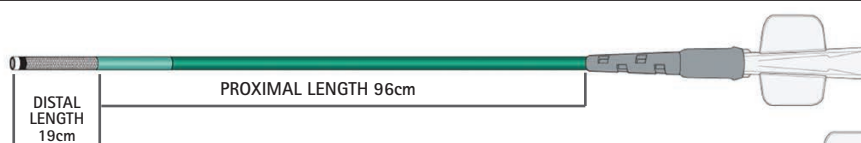
Large inner diameter and enhanced softness for superior distal navigation and procedural versatility



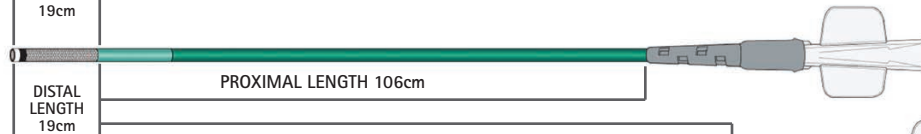
One unit per box, includes shaping mandrel and introducer sheath

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 Stentrievors

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



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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



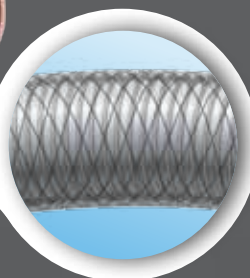
NAVIGATE

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



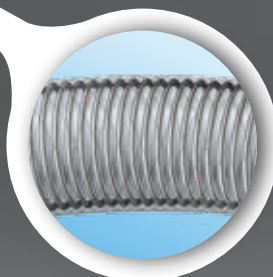
STABILITY

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



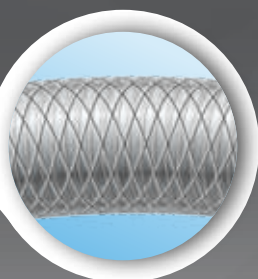
KINK RESISTANCE

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



Distal Access Catheter

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

SOFIA™

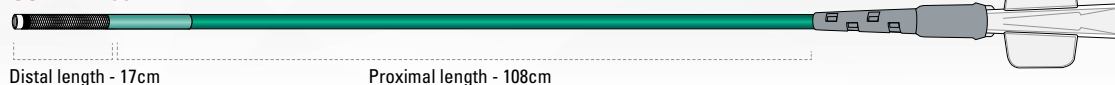
Distal Access Catheter

Soft Torqueable Catheter Optimized For Intracranial Access

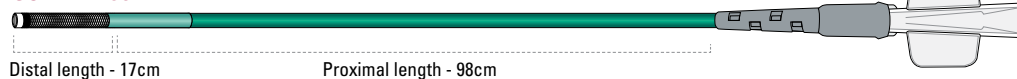
1 per box and includes shaping mandrel and introducer sheath

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

SOFIA™ 125cm



SOFIA™ 115cm



Features

Exceptionally Soft Distal Shaft

Low Profile

Steam Shapeable Tip and Torqueable Shaft

Enhanced Kink Resistance

Benefits

Easier navigation in tortuous vessels

Compatible with 6F .070 inch ID guide catheter systems

Steerable around bifurcations

Easy to handle with 1:1 push/pull control

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

SOFIA™

Distal Access Catheter

Soft Torqueable Catheter Optimized For Intracranial Access

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
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Features

Exceptionally Soft Distal Shaft

Low Profile

Steam Shapeable Tip and Torqueable Shaft

Enhanced Kink Resistance

Benefits

Easier navigation in tortuous vessels

Compatible with 6F .070 inch ID guide catheter systems

Steerable around bifurcations

Easy to handle with 1:1 push/pull control



CERTIFICATE



This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvier
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

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:

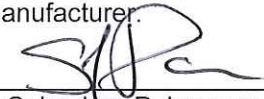
EC Design Examination: 487703 MRA (Section 4)
Full Quality Assurance: 487703 MR2 (Excluding Section 4)

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



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 **d**istal Access Catheter
SOFIA **S**elect Catheter
SOFIA **PLUS** Catheter
SOFIA **d**Flow PLUS Catheter
SOFIA **d**Guiding Catheter
SOFIA **d**Flow 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



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
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
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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 Nanoparasol Embolic Protection System	III	1
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	2
Aspiration Syringe Kit		Aspiration Syringe Kit	Is	1