# CERTIFICATE

This is to certify that the company

## MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
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 |

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

**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<br>DA6105ST<br>DA5115ST<br>DA6115ST<br>DA5125ST | III – Annex 9, rule 7 | 2018-04-27 | 58173 |
| **SOFIA™ PLUS** | DA6125ST<br>DA6131ST<br>DA6135ST | | | |

| Manufacturer | Notified Body | Production Site |
|---|---|---|
| **MicroVention Europe**<br>30 bis, rue du Vieil Abreuvoir<br>78100 Saint-Germain-en-Laye<br>France | **DQS Medizinprodukte GmbH**<br>Notified Body Number: 0297<br>D-60433 Frankfurt am Main,<br>Germany | **MicroVention, Inc.**<br>1311 Valencia Avenue<br>Tustin, CA 92780, USA<br>**MicroVention, Inc.**<br>35 Enterprise<br>Aliso Viejo, CA 92656, USA<br>**MicroVention Costa Rica, S.R.L.**<br>Zona Franca Coyol<br>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 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

# 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.**



411.20 Version 1.0

## 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<br>- Helical – Standard Helical-Reg. and Soft 10 & 18,<br>- HyperSoft® 10 & 3D<br>- Complex 10 & 18<br>- Compass 10 & 18,<br>- COSMOS® 10 & 18<br>- VFC™ | III | 1,2,3 |
| | | HydroCoil® Platinum/Hydrogel Detachable Embolization Coils<br>- HydroCoil® 10 & 14 & 18,<br>- HydroSoft® 10<br>- HydroFill®<br>- HydroFrame® 10 & 18<br>- HydroSoft 3D | III | 1,2,3 |
| | AZUR® Peripheral Coil System | AZUR® HydroCoil Detachable Embolization Coils 18 & 35<br>AZUR® HydroCoil Pushable Embolization Coils 18 & 35<br>AZUR® Framing Detachable Coils 18 & 35<br>AZUR® Injectable Coil System 18 & 35<br>AZUR Detachable 18<br>AZUR PURE Pushable Coil System 18 & 35<br>AZUR CX Detachable 18 & 35 | IIb | 1,2,3 |
| Detachment Controller Units | | V-Grip® Detachment Controller<br>V-Grip® PLUS Detachment Controller<br>WEB Detachment Controller<br>AZUR® Detachment Controller | IIa<br>IIa<br>IIa<br>IIa | 1<br>1<br>1<br>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
## 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 |
|---|---|---|---|---|
| Stents | | LVIS™ Intraluminal Support Device | III | 1,3 |
| | | LVIS Jr.™ Intraluminal Support Device | III | 1,3 |
| | | FRED® Flow Re-Direction Endoluminal Device | | 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 |

# 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

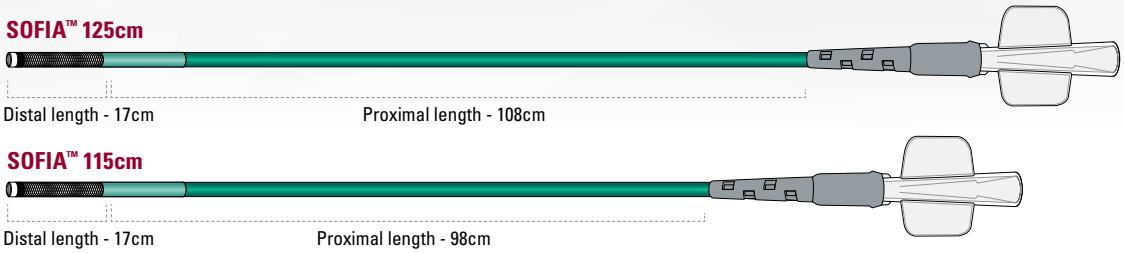
*Enhanced control and stability for superior microcatheter performance and reliable device delivery*

**SOFIA™**
Distal Access Catheter

**S**oft 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**

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

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

**S**oft 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, Inc.**
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**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.

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

6F

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*

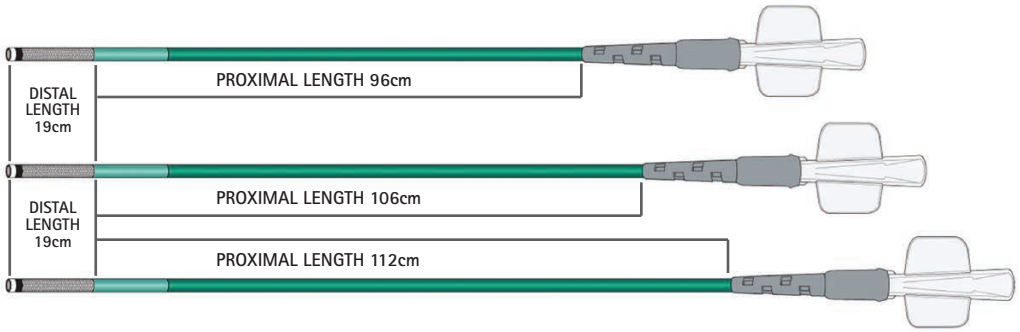
One unit per box, includes shaping mandrel and introducer sheath

| 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

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MicroVention® TERUMO



microvention.com