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

Digitally signed by Grabazei Alexan
Date: 2019.03.28 20:24:06 EET
Reason: MoldSign Signature
Location: Moldova

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

CERTIFICATE

This is to certify that the company

MicroVention Europe

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 Device 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	170726669
Effective date	2018-10-31
Expiry date	2019-12-26
Frankfurt am Main	2018-10-31

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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