

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:

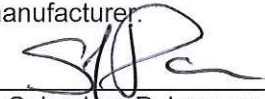
EC Design Examination: 487703 MRA (Section 4)
Full Quality Assurance: 487703 MR2 (Excluding Section 4)

| 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 **Distal Access Catheter**
SOFIA **Select Catheter**
SOFIA **PLUS Catheter**
SOFIA **Flow PLUS Catheter**
SOFIA **Guiding Catheter**
SOFIA **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



CERTIFICATE



This is to certify that the company

MicroVention Europe

30 bis, rue du Vieil Abrevoir
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



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