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
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