

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:

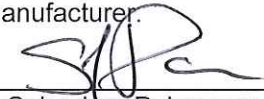
487703 MR2 (Excluding Section 4)

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

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Prepared for Romania