EC DECLARATION OF CONFORMITY

FD08-011 / W

We, MicroVention, Inc., located in Tustin, California, USA 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: 435827 MRA (Section 4)
Full Quality Assurance: 411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Headway 17 Advanced Soft Microcatheter	MC172150S	III – Annex 9, rule 7	2018-12-19	10691
Headway 17 Advanced Microcatheter	MC172150STX, MC17215045X, MC17215090X, MC172150AX, MC172150BX, MC172150CX, MC172150DX, MC172150WX, MC172150JX, MC172150SX			
Headway 21 Microcatheter	MC212150S, MC212156S			
Headway 27 Microcatheter	MC272150S, MC272156S			
Headway Duo	MC162156S, MC162167S			
Wedge Microcatheter	MCWED21160	III – Annex 9, rule 8	2018-12-19	10691

Manufacturer/ Production Site:
MicroVention, Inc.
1311 Valencia Avenue
Tustin, CA 92780 USA

Notified Body:
DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main,
Germany
Notified Body Number: 0297

EU Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
MicroVention Costa Rica
Zona Franca Coyol
Alajuela, Costa Rica

Intended Use:
The Headway Microcatheter (Headway 17 Advanced Soft, Headway 17 Advanced, 21 & 27) is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

The Wedge Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.

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, Inc.

Tustin, CA 92780, USA
Place of Issue

19-DEC-2018
Date of Issue

Expiry Date: 2022-12-19

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